University of Basel
Institute for Biomedical Ethics

Governance of research with supernumerary embryos, stem cells and embryo-models.

Mapping the evolving ethical territory and international regulatory landscape.

On behalf of
Federal Office of Public Health FOPH, Switzerland

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1. Introduction and context

In March 2005, the Swiss Stem Cell Research Act (StRA)[1] came into force, around two years after its adoption by the parliament. The StRA was the result of an articulated lawmaking process that included a debate on how different aspects related to research with embryos were to be regulated. In its final form, the StRA defines the conditions for deriving human embryonic stem cells (hESCs) from surplus embryos and their use for research purposes. Its aim is to prevent the misuse of surplus embryos and hESCs and to protect human dignity. In its current form, the StRA contains a ban on research with embryos themselves. Thus, in Switzerland, the StRA has constituted the main piece of legislation governing embryonic stem cell research for the last 20 years.

However, the state of the research with hESCs and embryos has advanced considerably since the enactment of the StRA. Consequently, questions have arisen as to whether the detailed rules established two decades ago still align with how the societal, scientific and ethical debates around these topics developed. In response, the Federal Council tasked the Federal Department of Home Affairs with the preparatory works for revising the legislation. As part of this mandate, the Federal Office of Public Health (FOPH) initiated and financed a project aimed at producing results to inform the policy- and law-making process by providing an overview of the policy and ethical debates around embryonic research.

This report is the results of the work done by our team, after being selected to conduct an overview of the ethical and policy debate concerning research with embryos, hESCs, human induced pluripotent stem cells (hiPSCs) and human stem cell-based embryo models (SCBEMs). For simplicity in the following we will refer to collectively to these topics as EmRe (Embryonic Research). Given that the use of embryos for research is often regulated in connection with the regulation of Medically Assisted Reproduction (MAR), it is important to examine also rules at the crossroad between these two practices (e.g. rules on the conditions that informed consent forms should have for MAR patients that decide to donate supernumerary embryos for research).

The structure of the report is as follows. After these short introductory remarks, **Chapter 2** outlines the methodological approach adopted to produce the findings. This ensures transparency and accountability regarding the processes we followed, while also pointing at both the strengths and limitations of the project. In **Chapter 3**, we present the findings of our research. This chapter represents the core of this report, and it is divided into two parts. **Chapter 3.1** concerns the overview of the ethical debates around EmRe, thus identifying the key moral considerations at stake. **Chapter 3.2** offers a policy analysis, which explores in detail the regulatory frameworks for EmRe of selected countries. In **Chapter 4**, we discuss a selection of the main findings of the report. The report ends with a short overview of the limitations of this report and section for supplementary material.

[1] https://www.fedlex.admin.ch/eli/cc/2005/104/en

2. Methodological approach

In the following paragraph, we provide a concise overview of the methods used for producing this report. Since the research work was organized in three different Work Packages (WPs), we explain the methodological approach for each of them separately. However, the findings presented in the Result section of this report are a synthesis of the insights collected in all WPs.

2.1 WP1 - Review of ethical issues surrounding the governance of EmRe

The aim of WP1 was to provide a structured, and methodologically robust identification and synthesis of the relevant literature on ethical considerations in EmRe.
Methodologically, this WP was based on a process following the "Rapid review" model as categorized by Grant and Booth.[2] They describe rapid reviews as a rigorous and explicit method for assessing "what is already known about a policy or practice issue, by using systematic review methods to search and critically appraise existing research". Although we employed the methodology of rapid, rather than a systematic review, we considered the methodological recommendations for bioethics reviews as formulated by McDougall[3] and by Kahrass et al.[4] In line with these approaches, our review began with a search for already existing reviews of the ethical literature. To enhance the objectivity of the process and avoid bias stemming from familiar journals, sources, articles, or experts, we initiated the review by conducting a PubMed search. PubMed is one of the most comprehensive and widely recognized international databases for publications in medicine and related fields, including ethics in medical research. In Table 1 below, we give an overview of the search string used for this database.

Search strings used - Search conducted on 09.02.2025		
(((Review[Publication Type]) AND (social[Title/Abstract])) AND (stem cell [Title/Abstract]))	(((Review[Publication Type]) AND (legal[Title/Abstract])) AND (stem cell [Title/Abstract]))	(((Review[Publication Type]) AND (ethics[Title/Abstract])) AND (stem cell [Title/Abstract]))
43 results	58 results	63 results
OVERALL 164 results		

Table 1. Overview of the search string used for the review

We then complemented this with a targeted search focusing on specific entities and topics that are related to the general research aims of this report (e.g. SCBEMs, iPSCs). Finally, we also added additional document types beyond published review papers in medical journals, including theoretical bioethical analyses, policy papers, and commentaries in scientific journals. The time frame of our search was limited from 2001 to 2025. Searches were conducted on an ongoing basis between January and September 2025, to be able to also include newly published articles. This approach was particularly important given that the discourses around topics such as SCBEMs and their ethical implications are continuously evolving.

[2] Grant MJ, Booth A. A typology of reviews: an analysis of 14 review types and associated methodologies. Health Info Libraries J. 2009 Jun;26(2):91–108.
[3] McDougall R. Reviewing Literature in Bioethics Research: Increasing Rigour in Non-Systematic Reviews. Bioethics. 2015 Sep;29(7):523–8.
[4] Kahrass H, Borry P, Gastmans C, Ives J, Van Der Graaf R, Strech D, et al. RESERVE - REporting of SystEmatic ReViews in Ethics: development, explanations and examples. bioethopenres. 2023 Dec 14;1:4

To be included in this review of the ethical literature for the report, publications had to describe and/or assess an ethical issue involved in research with human embryos, human embryonic stem cells, induced pluripotent stem cells or human stem cell-based embryo models via either conceptual or empirical methods. These topics were selected in line with the initial research project and refined through interactions with the FOPH. Only publications in English or German were considered.

Based on the inclusion criteria, we screened all titles, abstracts, and summaries of the identified publications. This is the process by which, in reviews of the literature, the identified publications are checked in order to assess their eligibility for inclusion for full text review. It is a process that allows to eliminate irrelevant literature that is captured through the search string as applied to the databases, given that this always gives more results than those relevant for the review. After this initial selection, the full texts of potentially relevant documents were screened in detail to ensure that the review included only the most relevant publications satisfying the inclusion criteria.

Included full texts of the publications identified through the above-mentioned process were then analyzed using conventional qualitative content analysis.[5] For this purpose, we used the qualitative data analysis software MAXQDA, one of the most widely employed tools for this type of analysis. Passages in the selected publications that discussed a relevant ethical issue were labeled with a specific tag (or code). The same code was applied to passages from different publications when they addressed the same issue while constantly refining code names.

Findings were then organized as higher- and lower-level categories in a coding frame, which was developed inductively from the data. Only the highest-level themes were generated deductively to reflect entity-specific ethical considerations: [1] Ethical considerations in research with human embryos; [2] Ethical considerations in research with human embryonic stem cells; [3] Ethical consideration in research with human induced pluripotent stem cells [4]; Ethical considerations in human stem cell- based embryo models; [5] Cross-cutting ethical considerations. The draft framework was discussed in regular research team meetings to enhance validity and reliability. Moreover, it was also shown in an intermediary report presented at the FOPH in June 2025, thus allowing to receive feedback and adjust the analysis. The comments received were then incorporated in the analytic structure and used to refine codes and categories of ethical issues for the results of this final report. Insights from WP3 were also integrated into the analysis (see below).

Ultimately, this process resulted in the development of a comprehensive ethics matrix offering a general overview of the ethical issues and controversies discussed in the literature concerning EmRe. This matrix will be presented in the result section of this report.

2.2 WP2 - Comparative policy analysis of international approaches to EmRe regulation

This WP was aimed at mapping in detail how various countries regulate EmRe through a comparative analysis. For this, we followed the established methodological guidelines of comparative legal analysis.[6] The WP focused on major European countries that are at the forefront of such research, as well as neighboring countries of Switzerland. The choice to limit to a selected number of countries enabled an in-depth examination of relevant regulatory frameworks and – especially – of additional details regarding how the regulatory framework plays out in practice.

To retrieve material for the legal analysis, we mainly consult three types of sources:

- publications in legal databases describing the policies in different countries
- publications by the relevant authorities and institutions – both at a national and international level – that are concerned by EmRe

[5] Schreier M. Qualitative Content Analysis in Practice. London: Sage; 2012.

[6] Van Hoecke M. Methodology of Comparative Legal Research. Law and Method [Internet]. 2015 Dec [cited 2024 Nov 29]; Available from: http://www.bjutijdschriften.nl/doi/10.5553/REM/.000010

- Soft and hard law of the selected countries
- Secondary literature that categorizes the different types of regulatory approaches on EmRe (e.g.[7])

The process of selection of countries was organized in this way:

- First, a preliminary discussion with the mandating team from the FOPH was held at the kick-off meeting of the project on January 28, 2025
- Second, a proposal of countries to include (with justification) was made by the research team and then shared with the mandating team from the FOPH on March 3, 2025
- Third, feedback was provided by the mandating team of the FOPH on March 7, 2025, thus defining the final list.

The final section of countries, including the motivation for including them in the analysis, is presented in Table 2.

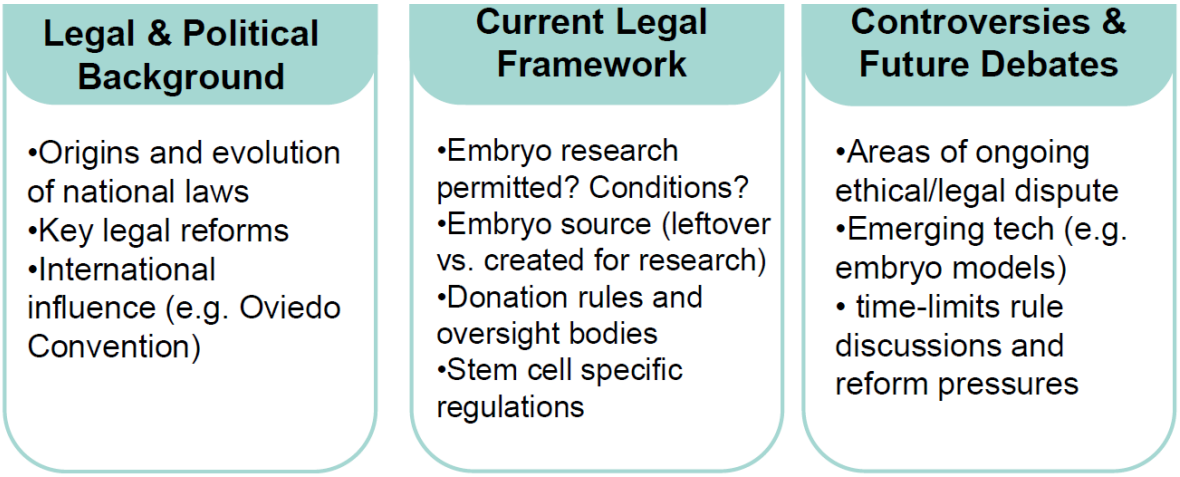
Country	Justification
Belgium	Belgium is a country with a quite liberal approach to regulating research on embryos. Research on embryos is mostly regulated in a specific law on this topic and a law on Medically Assisted Reproduction, a regulatory framework with some similarities to Switzerland. For this reason, it is valuable to examine how the process of liberalization worked in Belgium and to see what is the current legal debate in a country where such research is permitted.
France	France represents possibly one of the most interesting cases to include in the comparative legal analysis, as it has undergone a progressive liberalization of the rules concerning Medically Assisted Reproduction and the handling of embryos (including for research).
Germany	The German case mirrors quite closely Switzerland's restrictive approach in its law on Medically Assisted Reproduction and the regulation of embryo research. The use of embryos is regulated – like in the Netherlands – in a law centred around the status of the embryo itself, an issue that still dominates the German legal debate. Moreover, a law regulating the import of stem cells for research exists. Given that calls to update this legislation are present, Germany represents another useful case study to consider.
Italy	Italy regulates the handling of embryos (including for research) in a law on Medically Assisted Reproduction dating back to the early 2000s, similarly to Switzerland. Another parallel is its quite strict prohibition on the use of embryos for research, although calls for some liberalization are present. For this reason, it is valuable to explore the legal situation in Italy and the evolution of the legal debate there.
Netherlands	The Netherlands belong to the countries in Europe that allow some research on embryos. Analysing the Dutch case is particularly relevant, since the approval process of this law was heavily contested, and many discussions on the status of the embryo (and its implication for embryo-research regulation) remain ongoing. For example, it is still prohibited – albeit this ban is very discussed – to create embryos for research.
Sweden	Sweden is a traditionally very liberal country when it comes to regulating EmRe. It is thus valuable to explore the legal setup of a country that has a long-standing and established system to allow research with embryos.
United Kingdom	The UK is well-known for its liberal approach EmRe laws. It has always been at the forefront of developing policies in this field, aiming to 'tame' technology, rather than 'prohibit' innovative biotechnological research. For this reason, although the liberalization of embryo research dates back a few decades, it is still useful to observe how the legal debate on this issue has been evolving in the last few years, and how UK regulators are preparing to legislate on two very important and forward-looking issues: embryo models, and the potential extension of the 14-day limit.

Table 2. Overview of Selected Countries and Rationale for Inclusion

Based on the types of sources listed above and on the list of countries selected, information on the regulatory framework and application was collected and systematized. During a meeting

[7] Matthews KR, Moralí D. National Human Embryo and Embryoid Research Policies: A Survey of 22 Top Research-Intensive Countries. Regen Med. 2020 Jul;15(7):1905–17.

with the mandating team of the FOPH on June 17, 2025, a proposal on the categories of information to focus on for each country was presented. This suggested to present the type of information for the analysed countries as shown in the image below.



After a feedback session and the sharing of additional input by the mandating team on the 3rd July, it was agreed to include the following modifications: 1) reduce the information on the rules on creation of embryos for research (only a brief note); 2) add some indicative details about how informed consent for embryo donation is actually operationalized in the countries; 3) add some details on the public attitudes regarding embryo regulation in the countries.
The results of this legal analysis were then supplemented by information retrieved from the expert interviews conducted under WP3 (see below).

2.3 WP3 - Integrative and complimentary expert interviews

To complement the findings of WP1 and WP2 and ensure that – given the breadth of topics covered within a small project – the final report did not overlook any key ethical issues and regulatory approaches to EmRe, in WP3 we conducted selected expert interviews. Expert interviews are a widespread methodological approach in bioethics, employed to explore a variety of topics, including stem cell research and its governance, as visible in the publications by Hu et al.[8] and Alahmad et al.[9] Moreover, the use of interviews to complement the literature findings in projects aimed at producing reports to support policy development of EmRe is a common practice; e.g. this approach was also employed as part of a recent report published by the influential Nuffield Council on Bioethics in the UK.[10]
For WP3, we conducted unstructured interviews, as this methodological approach is particularly suited to the purpose of this project: mapping and providing a general overview – based on both the literature and expert-knowledge – of the main ethical issues and regulatory approaches related to EmRe. Unstructured interviews as a method are characterized by their openness. Indeed, they follow "the interviewees' narration and generate questions spontaneously based on their reflections on that narration"[11]. However, the course of the interview can be flexibly oriented around a predefined set of guiding questions, commonly termed an aide-mémoire or agenda.[12]

[8] Hu M, Santos D, Lopes E, Nicol D, Kurtz A, Mah N, et al. Australian researchers' perceptions and experiences with stem cell registration. Stem Cell Research. 2024 Sep;79:103482
[9] Alahmad G, Aljohani S, Najjar MF. Ethical challenges regarding the use of stem cells: interviews with researchers from Saudi Arabia. BMC Med Ethics. 2020 Dec;21(1):35.
[10] https://www.nuffieldbioethics.org/publication/human-stem-cell-based-embryo-models-a-review-of-ethical-and-governance-questions/
[11] Wildemuth BM. Applications of social research methods to questions in information and library science. Bloomsbury Publishing USA; 2016.
[12] Wildemuth BM. Applications of social research methods to questions in information and library science. Bloomsbury Publishing USA; 2016.

We designed our interview agenda based on the preliminary findings of WP1 and WP2, while also ensuring interviewees have the freedom to explore new subjects not identified in the literature (e.g. because of their novelty). We also collected feedback on the interview agenda from the mandating team of the FOPH. The final interview agenda is attached as an annex to this report.

To recruit experts, we used a widespread sampling strategy for qualitative interview-based studies: purposive sampling. Purposive sampling involves selecting participants identified a-priori as likely to provide the most relevant information for the study. To identify them, we relied on the literature identified by WP1 and WP2. A final list of potential participants was drafted, and the selected experts were contacted by email. One reminder was sent. The list of participating experts is included, given their permission, at the end of the report (see additional material).

We interviewed nine experts between June and September 2025, which represent a suitable sample size, especially considering the integrative and complementary nature of WP3. Methodological literature shows that with homogeneous samples, even a small number of interviews is sufficient.[13] The interviews were conducted in English or German, recorded and analyzed based on a methodology called “rapid qualitative data analysis method”, which is particularly well-suited for short studies like this one.[14] Instead of full verbatim transcription, the researcher, who had not conducted the interview, listened to the audio recording and transcribed only relevant information revealed by the expert participant. These transcriptions were then double-checked by the interviewer. The results of the interviews were then incorporated in the results of WP1 and WP2. In this way, we ensured that both our ethical and legal analysis could also profit from additional insights and experts’ knowledge.

[13] Guest G, Bunce A, Johnson L. How Many Interviews Are Enough?: An Experiment with Data Saturation and Variability. Field Methods. 2006 Feb;18(1):59–82.

[14] Nevedal AL, Reardon CM, Opra Widerquist MA, Jackson GL, Cutrona SL, White BS, et al. Rapid versus traditional qualitative analysis using the Consolidated Framework for Implementation Research (CFIR). Implementation Sci. 2021 Dec;16(1):67

3. Results

3.1 An update on the ethics debate around EmRe

Our rapid literature review included 94 publications in the final analysis. Of these, 82 were journal articles and the remaining 12 were book chapters, policy papers or conference reports. A list providing full bibliographical information of all 94 publications is provided in the additional material. The insights from WP3 are also integrated in the following report.

As requested by the FOPH team, we sought to achieve both breadth and focus: on the one hand, to capture as many aspects as possible ("a bit of everything"), and on the other, to maintain an emphasis on the ethical challenges posed by recent developments in EmRe. However, while the emergence of iPSCs and human SCBEMs has introduced new ethical issues, many longstanding concerns (e.g. to which degree of moral status and protection are the entities entitled and depending on which capacities) remain central also to the contemporary debates, as was also emphasized in the expert interviews. Since many of these concerns are not entity-specific but pertain to EmRe as a whole, the section on cross-cutting ethical considerations is more extensive than the preceding themes and serves as an essential complement to the analysis of ethical issues tied to specific forms of EmRe.

3.1.1 Ethical considerations in research with human embryos

Within the first theme *Ethical Considerations in research with human embryos* central ethical questions concerns the question from when on an embryo acquires a particular moral status, as well as the protective and personal rights to which it is entitled respectively. Research on embryos usually results in their destruction, either during the study itself or once the investigation has been completed. The subsequent section provides a brief outline of the principal perspectives on this issue. In Switzerland as well, a constitutional debate exists regarding the moral status of the embryo, as also briefly hinted at in the beginning of Chapter 3.2.[15] Additional recurrent and significant debates in this context address which embryos may be used for research purposes and, if so, under what specific conditions.

3.1.1.1 Moral status debates

One of the central ethical debates concerns the (degree of) moral status that embryos possess and, consequently, the rights and level of protection to which they are entitled – that is, what should or should not be permitted to be done with them. This debate is also present in the Swiss context, as briefly explained at the beginning of Chapter 3.2. Moral status means the inherent worth of someone or something, independent of the value or usefulness it may hold for others and thus has to be treated in a certain way for its own sake. Views on the moral status of embryos vary widely, ranging from considering embryos as just a bunch of cells with no moral status to attributing to them the same moral status as a fully developed human being, with numerous intermediate positions in between. The following sections provide an overview of some of the most prominent ethical discussions in this regard.

Full moral status

One perspective is that embryos possess full moral status from the moment of fertilization or conception, granting them full personhood and a right to life. Proponents of this view emphasize that moral status is not dependent on properties such as consciousness, sentience, or viability, but on the fact of belonging to the species of human. This is why this position has also been critiqued as "speciesism" and opponents argue that it is difficult to provide a strong justification for the idea that merely being a member of the human species automatically grants every human equal moral status – and often, a superior moral status compared to non-human animals. Some argue that this distinction can be defended by appealing to the greater cognitive capacities of humans. However, this reasoning is problematic, since certain animals such as great apes or dolphins demonstrate more advanced cognitive abilities than some humans, e.g. than embryos, small children or people those with profound cognitive impairments.

[15] See e.g. Fortpflanzungsmedizingesetz (FMedG) (Stämpflis Handkommentar) A. Büchler & B. Rütsche, Stämpfli Verlag AG, 2020.

Arguments around potentiality

The argument from potentiality emphasizes that embryos, although not yet persons, are potential persons. A fertilized human embryo contains the genetic material and intrinsic biological organization that, under suitable conditions, can lead to the development of a mature human being. On this account, destroying an embryo is ethically significant because it prevents the realization of a life that, in principle, could come to exist. Respect for this potential is often invoked to justify limits on embryo research, even when embryos are at very early stages of development. Critics, however, question whether potentiality alone can ground strong moral claims. While embryos may have the potential to become persons, they are not yet actual persons with consciousness, interests, or experiences. Moreover, not every biological entity with developmental capacity is accorded (full) moral status. For instance, a somatic cell, through nuclear transfer or genetic reprogramming, could in principle give rise to a new organism. Yet few would argue that skin cells or induced pluripotent stem cells deserve protection as potential persons. Furthermore, many embryos naturally fail to implant or develop successfully to term, raising doubts about whether the mere possession of potential confers decisive moral status. Proponents respond by distinguishing between an embryo's active, inherent developmental potential and passive potential, which requires external intervention.

Threshold-concepts

Further accounts of moral status ground it in the attainment of certain thresholds or sets of thresholds that mark important stages of development or the emergence of specific capacities and at which moral status increases until full moral status is reached. Suggested thresholds include the establishment of numerical identity, when twinning is no longer possible and the embryo becomes a unique individual; the appearance of the primitive streak, signaling the earliest organization of the nervous system; the onset of sentience; consciousness; the capacity for self-motivated activity; viability outside the womb; the ability to communicate, in any form; self-awareness; or the ability to value one's own existence.

Gradualism

The gradualist position rejects the notion that moral status appears in an all-or-nothing way. Instead, gradualist perspectives hold that moral status arises from the presence of specific morally significant capacities – such as, but not limited to, consciousness, sentience, rationality, autonomy, and the capacity to develop and act upon preferences. For gradualists, these properties matter ethically because they are linked to the kinds of interests and rights we recognize in persons. These capacities can vary in degree, implying that moral status might not be a binary concept but rather exist on a spectrum. Accordingly, entities may hold a partial moral status that corresponds to the extent to which they possess morally significant capacities, instead of simply having complete moral status or none whatsoever. An early embryo, therefore, may warrant a degree of protection, but not the same protection as a fetus at later stages of development or a newborn.

Human dignity

Human dignity is frequently invoked as the foundation for the rights accorded to every individual. However, a challenge in relying on this notion is that dignity can be understood in multiple ways, and these differing interpretations influence who or what is regarded as worthy of being afforded dignity. When invoked in debates on embryo research it often means the requirement to avoiding instrumentalization, that is, treating entities as merely as means to an end, e.g. as tools for research.

Specific religious views

Religious and cultural traditions provide diverse perspectives on research with embryos. E.g. the Catholic Church often maintains that human life begins at conception and therefore opposes all research that involves the destruction of embryos. Many Protestant traditions adopt varied positions, with some allowing research e.g. before implantation. In Judaism, the embryo is not considered a full person before 40 days, which allows for early research when justified by necessity. In Islam, ensoulment is often placed at 40 or 120 days, leaving some

room for embryo research before this point. In Eastern traditions (e.g., Hinduism, Buddhism), respect for life is paramount, but practical ethical approaches often depend on contextual judgments.

3.1.1.2 Developmental time limits and their justifications

Another related central topic debated in the ethical literature concerns the temporal limits within which research with embryos should be confined, in case it is allowed. This debate is focused on whether there is a point in the development of an embryo, beyond which any kind of research should be stopped.

The 14-day rule

The 14-day rule has become a widely recognized compromise in embryo research. It permits experimentation on human embryos only up to the point when the primitive streak forms and/or until day 14 after fertilization. This stage carries symbolic and biological significance. First, it marks the beginning of individuation: after this point, twinning or fusion is no longer possible, meaning the embryo represents a distinct individual. Second, it marks the initiation of neural development, although the embryo is far from capable of sentience or pain perception. The 14-day limit was first proposed in the UK's Warnock Report (1984) and later enshrined in the Human Fertilization and Embryology Act (1990). Although the ethical legitimacy of its underlying rationales has been criticized over time, the rule was politically powerful because it offered a pragmatic, clear, enforceable boundary that balanced competing interests: it permitted some embryo research, while reassuring the public that the embryo's moral significance was acknowledged and not disregarded. Many countries have since adopted similar rules or used the 14-day threshold as a reference point in shaping their own policies.

Debates over extension

Advances in stem cell culture and embryology now make it technically feasible to maintain embryos in vitro beyond 14 days. This has prompted renewed debates about whether the limit should be extended, e.g. until 28 days. These debates concern supernumerary embryos from IVF treatments as well as embryos that are specifically created for research purposes. Arguments for extension emphasize the scientific and medical opportunities that lie just beyond the current boundary. Development between days 14 and 28 is often stated to be a "black box" and critical for understanding early organ formation, implantation disorders, and the origins of congenital anomalies. Extending the limit could provide insights into why many pregnancies fail in the first weeks, potentially informing new treatments for infertility and miscarriage. Some argue that the original 14-day limit was technologically motivated (since embryos could not survive that long in culture in the 1980s) rather than ethically robust, and that rules should adapt as science progresses. Arguments against extension stress the importance of maintaining clear, stable boundaries. The 14-day rule has functioned effectively as a social compromise, commanding widespread legitimacy despite deep disagreements about embryo moral status. Allowing constant boundary-shifting – in arbitrary multiplicators of 7 – whenever science demands it, risks eroding public trust and weakening respect for human life. Critics also caution that even if embryos remain non-sentient beyond 14 days, pushing the boundary may normalize incremental encroachments into later and later stages. Any imposition or extension of time limits would require clear ethical justification and well-founded underlying rationales.

3.1.1.3 Use and creation of embryos

Supernumerary embryos from IVF

In the context of IVF procedures, frequently more embryos are generated than are required for implantation, resulting in so-called supernumerary embryos. These may subsequently: remain cryopreserved indefinitely, be discarded, be donated for reproductive purposes (embryo adoption), or be donated to research. Arguments against the use of supernumerary embryos in research include those previously mentioned, such as concerns about moral status, instrumentalization and violations of human dignity. In addition, some commentators have suggested that the possibility of donating embryos for research could have a normalizing effect

on abortion. Ethical arguments in favor of donation for research emphasize that the alternatives of indefinite storage or immediate destruction are not preferable. Even if research ultimately entails the destruction of the embryo, it may at least first contribute to scientific knowledge and potential therapeutic advances. Furthermore, respecting the autonomy of responsible citizens, couples should retain their right to decide the fate of their embryos. Proponents further argue that permitting the use of supernumerary embryos in research does not diminish the value society attributes to human life or weaken commitments to its protection. Rather, when balanced against the moral and societal costs of prohibiting research, the arguments for absolute protection of embryonic life are considered insufficiently compelling to justify such restrictions.

Embryos created explicitly for research

Unlike the use of supernumerary embryos this practice involves generating embryos from oocytes and spermatocytes with the explicit intention that they will be used as research material and be ultimately destroyed, which is highly controversially discussed and for critics represents a morally significant boundary. In Switzerland, the creation of embryos for research purposes is prohibited due to its ratification of the Oviedo Convention, as well as for constitutional provisions. Counterarguments draw on issues mentioned above under the moral status debates, including concerns about instrumentalization and human dignity, worries about "playing God" and "unnaturalness" etc. A further concern relates to the means of embryo creation, which requires oocytes donation. Oocyte retrieval is invasive, potentially medically risky, and burdensome for women, raising issues of bodily autonomy and potential exploitation. This concern is heightened when financial incentives are offered, as they may unduly influence economically vulnerable women, creating risks of commodification and inequity. Proponents argue, however, that under certain conditions the creation of embryos for research purposes may be ethically defensible. These conditions include the principle of subsidiarity – that is, embryos should only be created when no scientifically adequate alternatives (which include supernumerary embryos from IVF treatments) exist – and the pursuit of highly significant research aims, alongside robust safeguards concerning valid informed consent and against exploitation of donors.

3.1.1.4. Conditions under which to allow research with embryos

Highly significant research aims and proportionality

The most frequently cited condition for the permissibility of embryo research is that it must pursue high-ranking research goals. Research with embryos holds significant promise for alleviating human suffering caused by disease and injury through advancing knowledge and developing new therapies, such as regenerative medicine, personalized medicine, and reproductive medicine. Advocates therefore emphasize that such research is necessary for discovering new therapies, which constitutes a responsibility of politics and science toward society. However, the exact definition of what constitutes a highly significant research aim remains challenging. Critics caution against overpromising translational benefits, as many therapeutic applications remain distant. Others argue that many potential benefits would concern only a small subset of the population, and that purposes such as advancing fertility treatments may too readily be assumed to represent highly significant research aims. In this context, also the principle of proportionality is often invoked, meaning that the potential scientific and therapeutic benefits of using embryos must be carefully weighed against the ethical concerns associated with their use.

No alternatives / subsidiarity

The principle of subsidiarity requires that embryo research be undertaken only if no viable alternatives exist, for example, because animal models inadequately replicate many aspects of human embryonic development. At the same time, critics argue that in highly complex research projects it is often easy to give the impression that embryos are the only means of pursuing a research objective. For approval, researchers would need not only to demonstrate that no alternative methods exist but also to provide a precise justification for the number of embryos required for the project. Furthermore, there is criticism of the use of the term

subsidiarity in this context, as it does not correspond at all to the original concept, for example in relation to the governance of the EU.

Table 3 gives a full and detailed account of the ethical considerations identified in research involving human embryos. The first column ("Code") presents the highest-order codes, while the second column ("Subcode") lists, where applicable, the lower-order codes. The third column contains the publications in which the respective ethical issue is discussed, enabling readers to locate the relevant literature for a more detailed examination of specific arguments and debates. The final column presents illustrative quotations exemplifying each ethical issue.

THEME 1 **ETHICAL CONSIDERATION IN RESEARCH WITH HUMAN EMBRYOS**		
CODE: SUBCODE	PUBLICATIONS	EXAMPLE QUOTE
Moral status debates: **Full moral status**	• Porsdam Mann et al. 2025 • Hyeon et al. 2023 • Nationale Akademie der Wissenschaften Leopoldina 2021 • Nicolas et al. 2021 • Devolder 2019 • Kirkpatrick et al. 2013 • Bahadur et al. 2010 • Einsiedel et al. 2009 • Lo & Parham 2009 • Jung 2009 • Devolder & Harris 2007 • Rubin 2006 • Moore et al. 2006 • Patel 2006 • White 2005 • Walters 2004 • Maienschein 2002	*Some people, however, believe that an embryo is a person with the same moral status as an adult or a live-born child. As a matter of religious faith and moral conviction, they believe that "human life begins at conception" and that an embryo is therefore a person. According to this view, an embryo has interests and rights that must be respected. From this perspective, taking a blastocyst and removing the inner cell mass to derive an embryonic stem cell line is tantamount to murder.* Lo & Parham 2009 *…dass die Maximalposition zum Embryonenschutz, die menschlichen Embryonen von der Befruchtung an vollen moralischen Status zuschreibt, nicht nur in Deutschland einen erheblichen biopolitischen Einfluss besessen hat. Ethisch wird diese Position oft religiös, aber auch säkular damit begründet, dass menschliches Leben in allen seinen Phasen heilig oder absolut schützenswert sei. Mit Blick auf außerkörperlich kultivierte (extrakorporale) Embryonen wird nicht selten auch mit der Sorge argumentiert, hier werde durch die leichten Zugriffsmöglichkeiten Dritter einer Instrumentalisierung menschlichen Lebens Vorschub geleistet. Nach dieser Auffassung hätten bereits frühe menschliche Embryonen den Anspruch auf denselben Lebens- und Würdeschutz wie geborene Menschen.* Nationale Akademie der Wissenschaften Leopoldina 2021
Moral status debates: **Arguments around potentiality**	• Blasimme 2025 • De Graeff & De Proost 2025 • Gyngell et al. 2025 • Bundesministerium für Bildung und Forschung (BMBF) 2023 • Nationale Akademie der Wissenschaften Leopoldina 2021 • Devolder 2019 • Cavaliere 2017 • Kirkpatrick et al. 2013 • Jung 2009 • Lo & Parham 2009 • Devolder & Harris 2007	*Some of those arguing against embryo research in principle referred to the potentiality of the embryos to become fully developed persons and concluded that human life, no matter at what stage of development, should be granted full protection, and that embryos should not be used for research.* Cavaliere 2017 *Ein zentrales Argument der Vertreterinnen und Vertreter eines strikten Embryonenschutzes ist dabei das sogenannte Potenzialitätsargument, nach dem das biologische Entwicklungsspotenzial einen umfassenden Schutzanspruch begründet. Dieses Argument wird allerdings von vielen als nicht überzeugend angesehen, da ihm die Anschlussfähigkeit an andere ethische Begründungen fehlt. Die tatsächliche Realisierung des Potenzials, also die Entwicklung des Embryos zu einem*

	• Patel 2006 • Walters 2004 • Maienschein 2002	*geborenen Menschen, sei an zahlreiche Voraussetzungen geknüpft und könne in vielerlei Hinsicht beeinflusst werden. Die Zuschreibung intrinsischer Schutzansprüche für menschliche Embryonen lasse sich nur mit aktual ausgebildeten, also tatsächlich vorhandenen Eigenschaften rechtfertigen und nicht bereits mit den biologischen Teilvoraussetzungen hierfür, wie sie im Genom einer befruchteten Eizelle verankert sind.* Nationale Akademie der Wissenschaften Leopoldina 2021
Moral status debates: **Threshold concepts**	• Porsdam Mann et al. 2025 • Nationale Akademie der Wissenschaften Leopoldina 2021 • Devolder 2019	*Vor dem Hintergrund dieser verbreiteten Auffassung bieten sich verschiedene Alternativen schwächerer Schutzpositionen an. Sie gehen entweder von einer graduellen Zunahme des Schutzanspruchs des Embryos aus oder bewerten verschiedene Zäsuren als moralisch wichtig oder entscheidend. Dabei geht es teils um biologische, teils um anthropologische Aspekte, denen ethische Bedeutung zugeschrieben wird. Hierzu gehören die Ausbildung des eigentlichen Embryos (sogenannter Embryo proper) nach morphologischer Trennung von seinem ernährenden Gewebe, seiner Einnistung in den Uterus, die beginnende Herausbildung neuronaler Strukturen, die zunehmende äußere Ähnlichkeit mit geborenen Menschen, die prinzipielle Überlebensfähigkeit des Fötus außerhalb des Körpers der Frau oder die Geburt als Trennung von der mütterlichen Umwelt und faktischer Abschluss der körperlichen Verselbstständigung eines neuen Menschen. Besonders großen Zuspruch findet in der ethischen Debatte der Beginn der Empfindungsfähigkeit (engl. sentience) und insbesondere des Schmerzempfindungsvermögens als relevante Schwelle – nicht zuletzt, weil sie auch in vielen anderen Zusammenhängen als Voraussetzung für das Zuschreiben von Interessen und moralischen Ansprüchen gilt.* Nationale Akademie der Wissenschaften Leopoldina 2021
Moral status debates: **Gradualism**	• Porsdam Mann et al. 2025 • Nationale Akademie der Wissenschaften Leopoldina 2021 • Nicolas et al. 2021 • Devolder 2019 • Cavaliere 2017 • Farajkoda 2017 • Einsiedel et al. 2009 • Lo & Parham 2009 • Whittaker 2007 • Rubin 2006 • Yoshimura 2006 • White 2005 • Maienschein 2002	*Alternatively, there are those who argue that the moral status of the embryo is more graduated—that there is a discontinuity from conception to the establishment of personhood. The early embryo is recognized as a form of human life but not with the same rights as an infant or a child.* White 2005
Moral status debates: **Human dignity**	• Nuffield Council on Bioethics 2024 • Bundesministerium für Bildung und Forschung (BMBF) 2023 • Nationale Akademie der Wissenschaften Leopoldina 2021 • Farajkhoda 2017 • Jung 2009 • Rubin 2006	*The core reason for objection to hES cell research is that it destroys human blastocysts or embryos, which means it destroys human lives and eventually violates human dignity.* Jung 2009 *Verschiedentlich wird zudem die Position vertreten, Embryonenschutz sei auch damit begründbar, dass er die Rechte geborener Menschen auf bedingungslosen Würde- und Lebensschutz gewissermaßen mit zementiere.* Nationale Akademie der Wissenschaften Leopoldina 2021

	• Daar et al. 2004	
Moral status debates: **Specific religious views**	• Park et al. 2024 • Nicolas et al. 2021 • Alahmad et al. 2020 • Khan & Konje 2019 • Farajkhoda 2017 • Al-Aqeel 2009 • White 2005 • Maienschein 2002	*Despite the current consensus within the Catholic Church that human life starts at conception, some theologians actually posit that the moral status is biologically emergent. According to Aquinas, it is only once the fetus has become animated by the rational soul that it is homicide to kill it. The Vatican was not happy, seeing such manipulation of even early developmental stages as morally illicit, since Pope Pius IX had in 1869 declared that "ensoulment" and hence life begins at conception.* Nicolas et al. 2021 *The early pre-embryos are regarded in Islamic jurisprudence as worthy of respect but do not have the full sanctity offered to the embryo after implantation in the uterus and especially after ensoulment. According to Islamic view ensoulment is happened at 120 days after fertilization (whereas a minority of Muslims believe that it is occurred 40 days after conception).* Farajkhoda 2017
Developmental time limits and their justifications: **The 14-day rule**	• Gyngell et al. 2025 • Porsdam Mann et al. 2025 • Venkatesh et al. 2024 • Human Developmental Biology Initiative 2023 • Bundesministerium für Bildung und Forschung (BMBF) 2023 • Fabbri et al. 2023 • De Jongh et al. 2022 • Lendahl 2022 • Matthews et al. 2021 • Nicolas et al. 2021 • Matthews & Moralí 2020 • Cavaliere 2017 • Farajkhoda 2017 • Kirkpatrick et al. 2013 • Bahadur et al. 2010 • Jung 2009 • Whittaker 2007	*When the 14-day rule was first introduced it was not technically possible to develop embryos past 14 days. The 14-day limit was not chosen because of rigorous ethical analysis, but rather 'it provided a pragmatic means to allay public anxiety while delineating a clear-cut and enforceable boundary'. Some ethical justifications for the 14-day limit have been offered in the literature. For example, some have argued that the fundamental purpose of the 14-day rule is to prevent the possibility of embryos experiencing pain or sentience as part of research. However, it is believed that this capacity does not develop until closer to 20 weeks. This consideration supports a much longer limit than 14 days. Other theorists have argued that the justification for the 14-day rule is that the formation of the primitive streak signifies the beginning of a unique human being, as it is at this stage that twinning is no longer possible. One version of this argument holds that as numerical identity is not fixed before 14 days, the entity in question cannot be said to have an (active) potential to develop into a future person. However, arguments about numerical identity being morally important do not hold up to philosophical scrutiny.* Gyngell et al. 2025
Developmental time limits and their justifications: **Debates over extension**	• Gyngell et al. 2025 • Porsdam Mann et al. 2025 • Foreman et al. 2023 • Lendahl 2022 • Lovell-Badge et al. 2021 • Matthews et al. 2021a • Nicolas et al. 2021 • Matthews & Moralí 2020 • Cavaliere 2017	*There is now building pressure to extend or even abolish this limit in order to permit research into very important stages of human embryo development, about which we know little, but where many cases of miscarriage or birth defects are likely to have their origins. Other reasons for extending the culture period include (1) to provide control material against which to validate stem cell-based embryo models (see below), which, if successful, would reduce the future need to carry out some types of research directly with human embryos, and (2) to enable more thorough analysis of safety and efficacy of a wide range of methods either currently employed in IVF or that could be introduced, notably mitochondrial replacement techniques, heritable human genome editing, and in vitro-derived gametes (see below).* Lovell-Badge et al. 2021

Use and creation of embryos: **Supernumerary embryos from IVF**	• Park et al. 2024 • Bundesministerium für Bildung und Forschung (BMBF) 2023 • German Stem Cell Network 2023 • Nationale Akademie der Wissenschaften Leopoldina 2021 • World Medical Association 2020 • Alahmad et al. 2020 • Devolder 2019 • Sharma 2019 • Khan & Konje 2019 • Farajkhoda 2017 • Kirkpatrick et al. 2013 • Bahadur et al. 2010 • Einsiedel et al. 2009 • Lo & Parham 2009 • Outka 2009 • Devolder & Harris 2007 • Patel 2006 • Devolder 2005 • White 2005 • Daar et al. 2004 • Baylis 2002 • Maienschein 2002	*One argument holds that research on unwanted IVF embryos is acceptable since these embryos are never going to be used for reproductive purposes even if not used in research. The thought is that destroying unwanted IVF embryos does not result in any loss that was not going to occur anyway […] It is then argued that because nothing is lost, and significant benefits are expected to come out of research with unwanted IVF embryos, it is acceptable to conduct such research. This is so, even if embryos have a significant moral status, so that it would normally be unacceptable to conduct destructive research on them.* Devolder 2019
Use and creation of embryos: **Embryos created explicitly for research**	• Porsdam Mann et al. 2025 • Bundesministerium für Bildung und Forschung (BMBF) 2023 • De Graeff et al. 2023 • Hyeon et al. 2023 • Lovell-Badge et al. 2021 • Nationale Akademie der Wissenschaften Leopoldina 2021 • Devolder 2019 • Farajkhoda 2017 • Kirkpatrick et al. 2013 • Brock 2010 • Einsiedel et al. 2009 • Lo & Parham 2009 • Outka 2009 • Doerflinger 2008 • Moore et al. 2006 • Devolder 2005 • White 2005 • Walters 2004 • Daar et al. 2004 • De Wert & Mummery 2003 • Baylis 2002	*One crucial objection centres on Kantian concerns about using human life instrumentally. Some argue that human embryos, as potential persons, should never be treated merely as means to an end but always as ends in themselves. This argument appears to preclude creating embryos specifically for research. […] [T]he key question then becomes whether there is a morally relevant distinction between using surplus embryos and creating embryos specifically for research. While creating embryos purely for research might seem to involve a more direct instrumental use, both practices ultimately involve using embryos as means to advance scientific knowledge and medical treatment. A more nuanced version of this objection holds that while we may use already-existing surplus embryos instrumentally, we should never create new embryos with the sole intention of using them as means.* Porsdam, Mann et al. 2025

Conditions under which to allow research with embryos: **Highly significant research aims and proportio-nality**	• Bundesministerium für Bildung und Forschung (BMBF) 2023 • Nationale Akademie der Wissenschaften Leopoldina 2021 • Lo & Parham 2009 • De Wert & Mummery 2003 • Baylis 2002	*In addition to the requirement of scientific validity there is the requirement of scientific value. This requirement underlines the need to avoid embryo wastage in experiments where the hypothesis is unimportant and uninteresting, where the research would generate non-generalizable results, or where there is substantial overlap with proven research results. As well, in recent years the requirement of social value has been added to the requirement of scientific value to underline the importance of pursuing research of potential benefit to individuals and the community-at-large. In sum, ethical embryo research must be valuable, where "value" encompasses both scientific interests as well as social consequences.* Baylis 2002 *Ob ein Forschungsziel hochrangig sei, müsse laut dem Molekularbiologen Jan Ellenberg daran gemessen werden, dass das Ziel letztlich einen gesellschaftlichen Beitrag leiste. Er mahnte aber an, dass hier eine Einschränkung auf Forschung zur unmittelbaren medizinischen Anwendung zu kurz gedacht sei. Denn für viele Krankheiten sei es zunächst wichtig, die (z.B. genetischen) Grundlagen und Mechanismen zu verstehen. Entsprechend solle auch Grundlagenforschung beim Thema Hochrangigkeit nicht außen vor gelassen werden.* Bundesministerium für Bildung und Forschung (BMBF) 2023
Conditions under which to allow research with embryos: **No alternatives / subsidiarity**	• Sugarman 2025 • Assen et al. 2021 • World Medical Association 2020 • Kimmelmann et al. 2016 • Baylis 2002 • De Wert & Mummery 2003	*Whenever possible, research should be carried out using stem cells that are not of embryonic origin. Research with stem cells from unused embryos after in vitro fertilization techniques should only be carried out if obtaining the potential results could not also be addressed with the use of other types of stem cells, including induced pluripotent stem cells.* World Medical Association 2020 *The "principle of subsidiarity" has curiously crept into ethics and policy deliberations about research with morally sensitive materials including embryos, stem cell-based embryo models, human pluripotent stem cells and assisted reproductive technologies to erroneously describe the obligation to minimize moral incursions. For example, it has been claimed that the "principle of subsidiarity states that one should not use an entity with a higher moral status if the research can be done using an entity with a lower moral status." (ESHRE et al, 2024). However, this is a misnomer that does not cohere with standard definitions of the term subsidiarity, nor with well-established uses of this principle.* Sugarman 2025

Table 3. Ethical considerations in research with human embryos coding framework with references and example quotations

3.1.2 Ethical considerations in research with human embryonic stem cells

3.1.2.1 Ethically different from research with embryos?

The ethical considerations discussed above in relation to research involving embryos also apply to research with human embryonic stem cells (hESCs). This is because embryos are required for their derivation, and because hESCs can, in principle, differentiate into gametes, which could theoretically generate new embryos upon fusion of derived oocytes and

spermatocytes. However, most investigators working with hESCs obtain them from an already established pool of cell lines and are not involved in their derivation. According to one position, actors cannot be held causally or morally responsible for the destruction of embryos from which these cells originated, given their research activities did not influence whether the initial, ethically problematic derivation took place. From this perspective, the use of stem cell lines already in existence would be ethically unproblematic. With this rationale, e.g. Germany introduced in 2002 as a societal compromise and concession to research, the regulation that stem cell lines from abroad may be imported but not allowed to be derived within Germany and – in respondence to the complicity critique – that those imported stem cell lines must not have been derived after 2007 (see Chapter 3.2.3).

3.1.2.2 Complicity critique

Nonetheless, critiques contend that researchers who use these cells are complicit in the destruction of the embryos from which the cells were derived, since they participate in a research enterprise creating the demand for hESCs. From this perspective, it is hypocritical and a normative contradiction to rely on stem cell lines produced by others while rejecting the derivation of new lines on ethical grounds. Others, however, maintain that if the derivation of hESCs would have occurred irrespective of external demand, the charge of complicity would be unfounded.

3.1.2.3 Superiority over other stem cells vs. contestable indispensability

Arguments in favor of hESC research emphasize the unparalleled scientific promise of pluripotency, enabling research for which neither adult stem cells nor iPSCs are as suitable as hESCs. The existence of alternatives such as iPSCs has been invoked both to question the necessity of hESC research and to underline potential harms of pursuing it in parallel. Critics argue that prioritizing embryonic sources may slow the development of ethically less contentious alternatives. Yet, advocates respond that comparative research remains essential, since iPSCs and adult stem cells do not yet fully replicate the developmental potential and stability of hESCs.

Table 4 gives a full and detailed account of the ethical considerations identified in research involving human embryonic stem cells. The first column ("Code") presents the highest-order codes, while the second column ("Subcode") lists, where applicable, the lower-order codes. The third column contains the publications in which the respective ethical issue is discussed, enabling readers to locate the relevant literature for a more detailed examination of specific arguments and debates. The final column presents illustrative quotations exemplifying each ethical issue.

THEME 2 **ETHICAL CONSIDERATIONS IN RESEARCH WITH HUMAN EMBRYONIC STEM CELLS**		
CODE: SUBCODE	PUBLICATIONS	EXAMPLE QUOTE
Ethically different from research with embryos?	• De Wert & Mummery 2003	*What is the ontological status of hES cells? Should they be considered equivalent to embryos or not? Let us first consider the status of the `naked', isolated inner cell mass (ICM; the source for deriving hES cell lines). The ICM is as it were the `essence' of the pre-implantation embryo, the precursor of the `embryo proper'. The isolated ICM, however, no longer has the potential to develop into a fetus and child, as trophoblast cells, necessary for implantation and nourishment of the embryo, and extra-embryonic endoderm, are absent. It does not necessarily follow, though, that the isolated ICM is no longer an embryo we suggest that the whole, isolated ICM could best be qualified as a disabled, `non-viable' embryo (even though it might, at least in theory, be `rescued' by enveloping the ICM with sufficient trophoblast cells). What, then, is the status of the*

		individual cells from the ICM once isolated, and the embryonic stem cell lines derived from them? Should we consider these cells/cell lines to be non-viable embryos too? De Wert & Mummery 2003
Complicity critique	• Bundesministerium für Bildung und Forschung (BMBF) 2023 • Siegel 2018 • Lo & Parham 2009	*…„dass man heute in der Medizin von der Forschung profitiere, die in Deutschland selbst nicht möglich sei […]. Das Fairness-Prinzip kann z. B. angeführt werden, um moralisches „Trittbrettfahren" zu kritisieren, nämlich wenn eine Gesellschaft humane Embryonenforschung verbiete, gleichzeitig aber die Vorteile des Wissens oder die Stammzelllinien, die durch die Forschung anderer geschaffen wurden, akzeptiere.* Bundesministerium für Bildung und Forschung (BMBF) 2023
Superiority over other stem cells vs. contestable indispensability	• Bundesministerium für Bildung und Forschung (BMBF) 2023 • Kimmelmann et al. 2016 • Kirkpatrick et al. 2013	*Since 2007, when Dr. Shinya Yamanka of Kyoto University and Dr. James Thomson of the University of Wisconsin produced iPSC from adult cells, much research has focused on the possibility of stem cell therapies that do not rely on cells of embryonic origin. Because evidence shows that iPSC do retain some epigenetic memory of their cells of origin, this alternative, while viable and exciting, does not replace hESC. In these early days of many unknowns, research on all sources of stem cells is necessary to realize stem cell therapy's full potential.* Kirkpatrick et al. 2013

Table 4. Ethical considerations in research with human embryonic stem cells coding framework with references and example quotations

3.1.3 Ethical considerations in research with induced pluripotent stem cells (iPSCs)

Induced pluripotent stem cells (iPSCs) like hESCs possess the ability to self-renew indefinitely in culture and differentiate into all specialized cell types, including gametes. Unlike embryonic stem cells, iPSCs do not occur naturally; rather, they are artificially generated – or "reprogrammed" – from somatic cells. Because iPSCs can be derived from any individual, they represent a valuable resource for regenerative medicine, offering the potential to replace diseased or damaged tissues. Moreover, reprogramming technology provides a valuable tool for the investigation of mechanisms of cell fate determination and to model human diseases, thereby enhancing opportunities to discover new drugs and to develop cell therapy-based strategies to cure life-threatening diseases.

3.1.3.1 Ethical advantages of iPSCs

Non-embryonic source

One major ethical advantage of iPSCs is that their derivation does not require the use and destruction of human embryos. Prior to 2006, pluripotent stem cells could only be obtained from pre-implantation embryos, raising all the above mentioned profound ethical concerns regarding research with human embryos or hESCs. In contrast, iPSCs are generated by reprogramming of somatic cells, thereby circumventing these ethical challenges. However, the functional evaluation of iPSCs and of gametes derived from iPSCs often still requires comparison with hESCs, hence the latter remain necessary and used for benchmarking purposes. This debate for example played a major role in the development of the Italian regulatory system. Proponents of the legalization of embryo and hESC research insisted on the importance of having both of them possible. On the contrary, opponents to the legalization were claiming that important scientific discoveries could be made relying on iPSCs alone (see Chapter 3.2.4).

Reduced risk of immunological reaction

Another advantage is the potential to generate patient-specific iPSCs, which are genetically identical to the donor. This autologous approach minimizes the risk of immune rejection commonly associated with stem cell therapies. However, it is also argued that the production of autologous clinical-grade cells for individual patients presents substantial logistical and scientific challenges, and large-scale implementation is likely to be economically unsustainable.

Easier accessibility

Finally, iPSCs can be obtained from a wide variety of adult somatic cells, such as skin fibroblasts or blood cells, making them more accessible than ESCs, which require limited embryo-derived sources. In addition, the collection of somatic cells via skin biopsy is considered minimally invasive, thereby raising fewer ethical and medical concerns for donors.

3.1.3.2 Potential ethical challenges

Concerns regarding donors' rights and control specific to iPSCs

The relative ease of obtaining starting cell sources for the generation of iPSCs gives rise to some distinct ethical concerns. iPSCs can be derived from any body cell of a person – including cells that individuals shed or leave behind in everyday life, such as skin cells or hair follicles. This accessibility implies that iPSCs could, at least in principle, be generated without the explicit consent or even the knowledge of the donor, raising serious issues of autonomy, privacy, and ownership of biological material. For example, the ability to create gametes (and in consequence embryos) from any somatic cell of an individual could enable the conception of a child without that person's knowledge or authorization or the prospect of reproductive cloning, whereby an entire individual could be generated from iPSC-derived material without their knowledge or consent.

Patent and intellectual property

Although the original invention of iPSC technology was appropriately patented, it remains unclear whether subsequent, only slightly modified methods of generating iPSCs qualify for patent protection or lack sufficient novelty. For example, if an already patented reprogramming technique is applied to a different somatic cell type, the question arises whether the resulting iPSCs can justifiably be patented. Several of the ethical concerns regarding patenting and intellectual property also arise in relation to the other entities discussed in this report (e.g., SCBEMs). However, as we found these issues examined in the literature primarily in connection with iPSCs, they are addressed here in that context.

Table 5 gives a full and detailed account of the ethical considerations identified in research involving human induced pluripotent stem cells. The first column ("Code") presents the highest-order codes, while the second column ("Subcode") lists, where applicable, the lower-order codes. The third column contains the publications in which the respective ethical issue is discussed, enabling readers to locate the relevant literature for a more detailed examination of specific arguments and debates. The final column presents illustrative quotations exemplifying each ethical issue.

THEME 3 **ETHICAL CONSIDERATIONS IN RESEARCH WITH INDUCED PLURIPOTENT STEM CELLS (iPSCs)**			
CODE:	SUBCODE	PUBLICATIONS	EXAMPLE QUOTE

Ethical advantages of iPSCs: **Non-embryonic source**	• Elia et al. 2024 • Hyeon et al. 2023 • Omole et al. 2022 • World Medical Association 2020 • Moradi et al. 2019 • Zheng 2016 • Petering & Cowing 2015 • Nielen et al. 2013 • Jung 2009 • Lo & Parham 2009	*hiPSCs combine the best properties of hESCs and adult stem cells, avoiding most ethical debates, since no embryos or oocytes are used to generate hiPSCs.* Elia et al. 2024
Ethical advantages of iPSCs: **Reduced risk of immunological reaction**	• Elia et al. 2024 • Moradi et al. 2019	*Moreover, iPSCs, as opposed to ESCs, could be easily produced from patient's own cells and would not face immune rejection upon autologous transplantation of its germ cell derivatives. Therefore, the derivation of patient-specific gametes (in particular, sperm) from iPSCs would lay the foundation for the successful treatment of male infertility in the future.* Moradi et al. 2019
Ethical advantages of iPSCs: **Easier accessibility**	• Elia et al. 2024 • Omole et al. 2022 • Moradi et al. 2019 • Lo & Parham 2009	*Furthermore, because a skin biopsy to obtain somatic cells is relatively noninvasive, there are fewer concerns about risks to donors compared with oocyte donation. […] Neither the donation of materials to derive iPS cells nor their derivation raises special ethical issues.* Lo & Parham 2009
Potential ethical challenges of iPSCs: **Concerns regarding donors' rights and control specific to iPSCs**	• Omole et al. 2022 • Moradi et al. 2019 • Zheng 2016 • Lo & Parham 2009	*The ability to produce human germ cells from iPSCs, despite all its hopes and benefits, is an ethical challenge, because the resulting germ cells may be illegally and immorally used for illicit reproductive practices. In this case, issues such as (i) informed consent, (ii) safety of the approaches used to generate and differentiate iPSCs.* Moradi et al. 2019
Potential ethical challenges of iPSCs: **Patent and intellectual property**	• Nuffield Council on Bioethics 2024 • Omole et al. 2022 • Chen & Li 2021 • Moradi et al. 2019 • Petering & Cowin 2015 • Nielen et al. 2013 • Lo & Parham 2009 • Martin-Rendon & Blake 2007	*Intellectual property rights, when efficiently applied, can present a stumbling block to the progress of iPSC research. […] If investors hold several patents for these many iPSC generation methods, this can impede the translation of the technology from bench to bedside. Although European patent law is set up to protect a person's dignity, the development of iPSCs has opened a worrying loophole.* Omole et al. 2022

Table 5. Ethical considerations in research with human induced pluripotent stem cells coding framework with references and example quotations

3.1.4 Ethical considerations in human stem cell-based embryo models (SCBEMs)

SCBEM refers to a broad category of stem cell-based structures that mimic or reproduce certain features of embryonic development. These stem cells originate either from embryos (hESCs) or from reprogrammed adult cells, such as those derived from skin or blood (hiPSCs). SCBEMs differ in their composition, complexity, methods of derivation, and research applications. Due to the rapid developments in this area, establishing clear definitions or classifications of SCBEMs remains challenging, both in technical terms and with regard to ethical and regulatory considerations. Various SCBEM models enable in vitro study of early human developmental events, including implantation and post-implantation stages, as well as investigations into how external influences, such as exposure to drugs or toxins during pregnancy, may affect embryonic growth. Over time, such research may yield insights or

applications that advance human health and wellbeing. Although SCBEMs hold promise as a complement to embryo research, they currently cannot be regarded as direct substitutes or replacements. For this reason, in some countries such as Belgium (see Chapter 3.2.1), ethical debates concerning SCBEMs are not considered central: since human embryos are still required to validate SCBEMs, the ethical debates surrounding human embryos remain more pressing and significant. Rapid advances in this field, coupled with the ongoing uncertainty regarding the ethical and legal frameworks governing research on SCBEMs, have prompted significant initiatives to provide guidance over the last years. Among the most prominent initiatives is the work of the International Society for Stem Cell Research (ISSCR), which has played a leading role in formulating and revising widely influential guidelines, but also the work of the British Nuffield Council on Bioethics. These guidelines have both drawn upon and stimulated substantial debate within the scientific community.

3.1.4.1 The challenge to find appropriate terminology

The question of how these structures should be named is itself a matter of ethical debate and carries significant ethical implications. A recently published review identified 53 different terms, for example embryoids, artificial embryos, synthetic embryos, stembryo or dense, jargon-heavy expressions such as «entities that 'recapitulate developmental events reflecting epiblast and amniotic ectoderm development in the post-implantation human embryo'».[16] It is crucial that the terminology employed be as precise as possible and not misleading to non-experts, for instance by misrepresenting the (dis)similarity to human embryos. The way SCBEMs are named and described not only shapes their ethical appraisal, but may also have consequences for research funding, regulatory oversight, and ethical review. The designation "stem cell-based embryo model" employed by e.g. the ISSCR has become increasingly established. The expression highlights the source material (stem cells), underscores the purpose (to construct a model rather than an actual embryo), and specifies the object of representation (the embryo, or particular aspects of it).

3.1.4.2 Challenging categorization of SCBEMs

SCBEMs differ significantly in both their degree of complexity and in how closely they replicate complete "natural" embryos, as opposed to modeling only specific components or stages of embryonic development – and hence it is argued that the different kinds of SCBEMs are also not morally equivalent. In addition, many aspects remain poorly understood – for instance, the mechanisms through which stem cells self-organize and react to varying conditions – making experimental outcomes not always predictable. Existing guidelines for research in this area operate on the assumption that certain types of SCBEMs raise greater ethical concerns than others and thus warrant more stringent oversight. Former ISSCR guidelines distinguished between non-integrated and integrated stem cell-based embryo models, based on their differing capacities for coordinated development and their potential to acquire ethically significant characteristics. In the most recent revision of these guidelines, however, this distinction was removed, largely on the grounds that non-integrated SCBEMs can also progress to stages of considerable developmental complexity, rendering the classification obsolete. Nonetheless, some scholars maintain that the integrated/non-integrated distinction continues to be significant, since it is appropriately linked to developmental potential rather than to structural complexity and for ethical oversight, the possibility that such models might attain morally relevant properties remains a critical consideration.

3.1.4.3 SCBEMs' moral status – Capacities, features and comparison with human embryos

A central ethical debate concerns the moral status of SCBEMs and whether or when they should be treated equally as "natural" human embryos, meaning which features and capacities are ethically relevant for assessing moral status.

[16] Iltis AS, Koster G, Reeves E, Matthews KRW. Ethical, legal, regulatory, and policy issues concerning embryoids: a systematic review of the literature. Stem Cell Res Ther. 2023 Aug 21;14(1):209. doi: 10.1186/s13287-023-03448-8.

Pain

It is widely recognized that the capacity for pain in the fetus emerges between 24 and 28 weeks of gestation, coinciding with the maturation of the cerebral cortex – responsible for processing thought – and the establishment of mechanisms for the experience of pain comparable to those in adults. However, it has also been argued that that earlier forms of pain perception could not be ruled out, noting that neural activity within the subplate, an early-developing region of the cerebral cortex, is detectable as early as 12 weeks.

Consciousness

A further specific morally relevant feature discussed is the possibility of consciousness. It has been argued that a conception of consciousness should be adopted, that focuses on subjective experiences and the ability to make anticipatory, goal-directed experiences (which has been observed in fetuses as early as 12 to 14 weeks, e.g. when they can perform movements of different body parts).

Potential

The notion of potential – namely, the degree to which SCBEMs might, under appropriate conditions, be capable of developing into a human being – represents a central issue in the ethical debate surrounding this research. Scientific practices can deliberately constrain or eliminate such potential, for instance by designing models without the features necessary for continued development. The significance of such developmental potential in determining the moral status of SCBEMs remains contested. One position maintains that even the theoretical possibility of human development warrants moral status comparable to that accorded to embryos in research contexts. It has been emphasized that this potential is frequently unrealized, even in naturally implanted embryos, many of which fail to reach term. By contrast, it has been argued that embryos, taken as a cohort, possess the capacity to develop into human beings, whereas SCBEMs (at least until empirical evidence demonstrates otherwise) do not. Another perspective holds that SCBEMs, embryos, and stem cells are all reliant on the adequate environment for further development, which renders the concept of potentiality insufficient on its own as a criterion for moral consideration.
A distinction can be drawn between the developmental potential of SCBEMs in vitro and the potential for reproductive use in vivo through transfer into a uterus. Although none research attempts of the latter have been evidenced, there is broad agreement that even if SCBEMs could theoretically implant and develop in vivo, doing so for the foreseeable future would entail extensive and high-risk clinical testing, that would be unjustifiable and ethically impermissible. It has further been stated that an explicit ban on transferring human SCBEMs into the reproductive tracts of either humans or non-human animals is essential to safeguard reassurance as to the aims and regulatory frameworks of future SCBEM research.

Intentionality

It has been argued that the explicitly research-oriented purpose of SCBEMs constitutes a morally relevant factor. On that view SCBEMs are not equivalent to human embryos, even if certain SCBEMs may eventually come to closely resemble them, since unlike SCBEMs, human embryos originate within a parental reproductive project – even when later donated for scientific use – whereas SCBEMs are never created with such parental intent. However, if one accepts the ethical legitimacy of creating human embryos specifically for research, this argument loses its force, and the broader question of whether research purpose alone is morally relevant remains contested.

Artificiality

It has also been argued that the artificial origin of SCBEMs constitutes a morally relevant difference between them and human embryos.

3.1.4.4 Developmental research limits

As with research involving human embryos, there is debate over whether and how time limits should be imposed on SCBEM research, in order to establish an upper boundary on how long

such models may be cultured given the uncertainties outlined above. Moreover, SCBEMs do not necessarily follow the canonical developmental stages of human embryos. So, it would be necessary, if one were to establish such a time limit for SCBEMs, to first define the point at which counting actually begins, since, for example, unlike in the case of human "natural" embryos, there is no fertilization to serve as a reference. The UK Nuffield Council on Bioethics, for instance, has suggested an interim threshold, which stipulates that SCBEMs should not be cultivated until they have capacity for pain or awareness, must not be created with the aim of testing the possibility of gestation outside the human body, prohibits the development of late-stage embryos genetically modified to suppress pain or awareness, and requires that models be cultured only to the minimum stage necessary.

3.1.4.5 Potential ethical advantages of SCBEMs

In addition to the aforementioned potential for generating valuable insights relevant to human knowledge and health, the literature identifies two primary ethical advantages of SCBEMs.

Circumvention of ethical considerations of human embryo research?

Research with SCBEMs may avoid some of the ethical concerns associated with the use of human embryos for research – particularly when human induced pluripotent stem cells (hIPSCs) are employed for their creation, as this approach could be argued to eliminate the destruction of human embryos. However, the extent to which ethical concerns are genuinely avoided ultimately depends on the ethical evaluation of the issues outlined above – namely, whether, and on the basis of which capacities or features, human embryos and SCBEMs are considered morally similar or different.

Reduction of animal studies

SCBEM-based research has the potential to reduce dependence on animals for research purposes, which is regarded as ethically desirable, given that animal experimentation – particularly with higher animals – is increasingly considered ethically problematic. The principles of the 3Rs (Replacement, Reduction, and Refinement), which have been embedded in national and international legislation and regulations in many countries, including Switzerland, explicitly call for the development and use of alternatives to animal experiments.

Table 6 gives a full and detailed account of the ethical considerations identified in human stem cell-based embryo models. The first column ("Code") presents the highest-order codes, while the second column ("Subcode") lists, where applicable, the lower-order codes. The third column contains the publications in which the respective ethical issue is discussed, enabling readers to locate the relevant literature for a more detailed examination of specific arguments and debates. The final column presents illustrative quotations exemplifying each ethical issue.

THEME 4 **ETHICAL CONSIDERATIONS IN HUMAN STEM CELL-BASED EMBRYO MODELS (SCBEMs)**		
CODE: SUBCODE	PUBLICATIONS	EXAMPLE QUOTE
The challenge to find appropriate terminology	• Nuffield Council on Bioethics 2024 • Bundesministerium für Bildung und Forschung (BMBF) 2023 • De Graeff et al. 2023 • Iltis et al. 2023 • Matthews et al. 2021b • Zarzeczny 2020 • Nielen et al. 2013 • Maienschein 2002	*Names can hold power in public perception, and much of the confusion of how to regulate human embryoids is linked to contradictory and sometimes inaccurate names scientists and science journalists have used. Just like how the term "cloning" elicits concern (bringing to mind pictures of newly created identical humans), so do many of the general terms, such as "artificial embryos" used by the media. However, more specific terms easily become obtuse and jargon laden, prohibiting nonexperts and new researchers from understanding the field. These problems with names highlight the need for an agreed-upon general term that will allow the public to understand the research. In addition, scientists should develop a nomenclature structure to adequately communicate similarities and*

		differences between cell models for scientific audiences. Ultimately, if scientists want to gain the public's trust and avoid giving rise to unnecessary regulations on human embryoids, especially for versions that are clearly not capable of developing into a fetus, then they must work to communicate to the public what these models are and are not. Matthews et al. 2021b
Challenging categorization of SCBEMs	• De Graeff & De Proost 2025 • Gaillard et al. 2025 • Lewis & Holm 2025 • International Society for Stem Cell Research (ISSCR) 2025 • Ismaili M'hamdi 2025 • Cave 2025 • Nuffield Council on Bioethics 2024 • Bundesministerium für Bildung und Forschung (BMBF) 2023 • De Graeff et al. 2023 • Fabbri et al. 2023 • Foreman et al. 2023 • Iltis et al. 2023 • Lovell-Badge et al. 2021 • Nicolas et al. 2021 • Matthews & Moralí 2020	*However, if the categories on which oversight mechanisms are based are (or become, due to unforeseen developments) ill-defined, the consequence could be that some research is subject to disproportionate levels of oversight. The costs of this might include inefficiency in the governance system and lost opportunities if research is disincentivised. It could also mean that research which might raise significant ethical concerns 'flies under the radar'.* Nuffield Council on Bioethics 2024 *There is also no consistent definition of embryoids. No criteria that an entity must meet to be considered an embryoid have been established. There are no shared mechanisms for differentiating between simpler models and more sophisticated models that have greater capacity to develop more fully. Other than the distinction between "integrated" and "non-integrated" embryoids that some scientists use, no additional work to understand what embryoids are has been conducted. […] One possibility is that we must identify a list of necessary and sufficient conditions an entity must meet to be an embryoid. Attempting to articulate the essence of what is an embryoid could prove impossible, much as essentialist approaches to defining species have faced serious challenges and fallen out of favor. Alternatively, there might be multiple different ways to think about when an entity is an embryoid. Although this still would require identifying the plurality of ways such entities might be classified, it would alleviate the need to identify a single set of criteria, which is what the many varieties of pluralist accounts of species definition offer biologists.* Iltis et al. 2023
SCBEMs' moral status – Capacities, features and comparison with human embryos: Pain	• De Graeff & De Proost 2025 • Gyngell et al. 2025 • Cave 2025 • Nuffield Council on Bioethics 2024 • Bundesministerium für Bildung und Forschung (BMBF) 2023 • Foreman et al. 2023 • Iltis et al. 2023	*With yet further advances, it will become increasingly difficult to be certain that the models could not reach the point of pain perception, consciousness or viability in supportive conditions.* Foreman et al. 2023
SCBEMs' moral status – Capacities, features and comparison with human embryos: Consciousness	• Porsdam Mann et al. 2025 • Cave 2025 • Nuffield Council on Bioethics 2024 • Bundesministerium für Bildung und Forschung (BMBF) 2023	*All stakeholders also suggested that it would be undesirable for the SCBEM to achieve a level of awareness or consciousness, were that to become scientifically feasible.* Nuffield Council on Bioethics 2024

	• Foreman et al. 2023 • Iltis et al. 2023	
SCBEMs' moral status – Capacities, features and comparison with human embryos: **Potential**	• De Graeff & De Proost 2025 • International Society for Stem Cell Research (ISSCR) 2025 • Gyngell et al. 2025 • Ismaili M'hamdi 2025 • Lewis & Holm 2025 • Cave 2025 • Nuffield Council on Bioethics 2024 • Perereia Daoud et al. 2024 • Fabbri et al. 2023 • Iltis et al. 2023 • Nicolas et al. 2021 • Piotrowska 2020	*For many of the SCEMs brought into existence, the scientific teams that created them have specifically stated that such models lack the capacity to result in a live birth, reflecting an intuitive view that this makes the research less ethically troubling. If SCEMs lack the potential to result in a live birth, and the potentiality argument is correct, then this could be a way to justify treating embryos and SCEM differently. However, the capacity to result in a live birth is something that SCEMs could potentially possess. There are no biological reasons that precludes SCEMs from being used to induce a pregnancy and lead to a live birth. If the capacity or potential of embryos to result in live birth is morally important, it suggests scientists should focus on creating SCEMs which clearly lack this capacity. Note though, this creates a tension regarding the scientific motivation for pursuing SCEMs. As we discussed above, the research case for creating SCEMs is to generate knowledge about human development and infertility. Restricting the creation of SCEMs to models which clearly lack some features needed for successful development will reduce their usefulness in research.* Gyngell et al. 2025
SCBEMs' moral status – Capacities, features and comparison with human embryos: **Artificiality**	• Nuffield Council on Bioethics 2024 • Pereira Daoud et al. 2024	*When we asked whether this participant would think differently if hELS [human embryo-like structures] could grow into human beings, the answer was still 'no' because the resulting clone would be an artefact: "... even then, it would not be a real human being in my view, because it originates from an existing DNA". Similarly, a professional who accorded the highest ranking to "everything that is or can become a human being" did not reason that hELS – if capable of growing into a human being – should be on the same level. Instead, the professional placed such hELS still "somewhat (...) lower because they are more artificial".* Perereia Daoud et al. 2024
SCBEMs' moral status – Capacities, features and comparison with human embryos: **Intentionality**	• Cave 2025 • Nuffield Council on Bioethics 2024 • Agence de la Biomédecine 2023	*Furthermore, not everyone will agree that the intention is morally relevant. For example, if two organisms A and B were identical in all relevant respects except that A was intended to be or become a companion animal, and B was intended to be or become a research subject animal, would it follow that A had a different (higher) moral status? It could also be countered that not all conceptions which result in human babies are intentional. However, it is still arguable that SCBEMs might be perceived as having a purely research-oriented value that differentiates them from embryos.* Nuffield Council on Bioethics 2024
Developmental research limits	• De Graeff & De Proost 2025 • Gyngell et al. 2025 • Lewis & Holm 2025 • Nuffield Council on Bioethics 2024 (siehe auch Iltis et al. 2023) • Bundesministerium für Bildung und Forschung (BMBF) 2023 • Foreman et al. 2023 • Nicolas et al. 2021	*Not only is it difficult to apply the notion of human organismal potential to embryo models, but it is also unclear to what extent the 14-day rule applies to human embryoids. In particular, it is unclear how the 14-day rule translates to in vitro embryoids which are known to have different timing and can bypass the developmental timeline of normal embryos. For instance, human pluripotent stem cells grown in micropatterns can form structures resembling the primitive streak stage within 48 h of culture and have a starting point made from pluripotent stem cells of epiblast nature which can only be loosely timed to an embryo in a window between day 7*

	• Kimmelmann et al. 2016	*and day 12. Since reaching a conclusion on the timing of these structures is not straightforward, the simple translation of the 14-day rule to these new entities is not advisable.* Nicolas et al. 2021
Potential ethical advantages of SCBEMs: **Circumvention of ethical considerations of human embryo research?**	• Gyngell et al. 2025 • Lewis & Holm 2025 • Iltis et al. 2023	*The benefits of SCEMs are predicated on the claim that they are different from embryos and should therefore be exempt from embryo regulations (such as the 14-day rule). SCEMs are proposed as offering a model that can capture the inner workings of the embryo but lack its moral sensitivities.* Gyngell et al. 2025 *Oversimplifying moral status by only concentrating on one dimension/ not only take intrinsic considerations into account, but also indirect (such as relational) considerations: First, the origin of SCEMs—how they came into being—might contribute to their value. […] Similarly, there may be a difference in the symbolic value between embryos and SCEMs. The process of fertilisation—whether in vivo or in vitro—may carry symbolic meaning, representing the beginning of life, life itself or procreation, which may hold socially important value. In contrast, the self-organisation of stem cells to form SCEMs may lack such symbolic connotations. Thus, although embryos and (integrated) SCEMs could, at some point in the future, appear or be(come) similar in terms of their properties, their origins diverge significantly, which may in turn influence their symbolic and therewith moral value. Second, the purpose for which SCEMs or embryos are created—or the reason for their existence—may be considered morally relevant. SCEMs, somatic cell nuclear transfer embryos and embryos created for research are designed to simulate embryonic development without the objective of being used for reproduction or producing a live birth. In contrast, in vitro fertilisation (IVF) embryos are part of a parental project aimed at initiating life, which may enhance their relational value. Additionally, some embryos created for infertility treatment will result in pregnancies, further increasing their relational value—especially when the pregnancy is our own or that of someone we know. […] the relational value of IVF embryos may differ—be higher— compared with embryos created for research and SCEMs. This undermines the binary thinking about moral value that underpins the debate on the moral (in)equivalence of embryos and SCEMs; the 'why' of their creation matters.* De Graeff et al 2025
Potential ethical advantages of SCBEMs: **Reduction of animal studies**	• Iltis et al. 2023 • Assen et al. 2021	*The differences between hard and soft impacts are as well highlighted in the example of how organoid technology affects animal research. A possible hard impact of organoid research is reduction and/or replacement of animal studies, two of the 3Rs principles (refinement, reduction, and replacement) that contribute to ethical research. Animal studies have been considered necessary and acceptable—even if controversial—for conducting safety and efficacy studies. […] Within this context, a conceivable soft impact of organoid technology is that it could affect how animal studies are perceived. Taking the 3Rs of animal studies in mind as an ethical ground rule, it is possible that the ethical acceptability of certain animal studies will be assessed differently because of the possibility to test efficacy and safety by means of organoids. […]. In the past, studies in which harm was*

		inflicted on animals were considered proportional for acquiring insights into the safety and efficacy of interventions. Nowadays, with organoid technology, animal testing could in certain cases be perceived as disproportional, since it may not be necessary to inflict harm on animals for acquiring insights in efficacy and safety. Therefore, the existence of organoid technology can affect the permissibility of using certain animal studies. Assen et al. 2021

Table 6. Ethical considerations in human stem cell-based embryo models coding framework with references and example quotations

3.1.5 Cross-cutting ethical considerations in EmRe

3.1.5.1 Risks for and rights of donors

Informed consent – Types, justifications and adequate consideration of future possibly unforeseen uses

Research with hESCs, human embryos, human iPSCs and human SCBEMs relies on tissues or embryos donated by individuals. Such research inherently establishes a biological link to donors – for example, through shared genetic material. Beyond these, a personal dimension is argued to be morally relevant, shaped by the experiences of donors in creating and contributing embryos or tissue for scientific use. Informed consent represents a fundamental ethical requirement in EmRe. Donors must be adequately informed regarding the objectives, nature, and potential outcomes of the research. Consent can be provided in two principal forms: specific consent, which applies to defined research projects, and broad consent, which permits the use of donated material in future studies that have received ethical approval. The rationale for broad consent lies in the inherently unpredictable trajectory of scientific advancements, though it raises concerns about whether individuals can provide valid informed consent for unforeseen future uses of their materials. Given the evolving and dynamic nature of embryo research, material donated for a particular study may subsequently acquire relevance for different, unanticipated areas of investigation. This introduces ethical challenges concerning the extent to which donors' original autonomy and intentions are sufficiently respected. To address such issues, models of dynamic consent – whereby donors can periodically review and modify their consent decisions – have been proposed, although these mechanisms entail significant administrative burdens. The tension between safeguarding donor autonomy and enabling scientific innovation needs to be carefully balanced. This also encompasses the right to withdraw consent at any time: while such a provision is typically regarded as a core element of informed consent, some scholars argue that in the context of embryo research it may be unfeasible or may impose disproportionate demands on research resources.

Genetic privacy and data protection

Any cell derived from any individual for EmRe will inherently contain a vast amount of genetic information (DNA), hence privacy protection and the (im)possibility of ensuring donor anonymity is a crucial concern. Even when the original cell donor is deceased, the cells still carry information about his/her close relatives'. Removing the donor's identity information right after donation cannot resolve the problem, because advances in genomic sequencing and the growing availability of data on public and private platforms might make it possible to re-identify donors or their family members from genetic information alone. Moreover, completely eliminating donor information is not always desirable, since future research may require continued access to health-related data, which in turn depends on retaining details such as the donor's name and address.

Furthermore, during the analysis of research data in a given project, investigators may incidentally uncover information that a donor could be affected by an undiagnosed genetic disorder. Here it is first important to ensure that this information is not revealed to third parties

such as employers or insurances. However, the question also arises whether and if so, how in the case of such incidental findings, the donors themselves should be recontacted.

Monetary compensation for donation – Fair or undue influence?

The issue of monetary compensation for donors, particularly when tissue procurement involves burdensome procedures such as oocyte donation, remains contested. On the one hand it is argued that compensation is ethically justified as a matter of fairness, given the demanding, potentially risky, and time-intensive nature of the process (including strict self-administration of ovarian stimulation drugs, risk of hyperstimulation, side effects, and repeated hospital visits for monitoring). On the other hand, it is cautioned that such payments may create undue inducement or risk exploitation, particularly of socioeconomically disadvantaged donors.

3.1.5.2 Commercialization and commodification

Concerns about commodification hold that if human tissues are bought, sold, or traded, this could erode societal respect for human life and risk exploitation. Concerns have been expressed that the motivation for conducting research may be driven more by profit than by public benefit, and that its outcomes may primarily serve the interests of private companies; such apprehensions are reflected in several studies on public attitudes toward different forms of EmRe. Furthermore, the question of the patentability of inventions that require human embryos or human ESCs for commercial purposes continues to be a matter of controversy. A nuanced balance must be struck between the societal costs and benefits of commercialization.

3.1.5.3 General principles to guide regulation

Balancing ethical considerations against risks of regulation

Regulations may delay or impede research, potential scientific progress, economic growth, and international collaboration. For this reason, ethical risks and concerns must always be carefully weighed against potential benefits. This applies particularly to the difficult justification of research bans to seriously ill patients who place their hopes for treatment in stem cell research.

Importance of freedom of research

In many countries, freedom of research is regarded as a highly valuable good that may only be restricted for serious reasons, making careful balancing here essential as well.

National Variations – Need for cross-border regulations and cooperations?

There are considerable cross-national differences in the regulation of EmRe, which give rise to a range of ethical challenges. One concern is the risk of research tourism, whereby scientists circumvent stricter ethical standards in their own countries by conducting work in jurisdictions with more permissive regulations.
In addition, researchers from restrictive countries who participate in international collaborations or carry out research abroad may inadvertently contribute to activities deemed unlawful in their home states, raising questions of potential liability. Most importantly, because manuscripts, protocols, biological materials, and even patients frequently move across national borders, stakeholders must be assured that their rights and interests are safeguarded – also when collaborating with partners who may hold divergent perspectives or objectives. Moreover, the issue of ethically problematic complicity is repeatedly raised in this context, namely, the extent to which it is acceptable for countries that prohibit certain research practices to nonetheless benefit from research findings, insights, or even therapeutic applications developed elsewhere. It has therefore been suggested that international guidelines, rather than national legislation alone, are better suited to ensuring adequate protections and ethical standards.

Governance flexibility but reliable legal framework for researchers

It is widely discussed that new regulations, guidelines, and policies must remain flexible – not only to keep pace with rapidly evolving scientific developments, but also to accommodate potentially shifting ethical evaluations of specific practices. This flexibility may be achieved, for example, by incorporating periodic reviews of legislation to allow for adjustments and avoid rigidity, by establishing only a broad and flexible legal framework so that new developments

can be covered without changing the written law, by making use of on flexible approaches of anticipatory regulation often referred to as regulatory sandboxes (see Chapter 3.2.7) or by assessing the permissibility of individual research projects on a case-by-case basis. At the same time, it is emphasized that legal clarity and predictability are of fundamental importance for researchers.

FAIR principles and ecological sustainability of research

The integration of the FAIR principles (Findable, Accessible, Interoperable, and Reusable) into embryo research – for instance, through the establishment of international registries, their dissemination, and the harmonization of naming conventions – has been highlighted as crucial. In addition, attention has been drawn to the need for ecological considerations, given that biomedical laboratories are typically characterized by substantial energy consumption and extensive reliance on single-use plastic materials, underscoring the importance of developing alternative methods and more sustainable materials.

Transparency

Transparency in EmRe is considered at risk due to several factors, including the absence or underutilization of comprehensive public registries and databases, insufficient metadata management, and incomplete or opaque methodology sections in scientific publications. These shortcomings hinder replication studies and undermine scientific validation. Promoting transparency requires not only disclosure of funding sources but also the systematic publication of negative or inconclusive findings, which are frequently not the case under the current publication system. Equally important is the thorough reporting of adverse events also in preclinical research.

Openness about both successful and unsuccessful experiments is crucial not only to advance scientific progress and ensure effective oversight, but also because the public has a legitimate interest in this research. Such transparency facilitates broader discussions regarding potential benefits, risks, and costs, while also reinforcing accountability among researchers and institutions involved.

3.1.5.4 Public trust

Public trust is essential not only as a value in itself but also because its erosion can have detrimental consequences, as illustrated e.g. by debates surrounding vaccine hesitancy. Trust in science is grounded in institutional trustworthiness, which is strengthened through responsible scientific conduct and sound governance. It is further supported when researchers and policymakers communicate and justify their decisions to the public. In addition, media coverage plays a pivotal role with the potential either to reinforce or to erode public trust.

3.1.5.5 Societal engagement and finding compromises in pluralistic societies

Finding a compromise on complex normative questions, such as those related to EmRe, represents a profound challenge in democratic and increasingly pluralistic societies – even more at the international level. The debates surrounding the moral status of embryos are deeply rooted in individual convictions and cultural values, which makes the prospect of achieving consensus between strongly opposing positions difficult.

Incorporating diverse public perspectives, societal values, and interests into discussions is essential for determining which forms of EmRe are pursued and how ethically appropriate governance frameworks should be designed. This is especially relevant for emerging technologies such as SCBEMs, where early engagement and inclusive dialogue offer the potential to co-create scientific objectives and broader research agendas. Such engagement should occur in parallel with scientific progress rather than being treated merely as a later-stage, top-down communication exercise.

Wider public dialogue does not replace ethical inquiry, but both are rather complementary and should be integrated with one another. Beyond ensuring that multiple voices are heard in pluralistic societies, such open dialogue can play a crucial role in countering misinformation, reducing mistrust, and mitigating polarization in societal debates about these sensitive areas of research.

Nevertheless, despite many statements on the importance of public engagement strategies, important questions are debated and to be defined: Which type and scope should meaningful societal engagement take (e.g., community advisory boards, deliberative democratic forums, or public referenda)? Who counts as "the public" or relevant stakeholders? Which methods or models are most effective for enabling substantive societal debate? How should their outcomes feed back into policy-making processes?
Overall, clear definitions and arguments are essential for a meaningful and rational public debate. For example, if it is clearly defined on what specific grounds the decision was made to permit research only up to the 14th day, this helps to render the debates more objective. The formulation of clear rationales also enables participants to articulate more reasoned arguments, including those that express disagreement with the established regulatory frameworks.

3.1.5.6 Human animal chimeras

The successful derivations of hESCs have expanded scientists' ability to create human/non-human chimeras by inserting human stem cells into non-human animals. Other ways involve the use of non-human oocytes to establish cell lines containing human nuclear DNA via somatic cell nuclear transfer (SCNT), particularly in response to the scarcity of human oocytes. These possibilities have given rise to extensive ethical debates. Central concerns include animal welfare and moral status as well as broader questions regarding the "unnaturalness" of such practices and the ethical implications of transgressing species boundaries. Another prominent objection posits that creating beings whose classification as human or non-human remains ambiguous could generate moral uncertainty, potentially destabilizing established social and cultural norms. Further issues are raised in relation to the preservation of human dignity.

3.1.5.7 Taking ethics seriously

Risk of narrowing ethical considerations to hard impacts

It has been argued that ethical considerations should not be reduced solely to quantifiable tangible impacts (such as physical safety) but must also take into account the wider range of concerns, including the potential influence of EmRe on social structures, moral norms, and human behavior.

Ethics not only a formality

Meaningful ethical engagement is argued to be undermined when researchers approach ethical considerations merely tick-the-box-exercise or limit their attention to fulfilling legal and policy requirements, rather than critically engaging with the underlying social and ethical questions. Incorporating ethics into academic curricula, offering dedicated conference workshops, and providing funding to support ethical reflection within research institutions are beneficial measures for fostering meaningful engagement with key socio-ethical concerns.

Uncover flawed arguments

One task of ethics is to uncover flawed arguments (which should not be mistaken with unreflectively refusing the valid arguments of one's counterpart). In the debate on EmRe, a number of such logical fallacies circulate, which both complicate the discourse and heighten its moral charge, thereby entrenching opposing positions.
One example is counterarguments based on the alleged "unnaturalness" of EmRe, which prove untenable and repeatedly reveal a series of inconsistencies. Modern societies rely on numerous techniques, practices, and procedures that are "unnatural" yet widely regarded as valuable (e.g., pacemakers), while conversely deeming many natural phenomena (e.g., earthquakes, diseases) undesirable; therefore, the mere (un)naturalness of an issue does not constitute a sufficient rationale for determining its ethical desirability. Another frequent case is the use of slippery slope arguments, such as claiming that permitting certain forms of EmRe will inevitably lead to the emergence of "designer babies," and therefore EmRe should be categorically prohibited.

Related is the importance of disentangling ethical debates that are connected but not identical. For instance, in several countries, discussions about EmRe are often conflated with and instrumentalized in debates about abortion, which – as abortion is already an intensely politicized and normatively charged issue – impedes a reasoned and constructive exchange of arguments about EmRe.

3.1.5.8 Translational ethical issues when moving from research to clinical applications

Risk of overpromising benefits

There remains considerable uncertainty regarding the potential therapeutic outcomes of EmRe, including both the probability of success and the timeframe within which such outcomes might materialize. A key ethical risk lies in the tendency to overstate the prospective benefits, which may foster unrealistic expectations, generate public hype, and lead to therapeutic misconceptions. This problem is exacerbated not only by sensationalized media portrayals but also by the increasing role of social media platforms, which disseminate information about stem cell therapies directly to patients worldwide, often employing emotionally charged narratives.

Safety concerns and premature clinical translation

One valid ethical concern whenever developing, testing and implementing new therapies are concerns about the bodily safety of patients and research participants. Safety concerns become even more pressing, when researchers and clinics prematurely market and provide unproven therapies sometimes exploiting gaps in regulation and thereby putting patients at risks physically and financially. E.g. in 2017 two Swedish stem cell pioneers, have been found guilty, because falsely reported receiving ethics approval for experimental operations conducted on three children.[17] This is often driven by the push to bring certain stem cell–based interventions rapidly into clinical use without adequate scientific justification, which includes rising numbers of direct-to-consumer, insufficiently tested, or even untested therapies. Another concern that has been raised is the lack of adequate follow-up for participants and patients.

Risk of exploitation

The risk of exploiting research participants and patients has been widely discussed in the literature and manifests in several dimensions. Patients with severe unmet medical needs are often particularly vulnerable to exaggerated claims of benefit and may be exploited both psychologically and financially, for example by enrolling in or even paying for studies that are unlikely to provide therapeutic value and may even pose physical harm. Limited education among patients and physicians, along with inadequate informed consent procedures, further increase the risk of exploitation. Stem cell tourism adds another layer of concern, as frustrated and desperate patients with debilitating conditions may seek treatment in countries with less strict regulatory frameworks. Moreover, individuals in economically less developed countries may be subjected to clinical trials as “test subjects” for interventions that would not be permitted in well-resourced countries sponsoring the research.

(Mis)Allocation of resources

General ethical issues also include concerns about the appropriate and fair allocation of resources. Critics argue, for example, that investing in disease control, basic healthcare for all, access to clean water, and similar measures would save far more lives than funding highly sophisticated therapies.

Risk of rising overall costs for health care system

There is a risk that the development of personalized stem cell-based therapies will lead to an overall increase in healthcare costs. This, in turn, could have negative ripple effects on solidarity and on public support for solidarity-based healthcare systems.

[17] Dyer O. Swedish stem cell “pioneers” are found guilty of research misconduct. BMJ. 2017 Apr 10;357:j1808. doi: 10.1136/bmj.j1808

Risk of discrimination for people with disabilities and illnesses

There are ethical concerns that the development and availability of therapies could lead to discrimination against people with disabilities or certain diseases in various ways. Some individuals view their disability or illness as an integral part of their identity rather than as a negative condition requiring a cure and it is argued that the existence and public funding of a cure express the message that their lives or ways of living are less valuable than of people without that condition. Another raised concern is that prioritizing medical cures would lead to less initiatives aimed at strengthening social support systems and improving societal conditions for those living with these conditions.

Risk of inequitable access to benefits – Global disparities and fair distribution of therapies

In addition to the justice-related considerations discussed above there is the concern that the benefits of EmRe may be distributed inequitably. This applies not only on a global scale but also within well-resourced countries, where access to EmRe-based treatments may remain uneven across different patient groups.

Table 7 gives a full and detailed account of the cross cutting ethical considerations identified in human stem cell based embryo models (SCBEMs). The first column ("Code") presents the highest-order codes, while the second column ("Subcode") lists, where applicable, the lower-order codes. The third column contains the publications in which the respective ethical issue is discussed, enabling readers to locate the relevant literature for a more detailed examination of specific arguments and debates. The final column presents illustrative quotations exemplifying each ethical issue.

THEME 5 **CROSS-CUTTING ETHICAL CONSIDERATIONS**		
CODE: SUBCODE	PUBLICATIONS	EXAMPLE QUOTE
Risks for and rights of donors: **Informed consent – types, justifi-cations and adequate consideration of future possibly unforeseen uses**	• Blassime 2025 • Gaillard et al. 2025 • International Society for Stem Cell Research (ISSCR) 2025 • Nuffield Council on Bioethics 2024 • Assen et al. 2023 • Bundesministerium für Bildung und Forschung (BMBF) 2023 • Iltis et al. 2023 • Omole et al. 2022 • De Jongh et al. 2022 • Lovell-Badge et al. 2021 • World Medical Association 2020 • Alahmad et al. 2020 • Zarzeczny 2020 • MacPherson & Kimmelmann 2019 • Moradi et al. 2019 • Farajkhoda 2017 • Frati et al. 2017 • Kimmelman et al. 2016 • Zheng 2016 • Kirkpatrick et al. 2013 • Bahadur et al. 2010	*One of the first issues pertains to cell donation and informed consent of donors. Informed consent of donors is a prerequisite for conducting research on donated biomaterial. For cell lines that already exist or material already collected, even if the donor has already consented to the use of their material in broad terms, consent was probably given without the donor and researchers considering the very possibility of replicating organs in vitro. How can one ensure that consent is actually informed in such a context? Does uncertainty about the future possibilities of biotechnology nullify the right of researchers to build new biotechnological entities from material already collected, or to conduct a battery of tests such as genomic sequencing? What is tolerated for existing […] cell lines entrenched in daily lab practice might not be for newly collected material. A reflection upon the management of consent through time has been launched: is broad initial consent sufficient, or should consent be demanded again—according to a "dynamic consent" framework—when substantively new progress in cell culture is made?* Gaillard et al. 2025

	• Einsiedel et. al 2009 • Lo & Parham 2009 • Mertes & Pennings 2009 • Caulfield et al. 2007 • Chaplin 2006 • Baylis 2002	
Risks for and rights of donors: **Genetic privacy and data protection**	• International Society for Stem Cell Research (ISSCR) 2025 • Iltis et al. 2023 • De Jongh et al. 2022 • Farajkhoda 2017 • Frati et al. 2017 • Kirkpatrick et al. 2013 • Lo & Parham 2009	*Researchers performing derivations should propose a plan to safeguard the privacy of donors and inform donors that, in this era of data-intensive research, complete privacy protection might be difficult or impossible to guarantee.* International Society for Stem Cell Research (ISSCR) 2025
Risks for and rights of donors: **Monetary compensation for donation – Fair or undue influence?**	• Gaillard et al. 2025 • International Society for Stem Cell Research (ISSCR) 2025 • Farajkhoda 2017 • Frati et al. 2017 • Kirkpatrick et al. 2013 • Bhardwaj & Macer 2003	*The concept of compensating women for time, effort, and inconvenience spent on donating oocytes presents considerable attractiveness in terms of justice and psychologic and physical involvement; in particular, compensation for oocyte providers is ethically justified by the philosophical aim of counter-balancing personal losses endured by the research volunteer. The granting of compensation is more justifiable considering the remarkable time, effort, risk of complications, and discomfort sustained by donors. […] An important matter of interest is about the threat of undue inducement and the possibility to enticing socioeconomically disadvantaged women.* Frati et al. 2017
Commercializa-tion and commodification	• Gyngell et al. 2025 • Elia et al. 2024 • Hopkins 2024 • Nuffield Council on Bioethics 2024 • Iltis et al. 2023 • De Jongh et al. 2022 • Lovell-Badge et al. 2021 • World Medical Association 2020 • Lv et al. 2020 • Kirkpatrick et al. 2013 • Nielen et al. 2013 • Einsiedel et al. 2009 • Caulfield et al. 2007 • Persson et al. 2007 • Moore et al. 2006 • Bhardwaj & Macer 2003	*Some participants assume that the research will inevitably, over time, involve those with commercial as well as public sector interests. This gives rise, in their view, to a potential harm from a profit motive. They see a risk in commercial interests, for example private clinics offering enhanced IVF techniques developed through research involving embryo models for a higher fee, private medical practices treating cancer, or private research laboratories dominating the research agenda because they have the funds. They see this as potentially undermining a public sector research ethos focused on addressing key issues for all society by making the discoveries from research involving embryo models available only to those who can afford them.* Hopkins 2024 *Financial access to therapies may be affected by private companies that will finance stem cell research for which federal funding is prohibited. Because the private sector tends to invest primarily in therapies that will be profitable, other therapies that may have important therapeutic value but do not promise much commercial success may remain undeveloped.* Moore et al. 2006
General principles to guide regulation:	• Bundesministerium für Bildung und Forschung (BMBF) 2023 • Hyeon et al. 2023	*Es wurde deutlich, dass die bestehenden Regelungen insbesondere in Bezug auf die Embryonenforschung die Wissenschaft in Deutschland einschränke und internationale Kooperationen verhindere.*

Balancing ethical considerations against risks of regulation	• Devolder 2019 • Poulos 2018 • Cavaliere 2017 • Farajkhoda 2017 • Einsiedel et al. 2009 • Jung 2009 • Mertes & Pennings 2009 • Yoshimura 2006 • Daar et al. 2004	Bundesministerium für Bildung und Forschung (BMBF) 2023 *This group also referred to the potentiality of embryos to become fully developed persons, but concluded that potential persons (i.e. embryos) were different from actual persons and that this was a sufficient reason to allow research on human embryos. Unsurprisingly, according to them, the potential benefits of such research, for instance an increased understanding of early human development, better IVF procedures and treating infertility and pregnancy losses outweighed the costs of embryo research* Cavaliere 2017
General principles to guide regulation: **Importance of freedom of research**	• Bundesministerium für Bildung und Forschung (BMBF) 2023 • Nationale Akademie der Wissenschaften Leopoldina 2021 • Mertes & Pennings 2009 • Walters 2004	*Zwischen den grundrechtlichen Schutzpflichten für die Menschenwürde, dem Recht auf Entfaltung der Persönlichkeit und körperlicher Unversehrtheit sowie der Freiheit von Wissenschaft und Forschung müsse ein angemessener Ausgleich gefunden werden.* Bundesministerium für Bildung und Forschung (BMBF) 2023
General principles to guide regulation: **National variations – Need for crossborder regulations and cooperations?**	• De Graeff et al. 2023 • Foreman et al. 2023 • Iltis et al. 2023 • Lyons et al. 2022 • Chen & Li 2021 • Matthews et al. 2021 • Nationale Akademie der Wissenschaften 2021 • Nicolas et al. 2021 • Matthews & Moralí 2020 • World Medical Association 2020 • Moradi et al. 2019 • Farajkhoda 2017 • Kimmelman et al. 2016 • Lo & Parham 2009 • Mertes & Pennings 2009 • Caulfield et al. 2007	*Although stem cell research is a field that stands to benefit a lot from international cooperation, collaboration between scientists of different countries is hampered by the great divergence in national stem cell legislations. More specifically, researchers from countries with restrictive stem cell policies find themselves unable to participate in international research or attend meetings or workshops in more permissive environments as they fear being prosecuted in their home country for activities that are deemed acceptable abroad.* Mertes & Pennings 2009 *Meanwhile, manuscripts, protocols, tissues and even patients routinely cross national boundaries. In this landscape, different stakeholders need to be confident that their interests will be protected when they collaborate with parties who might have differing views or goals. International guidelines are better positioned than national laws to help ensure protection.* Kimmelman et al. 2016
General principles to guide regulation: **Governance flexibility but reliable framework for researchers**	• Assen et al. 2025 • Nuffield Council on Bioethics 2024 • Assen et al. 2023 • Bundesministerium für Bildung und Forschung (BMBF) 2023 • Iltis et al. 2023 • Mertes & Pennings 2009	*Yet, in some instances, these frameworks pose problems for responsible conduct and innovation, for example, when the guiding norms are outdated and therefore do not sufficiently steward SC research or when such governance frameworks are not responsive to changing research practices or societal attitudes.* Assen et al. 2025

General principles to guide regulation: **FAIR principle and ecological sustainability of research**	• Assen et al. 2025 • International Society for Stem Cell Research (ISSCR) 2025 • Hu et al. 2024 • Farajkhoda 2017	*Despite the establishment of registries like hPSCreg, and a decade of journals calling for adoption of standardised cell line nomenclature, the available evidence shows that most hPSCs are not registered, and poor naming practises continues to plague the field. There were at least 12,168 hPSCs publicly known in 2016, which included more than 2,168 hESCs and 10,000 hiPSCs, a number that is no doubt an underestimate given the growth of the field. The current status of hPSCreg as of March 2024 was 6,539 registered hPSCreg lines (967 hESCs, 5572 hiPSCs), which accounts for only 54 % of the total number of lines estimated eight years ago. In assessing the effectiveness of the recommendation by ISSCR for registration of hPSCs, it is important to understand why the stem cell community are not currently adopting the practice of registration.* Hu et al. 2024 *[…] ecological sustainability, as biomedical laboratories often have a high energy consumption and usage of plastic disposable items. It has been recognized that different materials and new ways of working could reduce the carbon footprint, such as opting for glass or autoclavable plastics and implementing protocols and procedures to repurpose or minimize plastic use.* Assen et al. 2025
General principles to guide regulation: **Transparency**	• Assen et al. 2025 • International Society for Stem Cell Research (ISSCR) 2025 • Hu et al. 2024 • Nuffield Council on Bioethics 2024 • Venkatesh et al. 2024 • Assen et al. 2023 • Lovell-Badge et al. 2021 • Matthews et al. 2021 • Zarzeczny 2020 • MacPherson & Kimmelmann 2019 • Frati et al. 2017 • Benjaminy et al. 2016	*Even at this stage, the authors emphasize the importance of the publication of research results regardless of whether they are positive, negative, or inconclusive, as well as the need to report all possible adverse events. About the latter, the implementation must not be limited to the number of reports but rather to the characteristics of adverse reactions such as gravity and predictability. […] According to this view, it is also recommended the need for registration of all clinical trials in progress or carried out in public databases.* Frati et al. 2017 *Calls for public discussion and research oversight are part of broader calls for transparency in science reporting. One method for increasing transparency in human embryo research is to provide details in published manuscripts regarding features pertinent to the ethical conduct of research, such as how the embryos were obtained and the ethical oversight that was provided. […] we recommended that statements should be included and standardized to include guidelines or laws followed, how long the embryos were grown developmentally, whether consent was obtained from the embryo donors and what information they were given, and whether the research was subject to oversight and approval, and, if so, by whom. Requiring greater transparency regarding the ethical conduct of human embryo research is one way to respond to calls for more transparency in science reporting, emphasizes the importance of the ethical conduct of such research, and increases the likelihood of adherence to existing regulations and guidelines.* Venkatesh et al. 2024
Public Trust	• International Society for Stem Cell	*Ethical principles and guidelines help secure the basis for this collective effort together with an internationally coordinated framework to regulate research at all levels,*

	Research (ISSCR) 2025 • Nuffield Council on Bioethics 2024 • Assen et al. 2023 • Iltis et al. 2023 • Cavaliere 2017 • Frati et al. 2017 • Benjaminy et al. 2016 • Einsiedel et al. 2009	*including clinical trials and market access to proven interventions. This helps to give the public and research funding organizations confidence that generally accepted ethical boundaries will not be crossed in either basic or clinical research. Patients should be able to enroll in clinical research trusting that studies are well justified, appropriately designed and ethically sound, the risks and burdens are reasonable in relation to potential benefits, the quality and manufacturing of the experimental product fulfills the standards expected for safe human administration, and the study will collect meaningful information to support further development of the intervention. Physicians and payers need to be confident that the evidence they use to make important healthcare decisions is rigorous and unbiased. Organizations, including private firms, can invest in research and product development programs knowing that products will be promptly and fairly evaluated by regulators.* International Society for Stem Cell Research (ISSCR) 2025
Societal engagement and finding compromises in pluralistic societies	• Assen et al. 2025 • Elia et al. 2024 • Hopkins 2024 • Nuffield Council on Bioethics 2024 • Pereira Daoud et al. 2024 • Venkatesh et al. 2024 • Assen et al. 2023 • Bundesministerium für Bildung und Forschung (BMBF) 2023 • Fabbri et al. 2023 • Foreman et al. 2023 • GermanStemCellNetwork 2023 • HDBI 2023 • Hyeon et al. 2023 • Iltis et al. 2023 • Sugarman et al. 2023 • Assen et al. 2021 • Lovell-Badge et al. 2021 • Matthews et al. 2021a • Nationale Akademie der Wissenschaften Leopoldina 2021 • Nicolas et al. 2021 • World Medical Association 2020 • Cavaliere 2017 • Farajkhoda 2017 • Bahadur et al. 2010 • Mertes & Pennings 2009 • Caulfield et al. 2007 • Chaplin 2006 • Bhardwaj & Macer 2003 • Maienschein 2002 • Colman 2001	*Many publications mention the importance of trust, public or stakeholder engagement, and/or transparency. However, they rarely define engagement or transparency or indicate how it could be achieved. Often, they include little or no discussion of who counts as a stakeholder and how they understand "the public" with whom they recommend engagement. There is no clarity about the type and scope of engagement they recommend nor the purpose of engagement. In addition, there is little to no discussion on how such engagement should inform research and policy decisions. […] However, neither the paper nor the ISSCR guidelines it references offers any details regarding who this public engagement should include, what it should address, the approach, methods, or models for such engagement, or how it should be used. It is also unclear how researchers would respond if public engagement results in recommendations for limiting or even restricting research. […] True public engagement could help uncover broader social concerns related to research and ways to address them. These discussions, in turn, could play a key role in guiding future research or fostering public acceptance of new research.* Iltis et al. 2023
Human animal chimeras	• Gaillard et al. 2025	*iPSCs could also be used for the generation of humanized organs inside large animals through interspecies*

	• Porsdam Mann et al. 2025 • Iltis et al. 2023 • De Jongh et al. 2022 • Moradi et al. 2019 • Frati et al. 2017 • Kimmelman et al. 2016 • Einsiedel et al. 2009 • Jung 2009 • Lo & Parham 2009	*blastocyst complementation. […] The best animal hosts for growing human organs are considered to be large animals with high physiological similarity to humans such as cattle and pigs. […] Of note, host animals chimerized with human iPSCs provide a reliable functional assay for confirming the full pluripotency of human iPSCs. Due to ethical concerns of human-animal chimerism, it would be important to develop in vitro functional assays (that are more informative than teratoma formation) in order to exclude or reduce the use of animals as hosts for testing the pluripotency of human PSCs (including iPSCs). For regenerating human organs, however, animal hosts appear to be the best available option, although it is ethically challenging. In fact, blastocyst complementation might potentially lead to the generation of acute human/ non-human chimeras with an ambiguous moral status, because human iPSCs might differentiate into brain cells in the chimeric animals. In other words, acute human/ animal chimerism might create animals that not only have humanized organs but are also morally humanized. Acquiring a human-like consciousness by chimeric animals is ethically unacceptable, since consciousness represents a major distinction between animals and humans. Moreover, the human iPSCs injected into the host animals might give rise to human gametes in the chimeric animals, posing a serious ethical conundrum.[…] Therefore, further research and debate are needed to properly address major ethical concerns associated with human/animal chimerism.* Moradi et al. 2019
Taking ethics seriously: **Risk of narrowing ethical considerations to hard impacts**	• Assen et al. 2025 • Assen et al. 2021 • Cavaliere 2017	*The ethical implications of stem cell research are often described in terms of risks, side effects, safety, and therapeutic value, which are examples of so-called hard impacts. Hard impacts are typically measurable and quantifiable. To understand the broader spectrum of ethical implications of stem cell research on science and society, it is equally important to recognize soft impacts. Soft impacts are the effects on behavior, experiences, actions, moral values, and social structures; these are often indirect effects of stem cell research. The combined notions of hard and soft impacts offer a broader way of thinking about the social and ethical implications of stem cell research and can help to steer stem cell research into a sociable desirable direction. Soft impacts enable researchers to become more aware of the broad range of significant implications involved in their work and deserve equal attention for understanding such ethical and societal effects of stem cell research.* Assen et al. 2021
Taking ethics seriously: **Ethics not only formality**	• Assen et al. 2025 • Assen et al. 2023	Mere compliance could neglect ethical reflection on the research practice by SC researchers. Assen et al. 2025
Taking ethics seriously: **Uncovering of flawed arguments**	• Gyngell et al. 2025 • Bundesministerium für Bildung und Forschung (BMBF) 2023 • Nicolas et al. 2021 • Cavaliere 2017 • Nuffield Council on Bioethics 2015	*Moreover, the political climate in the USA has made it almost impossible to discuss human embryoids' ethical status without immediately opening the door to a broader discussion about abortion. The fervor around this debate has contributed to a mischaracteri-zation of these complex technological innovations. Despite efforts to engage in meaningful technical discussions, the debate always falls back to the vast and unsolvable debate around the moral sanctity of the human embryo.*

	• Bahadur et al. 2010 • Einsiedel et al. 2009 • Jung 2009 • Caulfield et al. 2007 • Whittaker 2007 • Patel 2006 • Daar et al. 2004 • De Wert & Mummery 2003	Nicolas et al. 2021 *Using naturalness as proxy for morality fails, however, when we consider other, highly accepted, medical procedures. Very basically, perhaps, we keep a patient on life support despite his natural tendency to die. The pacemaker we install creates an artificial, not natural, rhythm in the heart. We induce childbirth, sometimes as early as 32 weeks, if we feel that the baby's health would suffer during a prolonged pregnancy. Indeed, in vitro fertilisation itself is hardly natural, in that it eliminates copulation from the process of reproduction. It seems that all advances in medical technology do something unnatural in order to alleviate pain and suffering, or to offer the joys of very natural procedures like childbearing.* Patel 2006
Translational issues when moving from research to clinical applications: **Risk of overpromising benefits**	• Assen et al. 2025 • Nuffield Council on Bioethics 2024 • Assen et al. 2023 • Bundesministerium für Bildung und Forschung (BMBF) 2023 • Lyons et al. 2022 • Assen et al. 2021 • Nicolas et al. 2021 • Lv et al. 2020 • Sharma 2019 • Frati et al. 2017 • Benjaminy et al. 2016 • Lo & Parham 2009 • Maienschein 2002	*Whether the focus is print or online news, study after study has provided data about hyperbolic reporting of the benefits of biotechnology with little context of its risks, limitations or timeframes for application. […] The majority (58 %) of articles do not make timeframe projections about the research and development of stem cell interventions for neurodegenerative diseases, and none of the articles discuss the possibility that stem cell therapies may never be realized.* Benjaminy et al. 2016 *Internet-based, direct-to-consumer advertisement is a key component of the business models of clinics and biotech companies selling unproven and unauthorized stem cell–based interventions, with the aim to attract patients residing domestically and abroad. These treatments pose serious safety and financial risks to patients and their families. By raising their expectations and spreading misinformation, the companies also undercut efforts to develop safe and effective stem cell–based treatments for patients whose diseases or conditions currently have no effective treatment.* Lv et al. 2020
Translational issues when moving from research to clinical applications: **Safety concerns and premature clinical translation**	• International Society for Stem Cell Research (ISSCR) 2025 • Assen et al. 2023 • Lovell-Badge et al. 2021 • World Medical Association 2020 • Lv et al. 2020 • Zarzeczny 2020 • MacPherson & Kimmelmann 2019 • Sharma 2019 • Poulos 2018 • Barker et al. 2018 • Frati et al. 2017 • Kimmelman et al. 2016 • Einsiedel et al. 2009 • Jung 2009 • Lo & Parham 2009	*One challenge policy makers face is that it can be difficult to predict with any accuracy both the potential benefits and also the potential risks of new technologies and avenues of research. […] Most important concerns surrounding the wide range of allegedly stem cell based interventions offered in the private market concerns physical risks to patients. Reports of tumours, lesions, infections and vision loss, among other issues, associated with unproven stem cell interventions of one form or another highlight that the risks of stem cell related interventions are not insignificant. There are different kinds and degrees of risk, depending on the types of cells used, what has been done to the cells (i.e. whether and how they have been manipulated/ processed) and how they are administered. Unfortunately, these important distinctions often appear to be lost in many of the products and services currently advertised on the private market.* Zarzeczny 2020

	• Von Tigerstrom 2009 • Whittaker 2007 • Chaplin 2006 • Yoshimura 2006 • White 2005	
Translational issues when moving from research to clinical applications: **Risk of exploitation**	• Lyons et al. 2022 • Frati et al. 2017 • Mertes & Pennings 2009 • Chaplin 2006	*So far we have defended the right of researchers to travel to permissive environments to perform hESC research that is ethically justified in their eyes, even if it is morally condemned in their home country (although they should not divert public money to such research). However, fears could arise that if this principle is extended to include other research areas, it may lead to exploitation of more vulnerable populations in developing countries with less stringent laws, especially when the research involves human research subjects.* Mertes & Pennings 2009 *Those opposed to this form of research expressed fear that the technology may end up in the wrong hands and result in coercion to obtain access to eggs. There were fears that this could lead to the development of a black market for extra body parts.* Einsiedel et al. 2009
Translational issues when moving from research to clinical applications: **(Mis)Allocation of Resources**	• Einsiedel et al. 2009 • Waters 2004 • Whittaker 2007 • Bhardwaj & Macer 2003	*Is it acceptable to devote this level of resources to such medical research, which would be extremely expensive to develop, when these could be used to improve significantly the basic health of the large numbers of poor?* Whittaker 2007
Translational issues when moving from research to clinical applications: **Risk of rising overall costs for health care system**	• Assen et al. 2021	*Therefore, the development of organoids for personalized interventions may also increase the overall costs for healthcare. This financial harm is a possible negative hard impact of the success side of this technology. By focusing merely on the increasing costs of medical research and innovations, one may overlook the soft impacts and how technological developments are embedded in a broader social context. Within this context, organoid research used in personalized medicine could potentially affect the financial sustainability of solidarity-based healthcare systems. An example of solidarity in healthcare is the collective responsibility for paying the costs in healthcare. […] When organoid research-based innovations indeed lead to considerably increased healthcare costs, it could affect the surrounding system of solidarity and consequentially our attitudes to others.* Assen et al. 2021
Translational issues when moving from research to clinical applications: **Risk of discrimination for people with**	• White 2005	*Some in the disability community have balked at the call for stem cell research as a cure for spinal cord injury. There are those who identify with their disability as a part of who they are, not something negative that needs to be cured. Furthermore, some feel that the focus on cure diminishes those whose disabilities will never be amenable to curative interventions. There are others who value the notion of a possible cure but feel that funding would be misappropriated. […] Furthermore, there are some who assert that it is society, not disabling conditions,*

disabilities and illnesses		*that creates handicap. It is the lack of access, the lack of funding for attendant care and community reintegration, and the lack of tolerance by people in the community that diminish the quality of life of those with disability. Disability will always be with us in some form.* White 2005
Translational issues when moving from research to clinical applications: **Risk of unequitable access to benefits – Global disparities and fair distribution of therapies**	• International Society for Stem Cell Research (ISSCR) 2025 • Lyons et al. 2022 • Lovell-Badge et al. 2021 • MacPherson & Kimmelman 2019 • Frati et al. 2017 • Whittaker 2007 • Chaplin 2006 • White 2005 • Bhardwaj & Macer 2003	*Fairness demands that the benefits of clinical translation efforts should be distributed justly and globally, with particular emphasis on addressing unmet medical and public health needs. To that end, the scientific community is encouraged to work with private and public funders to emphasize addressing unmet needs by helping to identify promising areas of research, development, and application. […] Social justice considerations include challenges due to structural injustices, such as socioeconomic inequalities, extant discriminatory practices, and histories of exclusion and marginalization. Advantaged populations should make efforts to share any benefits of research with disadvantaged populations. This would include 'capacity building,' both training and establishment of facilities, which gives benefit in the longer term. There should also be appropriate sharing of the burdens with disadvantaged populations. Trials should strive to enroll populations that reflect diversity such as age, sex, gender identity, and ethnicity. Risks and burdens associated with clinical translation should not be borne by populations that are unlikely to benefit from the knowledge produced in these efforts. The scientific community is encouraged to work with governments and industry to develop mechanisms to reduce the cost of clinical applications.* International Society for Stem Cell Research (ISSCR) 2025

Table 7. Cross cutting ethical considerations in EmRe coding framework with references and example quotations

3.2 Regulatory landscape in selected countries

When it comes to operationalizing ethical considerations around EmRe in specific regulations, there is great variations amongst the analysed legal systems. This was identified during WP2 and the interviews in WP3 and is summarised in this part of the results. On the one hand, there are countries with a very restrictive regulatory framework. Italy and Germany prohibit categorically any research with embryos and research with hESC is very limited: Germany allows it only on imported hESC but under specific conditions; Italy does not have explicit rules, but funding for hESC is very contested and iPSC research is favoured. France and the Netherlands are more permissive, but – in terms of research with embryos – they only allow it on supernumerary ones. Belgium, Sweden and the United Kingdom are – on the contrary – very permissive and allow many types of EmRe, albeit with conditions (e.g. 14-day-rule). Countries differ a lot in terms of EmRe oversight, with some countries requiring approval by specialized centralized commissions, whereas others require only approval by 'regular' research ethics committees (i.e. the ones that approve any type of health-related research).

This diversity is also due to the fact that only some countries have signed and ratified the Oviedo Convention, which attempted to harmonise governance of embryo use, including for research. For those ratifying the Convention (e.g. the France), this requires to prohibit the creation of embryos for research purposes only. Some ratifying countries, like Switzerland, have also implemented its provisions into national law (e.g. Art. 119 of the Swiss Cconstitution and specific provisions on the law on MAR prohibit the creation of embryos for research), and have developed a lengthy debate on what that means in relation to the status of embryos (for example here[18]).

Table 8 gives an overview of some features of the regulatory frameworks, in order to provide a general idea of similarities and differences between regulatory approaches.

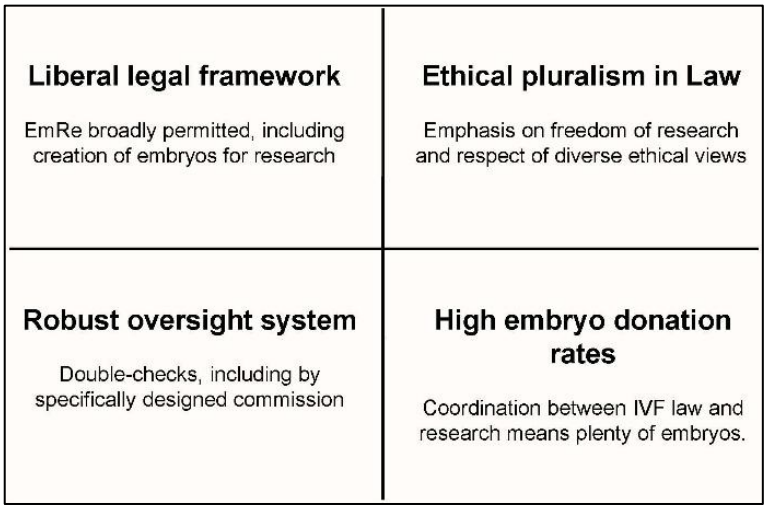
Country	Explicit definition embryo	Criteria for research with embryos	Informed consent & embryo preservation*	Governance structure & ethics review	Regulatory initiative SCBEM
BE	Yes	14-day rule, aim to increase scientific knowledge or therapeutic application	Specific & broad consent, 5y preservation	Approval by both specialized committee & regular ethics committee	No
FRA	No	14-day rule, medical purpose or to improve knowledge of human biology	Broad consent, 5y preservation	Approval by specialised authority	Yes
DEU	Yes	Forbidden. For hESC a "high end purpose" is required	N/A	Approval for hESC by specialised committee	No
ITA	No	Forbidden	N/A	N/A	No
NED	Yes	14-day rule, aim to generate new	Specific consent, 10y preservation	Approval by specialized committee	Yes

[18] Nationale Ethikkommission im Bereich Humanmedizin NEK-CNE, *Forschung an menschlichen Embryonen und Föten* (2006).

		insights into medical science			
SE	No	14-day rule, no specific aim required	Specific consent, 10y preservation	Approval by regular ethics committee	Yes
UK	Yes	14-day rule, list of purposes research must serve	Specific consent but Broad under consideration. Up to 55y preservation	License by specialized authority & ethics committee	Yes
* This indicates the standard maximum duration. Exceptions are possible.					

Table 8. Overview of the different regulatory systems

3.2.1. Belgium



Belgium has one of the most permissive regulatory frameworks in terms of EmRE in a European context, given that freedom of research is given central importance. Indeed, research is allowed both with supernumerary embryos and with those created specifically for research. At the same time, it has a strong oversight system, given that EmRe requires both approval by regular ethics committees and also a specialized commission on embryo research. Donation of embryos for research is facilitated by the fact that also donation for 'domains of research' rather than specific research projects is permitted. In the summary-box to the side, an overview of the main features of the Belgian system are offered. In the following paragraphs, a more detailed overview of the regulatory framework is presented.

3.2.1.1 Historical background

In Belgium, EmRe is regulated through a complex legislative framework evolved overtime. There were already early debates in the 1980s–90s about how embryo research should be regulated, and to what extent it should be permitted. However, any legislative initiative in the field was blocked due to the composition of governmental coalitions. Indeed, the Christian Democratic Party was in every government coalitions since the end of the second world war until 1999 and discussions on the regulation on EmRe "were largely avoided by every government that included the centrist Christian Democracy Party and the Socialists".[19] In this period, Belgium refused to sign the Oviedo Convention of 1997.[20] This action was made mainly to avoid future legal constraints on matters related to biotechnological research and also EmRe, since there are some articles in the convention that prevent national legislators to regulate freely (e.g. art. 13 and 18). In a way, Belgium lawmakers did not want to pre-emptively tie their hands. Even if the publication of a law on EmRe was not on the table at the time when

[19] G. Pennings, 'The Regulation of Human Germline Genome Modification in Belgium', in A. Boggio, C.P.R. Romano and J. Almqvist, eds, *Human Germline Genome Modification and the Right to Science*, 1st edn, (Cambridge University Press, 2020): 266–80.

[20] Council of Europe, *Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164)* (1997).

the Oviedo Convention opened for signature, the idea was to refrain from signing to avoid international constraints on national legislation.[21]
The stalemate changed drastically after 1999. For the first time in decades a new government coalition excluding Christian Democrats, but including socialists, liberals, and greens, was elected.[22] Due to ideological alignment of these parties, Belgium passed and enacted major bioethics legislation between 1999 and 2008. A cornerstone of this legislative effort (which included also a law on euthanasia), was the passing of two pieces of legislation that have then become central for EmRE: a law on embryo research in 2003 and a law on MAR in 2007.

3.2.1.2 Core legal sources and features

The principal legal instrument governing embryo research in Belgium is the Law on Research on Embryos In Vitro (2003).[23] This law lays out the conditions under which in vitro embryo research is permitted and prohibited. It is then supplemented by the Law on Medically Assisted Reproduction and the Disposition of Supernumerary Embryos and Gametes of 2007, which regulates MAR, including embryo donation for research.[24]
Belgian law follows a model of permissive default ("everything not forbidden is allowed"[25]), subject to oversight and conditions. In practice, this means that although the law places certain prohibitions, a wide range of research is allowed if authorized by the appropriate ethics bodies. Under the 2003 law, research may be conducted provided it is oriented toward therapeutic aims or the advancement of medical and scientific knowledge.[26] The law allows the creation of embryos for research when the research objective cannot be attained using surplus embryos. At the same time, the law prohibits certain practices, such as sex selection for non-medical reasons, eugenic manipulations, reproductive cloning and the commercial exploitation of embryos, gametes and embryonic stem cells. Belgium also adheres to the commonly adopted limit of 14 days (or before formation of the primitive streak) for in vitro embryo culture and research.
The regulatory framework is complemented by the 2007 law on MAR, which regulates how supernumerary embryos are handled, the options for donation and destruction, the conditions of informed consent, maximum storage periods, and contractual arrangements with fertility clinics.[27] A maximum storage period of 5 years is imposed for embryos, with the possibility of extension in exceptional cases (Art. 17), but fertility centres can refuse extensions. For gametes, the maximum is 10 years for personal use. There are some exceptions, for example concerning gametes collected for fertility preservation in young cancer patients. Embryos earmarked for scientific research or donation to others are not subject to a fixed storage period, which creates potential tensions because donors may still retract consent until the research begins.[28]
These provisions reveal the strict connection between the regulation of MAR and of EmRe, thus revealing a regulatory system where clinical creation of embryos for reproductive purposes and then their potential use in research is connected. This is demonstrated also by the fact that regulation requires that embryo "research must be performed in a laboratory of a university that is recognized as a center for reproductive medicine".[29]

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[21] Pennings, supra note 19.
[22] G. Pennings, 'New Belgian Law on Research on Human Embryos: Trust in Progress Through Medical Science', Journal of Assisted Reproduction and Genetics 20, no. 8 (2003): 343–6; Pennings, supra note 19.
[23] *Wet betreffende het onderzoek op embryo's in vitro* (2003).
[24] *Wet betreffende de medisch begeleide voortplanting en de bestemming van de overtallige embryo's en de gameten* (2007).
[25] Pennings, supra note 22.
[26] Ibid.
[27] G. Pennings, 'Belgian Law on Medically Assisted Reproduction and the Disposition of Supernumerary Embryos and Gametes', *European Journal of Health Law* 14, no. 3 (2007): 251–60.
[28] Ibid.
[29] G. Pennings, S. Segers, S. Debrock, B. Heindryckx, V. Kontozova-Deutsch, U. Punjabi, H. Vande Velde, A. Van Steirteghem and H. Mertes, 'Human Embryo Research in Belgium: An Overview', *Fertility and Sterility* 108, no. 1 (2017): 96–107.

3.2.1.3 Governance structure

The Belgian legal framework is characterized by a comprehensive institutional governance structure for EmRe. The law establishes that research projects including embryos, like any other research projects, need first to be examined by local research ethics committees. These are often organized at the hospital level, but they can also be setup by other medical institutions and there are thus a high number of them (more than 150 of them are active according to an estimate of 2019[30]). However, since EmRE can be conducted only in university hospitals or with their collaborations, the ethics committees that are concretely examining embryo research are a small number in the few hospitals that actually carry out this kind of research.

Once an ethics committee approves an EmRe project, it is sent for a further in-depth examination to the Federal Commission for Medical and Scientific Research on Embryos In Vitro.[31] This centralized federal institution constitutes the center of the governance structure for EmRe in Belgium. It is composed of 14 members, and an equal number of substitutes. Its composition is set by the law, and it requires experts in different disciplines (law, ethics, science, medicine) and from different language regions. Amongst its main duties, is that of examining any EmRe projects, even after they have received ethics approval in the first instance. The Commission has a maximum of 2 months to provide an answer once a project is submitted, and it can stop a project only if at least 2/3 of the members vote for it. Importantly, the Commission then receives from each approved EmRe project a yearly update report on the status of the research and on any legally and ethically relevant change in how it is conducted. If a breach to legal conditions is noticed, the Commission can terminate the projects. Beyond evaluating single projects after their ethics approval, the Commission has also a proactive role in shaping good governance for the MAR clinics that collect embryos for research, in order to operationalize the requirements of legislation. For example, the commission helps the clinics to elaborate informed consent forms and information materials, which are then used to inform patients that may want to donate supernumerary for research.

The last institution that plays a role in the governance structure for EmRe is the Federal Advisory Committee on Bioethics.[32] This provides ethical and policy guidance on sensitive bioethics matters, including embryo research and the implementation of good governance and research practices. It also plays a role in shaping national positions on sensitive issues related to this matter. For example, it has published a document regarding research on human embryos in vitro in 2002.[33]

3.2.1.4 Key rules on the procurement of supernumerary embryos for research.

Like in other countries, the majority of embryos used in research is procured through supernumerary embryos that are left over after MAR and are then donated to research. For this reason, MAR clinics play a central role in the legal framework. They are the ones which provide MAR patients with brochures and information on EmRe, and offer counselling sessions to patients about what the meaning of embryo donation for research entails. Moreover, they apply the consent requirements that are legally needed if patients want to donate embryos for research. In concrete terms, MAR clinics ensure that patients are asked before the treatment what they want to do with their supernumerary embryos (if any are left). Patients can choose between three possibilities: 1) donation to other couples that then use the embryo for MAR; 2) destruction of the embryo; 3) donation to research. In case they donate for research, two different practices are accepted. Patients can donate fresh embryos for a specific research project, in case there is a study already ongoing and it necessitates fresh embryos. Otherwise, in case the donation concerns embryos that are – or will be – cryopreserved, then a so-called broad consent applies. MAR patients are asked if they want to consent to donate their frozen

[30] Pennings, supra note 19.
[31] Federale Commissie voor medisch en wetenschappelijk onderzoek op Embryo's in-vitro (FCE), n.d., *available at*: <https://overlegorganen.gezondheid.belgie.be/nl/advies-en-overlegorgaan/commissies/federale-commissie-voor-medisch-en-wetenschappelijk-onderzoek-op> (last visited November 03, 2025).
[32] Belgian Advisory Committee on Bioethics, n.d., *available at*: <https://www.health.belgium.be/en/belgian-advisory-committee-bioethics> (last visited November 03, 2025).
[33] Belgian Advisory Committee on Bioethics, *Opinion no. 18 - research on human embryos in vitro* (n.d.).

embryos to be potentially used for future research projects which are undetermined at the time of consent. At the same time, this consent is not blank: patients are offered the choice to agree for pre-defined domains of research, so that they can still exercise some agency. The Federal Commission is responsible for defining these 'broad' domains of research to which patients can consent. An example of a consent form is can be found online,[34] and it shows the different domains of research for which a broad form of consent can be provided (e.g. research on "Embryonic development and implantation of the embryo in the uterus" or on "Embryonic stem cell" or on "Genome modification").
Although donation of supernumerary embryos for research can technically happen in all MAR centres (a total of 18 in Belgium), it is important to remark that only 8 MAR centers – which are also embedded within university hospitals – applied and received the specific license for conducting EmRe. Moreover, only 4 out of these 8 centers actually carry out research projects on embryo research, since they have the funding, resources and know-how available. This means that many more centers than those that actually conduct EmRe may still be collecting embryos for which patients have provided consent to do research.

3.2.1.5 Note on the creation of embryos for research.

According to Art. 4 of the 2003 law on Embryo research, the creation of embryos for research is possible but only as a last resort. This means that it is only allowed when there is a research project that cannot inherently be conducted with supernumerary embryos (e.g. project studying the creation of genetically modified embryos, or studying the very early phase of embryo development). This further enshrines the subsidiarity principles that characterizes Belgian law. Concretely, this means that – if researchers want to create embryos for research – they have to explicitly declare so in the ethics protocol they prepare and they have to also justify why the creation is necessary. It is then the job of the Federal Commission to assess if the creation for research is justified.
In total, less than 10% of all embryos used in research have been especially created for this purpose, whereas the great majority comes from supernumerary embryos donated by MAR patients.[35] This is not only due to the fact that the law makes it more difficult to use them (due to the principle of subsidiarity, which requires researchers to provide extra justification). It is also due to the fact that creating embryos for research still needs the donation of eggs and sperm, which are the basic material for embryo creation. Since there is scarcity of egg-donors in Belgium – like in many other countries in Europe and beyond – this has also an impact in limiting the use of embryos created specifically for research. Egg donors that donate their eggs for the creation of embryos for research receive a compensation that is the same as egg donation to other MAR patients (max 2000 euros).[36]

3.2.1.6 Other important features.

Despite being generally permissive in international comparison, the Belgian legal framework is not excessively laissez fair. There are indeed many explicit and blank prohibitions. For example, the law prohibits the commercialization of embryos, gametes and stem cells. Moreover, there is a total ban on germline gene editing of the embryos, when the objective of the intervention is to lead to enhancement. Eugenic practices and reproductive cloning are also prohibited.
It must also be noted that empirical research suggests there is general approval amongst the public for EmRe research. For example, a study examining embryo disposition decisions amongst patients from fertility clinics indicated an increase overtime of the popularity of the option of donating supernumerary embryos for science and research.[37] At the same time, other empirical research has also shown that patients knowledge about the meaning of embryo

[34] Brussel IVF, *INFORMATION ON THE USE OF GAMETES AND EMBRYOS FOR TRAINING PURPOSES AND SCIENTIFIC RESEARCH* (n.d.).
[35] Pennings, Segers, Debrock, Heindryckx, Kontozova-Deutsch, Punjabi, Vande Velde, Van Steirteghem and Mertes, supra note 29.
[36] Ibid.
[37] V. Provoost, G. Pennings, P. De Sutter, A. Van De Velde and M. Dhont, 'Trends in Embryo Disposition Decisions: Patients' Responses to a 15-Year Mailing Program', *Human Reproduction* 27, no. 2 (2012): 506–14.

research and research with embryonic stem cells is quite low.[38] Explorative qualitative research with Belgian fertility patients has suggested that their perception of science, rather than of the status of the embryo, can influence their decisions to donate embryos for research.[39]

In respect to international collaborations in EmRE, this is legally permitted. On the one hand, there is however not a lot of import of embryos for research, since in the country itself there are many embryos available without the need to import. This is because research is constrained by financial and capacity limits – rather than legislative bans – and not all embryos donated for research can be used. In terms of exports of embryos and embryonic material, this may happen, especially because complex research projects require collaboration with advanced labs in other countries. Here, the only necessary condition for exporting is that researchers must certify that the destination country follows comparable ethico-legal standards to those in Belgium – which is not problematic, since many countries are anyway more restrictive than Belgium. For stem cell lines – even when they are derived from embryos – they follow the general rules for the use of biological material. These are defined by the Belgian law on biobanks of 2008[40] as modified in 2022.[41]

3.2.1.7 Current debates and future challenges for the regulation

In general, the legal framework in Belgium is stable and there are no big demands nor projects for legal reform. At the same time, some topics are debated. One constitutes the definition of embryo and what it encompasses. There are some ambiguities with entities like parthenotes and aneuploid embryos – given that they do not have the potential to develop into human beings. At the same time, the federal Commission currently considers them “embryos” for precautionary reasons.[42]

Another topic of debate concerns whether the law regulating embryo uses defines research in a satisfying way. Some clinical activities (e.g. use of embryos for the application of new techniques within a lab) are not classified as research according to the current regulatory framework, even though these activities still include embryo use. Furthermore, many educational activities (e.g. for medical professionals that are training how to perform IVF) still require embryos to practice, but they are excluded from the application of governance framework for EmRE (e.g. no examination by the Federal Commission).[43]

There are also some debates on whether SCBEMs could require the change of the governance framework. Indeed, these entities – not being embryos in the strict sense – could bypass ethical and legal restrictions posed for EmRe in Belgium, including the accurate governance structures and institutions. There are thus signs of a preliminary debate in the Federal Commission to decide whether this necessitates legal changes. For example, a meeting was planned in November 2025 for the Commission to debate this issue, but it was recently postponed.[44] At the same time, Belgium tends to see SCBEMs as complementary, and not substitutes for embryo research – especially because there are plenty of embryos to use anyway in the country and the use of such embryos does not raise particular challenges within the actual regulatory and societal framework. Therefore, rather than regulating, facilitating or incentivizing their use, there are more discussions how the use of embryos collected could be

[38] V. Provoost, G. Pennings, P. De Sutter and M. Dhont, ‘Decisions on Embryo Disposition in Cross-Border Reproductive Care: Differences between Belgian and Dutch Patients at a Belgian Fertility Center’, *Facts, Views & Vision in ObGyn* 3, no. 4 (2011): 293–301.

[39] V. Provoost, G. Pennings, P. De Sutter, J. Gerris, A. Van De Velde and M. Dhont, ‘Reflections by Patients Who Undergo IVF on the Use of Their Supernumerary Embryos for Science’, *Reproductive BioMedicine Online* 20, no. 7 (2010): 880–91.

[40] S. Sterckx and K. Van Assche, ‘The New Belgian Law on Biobanks: Some Comments from an Ethical Perspective’, *Health Care Analysis* 19, no. 3 (2011): 247–58.

[41] Belgium – New Law Governing Use Of Human Body Material And Medically Assisted Reproduction, 2022., *available at*: <https://www.vbb.com/insights/corporate-commercial-regulatory/belgium-new-law-governing-use-of-human-body-material-and-medically-assisted-reproduction> (last visited November 03, 2025).

[42] Pennings, Segers, Debrock, Heindryckx, Kontozova-Deutsch, Punjabi, Vande Velde, Van Steirteghem and Mertes, supra note 29.

[43] Ibid.

[44] Supra note 31.

improved (e.g. central biobank for embryos to improve storage, donation, and access of real embryos).[45]

3.2.2. France

The French regulatory framework is charachterised by a continuous evolution, given that EmRe was once strictly limited, but has undergone a process of gradual liberalization through several reforms. Although some categorical restrictions remain (e.g. creation of embryos for research is prohibited), EmRe can now be performed under the supervision of a centralized authority issuing permissions. One peculiarity is that a specific regulatory pathway exists for research with hESC as compared to research on embryos. There are also some explicit rules addressing SCBEM, although the creation of an additional specific procedure for their examination is debated. In the summary-box to the side, an overview of the main features of the French system are offered. In the following paragraphs, a more detailed overview of the regulatory framework is presented.

Evolving framework Several legal changes, with a progressive liberalization of EmRe	**Central governing authority** Embryo research must be approved, hESC research notified
Clear prohibitions remain EmRe only with supernumerary embryos, no gene editing research.	**SCBEM mentioned** Explicit reference in the law, but uncertainties for the future

3.2.2.1 Historical background

The development of the French regulation for EmRe is one of the most complex in Europe, since it changed drastically many times, starting from a very restrictive approach and now being a rather liberal one. The history of the regulatory structure dates back to the 1980s, when the National Consultative Ethics Committee (CCNE – Comité consultatif national d'éthique) published consultative opinions on matter related to embryo usage.[46] In the 1986 opinion, a divided committee expressed concerns about allowing the use of embryos for purposes beyond reproduction (e.g. research), but it still listed some conditions upon which this could be deemed acceptable.[47] However, when the lawmaker eventually passed a series of laws on these issues (collectively known as “Bioethics laws” in France), it was decided to implement a very restrictive regime, which de facto banned any type of research with embryos, and only permitted their use for procreative purposes (i.e. MAR).[48] The lawmaker, since the status of the embryo was extremely divisive in the French legal debate, refrained from providing any definition in the regulation. However, the law provided already for a special clause, which requested the legislative framework to be re-examined by the parliament every five years to allow to accommodate changing scientific and societal conditions.

For this reason, and in response to the advances in respect to human cloning and the derivation of hESC, in 1999 “the prime minister charged the Council of State with the task of

[45] G. Pennings, ‘IVF Embryos in the Bin, Embryo-like Structures in the Spotlight’, *Reproductive Biomedicine Online* 48, no. 6 (2024): 103886.

[46] A.-M. Duguet, E. Rial-Sebbag, A. Mahalatchimy, M. Li and A. Cambon-Thomsen, ‘Ethical and legal frameworks for embryonic stem-cell based research in France and in Europe: a challenge for biotechnology’, in CUPL, ed., *Biotechnology Medicine and Law*, (2018).

[47] Comité consultatif national d’éthique, *Opinion 8 of the CCNE on Research and Use of Human Embryos In Vitro for Medical and Scientific Purposes* (n.d.).

[48] LOI no 94-654 du 29 juillet 1994 relative au don et à l’utilisation des éléments et produits du corps humain, à l’assistance médicale à la procréation et au diagnostic prénatal, n.d., *available at*: <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000000549618> (last visited November 03, 2025).

reviewing the totality of the Bioethics laws."[49] What followed were several years of intense and fierce debate on the issue. This were also shaped by a judicial case where the authorization granted to a group of researchers to import hESC from abroad to conduct research on them was challenged by a pro-life association, which considered this a violation on the complete ban on EmRe set by the 1994 law. The courts decided that the authorization was legal, and started drawing a distinction between research with embryos and with hESC, which was very influential for the French legislative evolution.[50] After this legal challenge, the Bioethics Laws concerning EmRe were updated in 2004. This update marked a u-turn in French regulation: despite maintaining a general prohibition to EmRe, the new law allowed for specific exemptions, so that – in exceptionally cases – both research with embryos and EmRe could be allowed for a maximum of 5 years. This wording (general ban with numbered exception) de facto legalized EmRe, but it was chosen as a political compromise to give a sense of continuity with the previous 1994 law (which contained a general prohibition).[51] This law revision also created the Agency of Biomedicine (ABM), the public body in charge of deciding whether individual requests by researchers to exceptionally use embryos for research could be granted for the limited 5-year period.[52] The ban on embryo creation was not uplifted.

Whilst many debates regarding the status of embryos, the risk of its instrumentalization and commercialization, and the need to ensure openness for research continued,[53] the law was modified again in 2011 introducing two important novelties: 1) the ABM was authorized to grant exceptions to the ban on research for longer than 5 years; 2) the CCNE was given the task to regular organize public debates (called Estates General of Bioethics - États géneéraux de la bioéthique) for future modifications of the Bioethics laws.[54]

In 2013 another substantial change occurred: a change of wording was made, so that "research on embryos and human embryonic stem cells is no longer subject to a prohibition regime with exemption but an authorized activity under conditions".[55] Moreover, the consent conditions were also relaxed, whereby patients donating supernumerary embryos for research needed only to be informed generally about the research purposes, without the need to provide specific details of individual projects. At the same time, any activity concerning research with embryos and/or hESC (production, research, import, etc.) needed to satisfy specific conditions and also be specifically approved by the ABM. The creation of embryos for research continued to be prohibited.[56]

The latest reform on EmRe regulation happened in 2021, after a long process of consultation as part of the Estates General of Bioethics.[57] This revision marked a step forward towards the liberalization of EmRe, and added a series of important changes to the regulatory framework – such as an 14-day time-limit beyond which embryos cannot be cultivated (there was no explicit limit before, but a recommendation to avoid development beyond the 7th day[58]) and separate approval regimes for research on embryos and hESCs. These are described in detail below. What continues to remain is a blanket prohibition on the possibilities to create embryos

[49] A. Blasimme, D. Caminiti and E. Vayena, 'The Regulation of Human Germline Genome Modification in France', in A. Boggio, C.P.R. Romano and J. Almqvist, eds, *Human Germline Genome Modification and the Right to Science: A Comparative Study of National Laws and Policies*, (Cambridge: Cambridge University Press, 2020): 380–408.

[50] S. Hennette-Vauchez, 'WORDS COUNT: HOW INTEREST IN STEM CELLS HAS MADE THE EMBRYO AVAILABLE--A LOOK AT THE FRENCH LAW OF BIOETHICS', *Medical Law Review* 17, no. 1 (2008): 52–75.

[51] Ibid.

[52] Blasimme, Caminiti and Vayena, supra note 49.

[53] Duguet, Rial-Sebbag, Mahalatchimy, Li and Cambon-Thomsen, supra note 46.

[54] Blasimme, Caminiti and Vayena, supra note 49.

[55] Duguet, Rial-Sebbag, Mahalatchimy, Li and Cambon-Thomsen, supra note 46.

[56] Blasimme, Caminiti and Vayena, supra note 49.

[57] Comité consultatif national d'éthique, Avis 129 Contribution du Comité consultatif national d'éthique à la révision de la loi de bioéthique 2018-2019, n.d., *available at*: <https://www.ccne-ethique.fr/fr/publications/avis-129-contribution-du-comite-consultatif-national-dethique-la-revision-de-la-loi-de> (last visited November 03, 2025).

[58] Comité consultatif national d'éthique, Avis 112 Une réflexion éthique sur la recherche sur les cellules d'origine embryonnaire humaine, et la recherche sur l'embryon humain in vitro, n.d., *available at*: <https://www.ccne-ethique.fr/publications/avis-112-une-reflexion-ethique-sur-la-recherche-sur-les-cellules-dorigine-embryonnaire?taxo=0> (last visited November 03, 2025).

for research. This is also due to the fact that France signed and ratified (in 2011) the Oviedo Convention, which explicitly prohibits the creation of embryos for research.[59]

3.2.2.2 Core legal sources and features

The main sources of law for EmRe in France are the Bioethics Laws, which – across the years – have been incorporated into the Code of Public Health.[60] Current rules have broadened the scope of permissible EmRe. Whereas since 2013 such research had to be directed toward a medical purpose, it may now also be authorized also for basic biology research.[61] Indeed, article L2151-5 lays down the conditions under which research on embryos may be authorized by the ABM: the scientific pertinence of the research must be established; the research must have either a medical purpose or the aim of improving knowledge of human biology; it must be demonstrated that the objectives cannot be achieved without the use of embryos; and the protocol must comply with relevant ethical and legal principles. In practice, commentators argue that the conditions set out are quite broad, so that the ABM has quite some discretionary power their application.[62] The expanded remit of research was challenged before the French Constitutional court, since it was only added by the 2021 reform. The court, however, rejected the challenges and stated that – despite the increase of purposes why EmRe can be conducted – sufficient legal safeguards remain.[63]

These additional legal safeguards also include that the creation of embryos for research purposes remains strictly prohibited (art. L. 2151-2). Indeed, only embryos conceived in vitro in the context of MAR and no longer part of a parental project can be used (L2151-5 II). Even then, embryos used for research cannot be transferred for gestation and must be destroyed no later than the fourteenth day after their constitution (L2151-5 IV). Furthermore, the law sets a clear statutory limit on the in vitro culture of human embryos, fixing the maximum duration at fourteen days following fertilization, a threshold that corresponds to the onset of gastrulation and has long been recognized in international guidelines. The commercialization of embryos is also prohibited.

The law also distinguishes between the regimes applicable to embryos, to hESCs, and to iPSCs – including SCBEMs. More details on this issue in the next chapter. The framework is completed by provisions on the import and export of embryonic stem cells, subject to authorization by the ABM and tied to respect for fundamental ethical principles (L2151-8), as well as rules on the authorization or declaration of laboratories that conserve embryos or embryonic stem cells for research (L2151-9). Finally, Article L2151-10 recognizes a conscience clause for all personnel, affirming that no researcher, technician, or medical professional can be compelled to take part in embryo or hESC research.

3.2.2.3 Governance structure

The key institutional actor in respect to EmRe is the ABM. This is a government agency supervised by the French Ministry of Health and established in 2004, which oversees key areas related to biomedical practice and research, including MAR and EmRe.[64] With around 250 employees, it is divided into several committees and working groups.[65] In respect to EmRe, it

[59] Blasimme, Caminiti and Vayena, supra note 49.

[60] Code de la santé publique: « Titre V : Recherche sur l'embryon humain, les cellules souches embryonnaires humaines et les cellules souches pluripotentes induites humaines (Articles L2151-1 à L2151-11) », n.d., *available at*: <https://www.legifrance.gouv.fr/codes/section_lc/LEGITEXT000006072665/LEGISCTA000006155017/#LEGISCTA000043896052> (last visited November 03, 2025).

[61] S. Hennette-Vauchez and L. Marguet, 'Bioéthique', *Cahiers Droit, Sciences & Technologies* no. 14 (2022): 153–69.

[62] G. Giovannini, 'The French Law on Bioethics and Its Limitations: Challenges for the Future from a Comparative Perspective', *International Journal of Law, Policy and the Family* 36, no. 1 (2022): ebac011.

[63] E. Roumeau, 'L'embryon Comme Objet d'expérimentation de Retour Devant Le Juge Constitutionnel: À Propos de La Décision N° 2021-821 DC Du 29 Juillet 2021', *Revue Des Droits de l'homme* (2021).

[64] Agence de la biomédecine, In brief, n.d., *available at*: <https://www.agence-biomedecine.fr/en/missions/in-brief> (last visited November 03, 2025).

[65] Agence de la biomédecine, A cross-functional and multi-disciplinary organization, n.d., *available at*: <https://www.agence-biomedecine.fr/en/organization/a-cross-functional-and-multi-disciplinary-organization> (last visited November 03, 2025).

exercises two key functions: publishing guidelines and acting as a supervisory and approval authority. Indeed, the law establishes that researchers aiming to use embryos, hESC and iPSCs (including SCBEMs) need to interact with the ABM. Since the modifications of the law in 2021, there are substantially different procedures to obtain authorizations for EmRe depending on the human material used: research with embryos requires explicit permission, whereas research with hESC and iPSCs is subject to a mere notification procedure.[66]

More specifically, researchers wanting to use embryos must apply to the ABM's legal department, using a standard file. After verifying admissibility, the Agency has four months to issue a decision following consultation with its Conseil d'orientation. Silence beyond that period is considered an implicit refusal. Authorized research is subject to strict follow-up obligations. Teams must notify the Agency of the actual start date of their project and submit annual activity reports as well as a final report. Any modification of an approved protocol must be declared: if deemed substantial, a new authorization must be requested and processed under the same conditions as the initial application. Authorizations are granted for a maximum duration of five years. Renewal requires a new application, assessed according to the same procedure.[67]

Research involving hESC in France is subject not to prior authorization but to a system of prior declaration. Protocols must be declared to the ABM's General Management, using a standardized file. The ABM verifies the completeness of the file and acknowledges receipt, setting deadlines if additional information is required. Once the file is declared complete, the ABM has two months to raise objections; if no objection is issued, the research may begin. For certain sensitive protocols (e.g. those aiming to differentiate hESC into gametes, to obtain in vitro embryonic development models) the period for possible objection is extended to four months. Researchers must submit a biennial activity report to the Agency, along with a final report.[68] A similar system of "prior declaration" is applied also for iPSCs (even when used to derive SCBEMs).[69] In this sense, French regulations is one of the few in the world that already directly addresses SCBEMs,[70] although some uncertainties remain (see the Chapter 3.2.2.6).

Beyond the ABM, some other relevant institutions participate in EmRe governance. First, the CCNE, which is an independent advisory body tasked to examine ethical questions raised by advances in biology, medicine, public health, and technology, and to provide opinions to government, Parliament, and public agencies.[71] It advised, for example, the revision process that led to the revision of the law in 2021, and the creation of different regulatory systems of authorization by the ABM.[72] Another important actor is Inserm (Institut national de la santé et de la recherche médicale), the French public research institute dedicated to human health, operating under the joint oversight of the Ministries of Health and Research.[73] It has also an internal authoritative ethics committee that publishes opinions on matters related to EmRe, for example in 2019 when it reflected on the future for EmRe in France and areas of potential legal

[66] Hennette-Vauchez and Marguet, supra note 61.

[67] Agence de la biomédecine, Authorization for human embryo research, n.d., *available at*: <https://www.agence-biomedecine.fr/en/research-on-embryo/authorization-for-research-on-human-embryo> (last visited November 03, 2025).

[68] Agence de la biomédecine, Authorization for human embryonic stem cell research, n.d., *available at*: <https://www.agence-biomedecine.fr/en/embryonic-research/authorization-for-human-embryonic-stem-cell-research> (last visited November 03, 2025).

[69] Agence de la biomédecine, Authorization for research on human induced pluripotent stem cells, n.d., *available at*: <https://www.agence-biomedecine.fr/en/embryonic-research/authorization-for-human-induced-pluripotent-stem-cell-research> (last visited November 03, 2025).

[70] Agence de la biomédecine, *Les embryoïdes : des modèles à la frontière des sciences et de l'éthique* (2024).

[71] Comité consultatif national d'éthique, Les missions, n.d., *available at*: <https://www.ccne-ethique.fr/fr/publications/les-missions> (last visited November 03, 2025).

[72] Comité consultatif national d'éthique, Rapport de synthèse des États généraux de la bioéthique, n.d., *available at*: <https://www.ccne-ethique.fr/fr/publications/rapport-de-synthese-des-etats-generaux-de-la-bioethique> (last visited November 03, 2025).

[73] Inserm, n.d., *available at*: <https://www.inserm.fr/> (last visited November 03, 2025).

reform.[74] Finally, when EmRe is transported to the clinic and concerns a clinical application, Inserm also plays a role to authorize experiments.[75]

3.2.2.4 Key rules on the procurement of supernumerary embryos for research.

As previously described, in France EmRe is only allowed with supernumerary embryos. The donation of embryos for research requires written informed consent by the MAR patients, and cannot be remunerated. Informed consent is normally collected by the treating clinic, although templates for the informed consent forms have been provided by the ABM.[76] These concern embryos discarded after Pre-implantation Diagnosis, other embryos deemed not transferable during MAR and cryopreserved embryos that are not necessary anymore for the realization of the parental project (e.g. because a pregnancy has already been obtained). Patients receive counselling during this process.[77]

One important set of rules concerns the potential donation for research purposes of cryopreserved embryos. The law maintains the principle whereby every couple (or single woman) whose embryos are preserved must be asked annually whether or not they wish to continue their parental project. If they do not respond to this annual consultation, the preservation of the embryos is terminated after 5 years. If they do respond, they can confirm in writing that their parental project continues, and thus the embryos need to be preserved for potential future use by them. If both members of the couple (or the single woman) say their parental project is terminated, they must consent in writing to one of these three options: the destruction of the embryos; the embryos being donated to another couple; or the embryo being used for research purposes. If they decide to consent for the donation to research, they have a limit of three months (or anyway until the embryo started being used for research) to withdraw consent: if they do not withdraw within this limit, embryos can be used for research, which simplifies administration for the ABM.[78] In this sense, the consent provided resembles the model of broad consent, as this is provided for the use of embryos in research, rather than being tied to a specific research project. A model for the informed consent can be found online.[79]

3.2.2.5 Other important features

In France, the evolution of the regulatory framework on EmRe is also accompanied by an evolution of research in this field. Indeed, it is claimed that “stem cell research in France is able to progress as a result of government support with appropriate legislation and funding, strong scientific research foundation, public support of biomedical research, and international cooperative relationships and partnerships”.[80] To increase transparency, the law also mandate that the ABM keeps a register of the authorized research with EmRe.[81] A list of the authorized

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[74] - Membres Comité d’Éthique de L’Inserm, ‘La recherche sur les embryons et les modèles embryonnaires à usage scientifique (MEUS)’, 2019.

[75] EuroStemCell, Regulation of stem cell research in France, n.d., *available at*: <https://www.eurostemcell.org/de/regulation-stem-cell-research-france> (last visited November 03, 2025); R. Isasi, M. Ginoza, K. Jongsma, L. Assen and M. Fabbri, ‘Mending the Gaps: Ethically Sensitive Cells and The Evolution of European Stem Cell Policy’, *Regenerative Medicine* 17, no. 8 (2022): 581–95.

[76] Agence de la biomédecine, Consentement au don d’embryons, n.d., *available at*: <https://www.agence-biomedecine.fr/fr/don-de-gametes-et-assistance-medicale-a-la-procreation/consentement-au-don-d-embryons> (last visited November 03, 2025).

[77] Agence de la biomédecine, Le don d’embryons, n.d., *available at*: <https://www.procreation-medicale.fr/don-embryons/> (last visited November 03, 2025).

[78] F. Barry, M. Rayssac, A. Gala, A. Ferrières-Hoa, V. Loup, T. Anahory, S. Brouillet and S. Hamamah, ‘Quels enjeux et adaptations pour les centres d’AMP dans le cadre de la mise en place de la nouvelle loi de bioéthique ?’, *Gynécologie Obstétrique Fertilité & Sénologie* 50, no. 12 (2022): 777–87.

[79] Formulaire pour le consentement au don d’embryons cyoconservés dépourvus de projet parental, n.d., *available at*: <https://www.agence-biomedecine.fr/en/don-de-gametes-et-assistance-medicale-a-la-procreation/formulaire-pour-le-consentement-au-don-d'-embryons-cyoconserves-depourvus-de-projet-parental> (last visited November 03, 2025).

[80] ‘France’, *Encyclopedia of Stem Cell Research*, (2455 Teller Road, Thousand Oaks California 91320 United States: SAGE Publications, Inc., 2008).

[81] « Article R2151-11 - Code de la santé publique », n.d., *available at*: <https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000045284585/2023-01-01> (last visited November 03, 2025).

research teams for EmRe is also available online.[82] Moreover, there is a list of hESC derived in France.[83]

In France, just like in other countries, it is reported that there is a high number of embryos donated for research.[84] As of the end of 2023, there were close to 25'000 embryos cryopreserved for donation to research or other couples.[85] It has thus been observed that there is a discrepancy between the availability of embryos (and willingness to donate) and the material and financial means to do research with them, which remains limited.[86]

In general, there is however scarce empirical evidence over stakeholders' preference concerning EmRe. A 2020 study with healthcare professional about embryo and gamete use collected views on embryo use in respect to MAR but not EmRe.[87] A 2016 study explored the preference of MAR patients in respect to embryo disposition and found that around one third prefer donation for EmRe, with an additional 11% opting for EmRe donation given their embryos do not meet the criteria for donation to other couples.[88]

3.2.2.6 Current debates and future challenges for the regulation

Given the continuous adaptations of the regulation of EmRe, including the recent reform of 2021, the debate around future modifications is more limited. At the same time, the revision clause contained in the Bioethics law in France – which requires periodical re-examinations of the legal provision – makes it likely that modification will follow in the future.

In this respect, there are two potential issues of discussion. First, there are some calls to reconsider the 14-limit for the cultivation of embryos from members of Inserm.[89] Second, there are some discussions on whether to further differentiate the regulatory oversight for research with SCBEMs. A recent (2024) letter published by a committee of the ABN mentioned some policy options in this respect. Whilst it is recognized that the French regulatory framework is quite unique in that it addresses SCBEMs specifically, some further adaptations were recommended. In particular, it recommended the establishment of a specific legal framework for embryo models, distinct from both embryo research (which is too tightly constrained by the 14-day rule) and ordinary stem-cell research (which is too permissive for such sensitive entities). The Agency proposes that research on embryo models be explicitly authorized, subject to rigorous oversight, and that in-vitro culture be permitted up to the equivalent of 28 days of development. At the same time, the ABM insists on maintaining absolute prohibitions against transferring these models into a uterus or attempting gestation. Finally, the document highlights the need to adapt rules on consent for the use of embryonic or stem-cell material in such research, and calls for France to engage actively in international debate, in particular in light of recent guidance from international organisations.[90]

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[82] Agence de la biomédecine, Liste des équipes autorisées aux protocoles de recherche sur l'embryon et des cellules embryonnaires, n.d., *available at*: <https://www.agence-biomedecine.fr/fr/recherche-sur-l-embryon/liste-des-equipes-autorisees-aux-protocoles-de-recherche-sur-l-embryon-et-des-cellules-embryonnaires> (last visited November 03, 2025).

[83] Agence de la biomédecine, La liste et caractéristiques des lignées de cellules souches embryonnaire humaines dérivées en France, n.d., available at: <https://www.agence-biomedecine.fr/fr/la-liste-et-caracteristiques-des-lignees-de-cellules-souches-embryonnaire-humaines-derivees-en-france> (last visited November 03, 2025).

[84] Pennings, supra note 45.

[85] Agence de la biomédecine, Assistance médicale à la procréation Les embryons conservés, n.d., *available at*: <https://rams.agence-biomedecine.fr/les-embryons-conserves-0> (last visited November 03, 2025).

[86] Pennings, supra note 45.

[87] H. Creux, M. Diaz, M. Grynberg, A. Papaxanthos-Roche, L. Chansel-Debordeaux, C. Jimenez, S. Frantz, N. Chevalier, J. Takefman and C. Hocké, 'National Survey on the Opinions of French Specialists in Assisted Reproductive Technologies about Social Issues Impacting the Future Revision of the French Bioethics Laws', *Journal of Gynecology Obstetrics and Human Reproduction* 49, no. 9 (2020): 101902.

[88] C. Bruno, C. Dudkiewicz-Sibony, I. Berthaut, E. Weil, L. Brunet, C. Fortier, J. Pfeffer, C. Ravel, P. Fauque, E. Mathieu, J.M. Antoine, S. Kotti and J. Mandelbaum, 'Survey of 243 ART Patients Having Made a Final Disposition Decision about Their Surplus Cryopreserved Embryos: The Crucial Role of Symbolic Embryo Representation', *Human Reproduction* 31, no. 7 (2016): 1508–14.

[89] Recherches sur l'embryon : un ouvrage pour mieux comprendre, n.d., *available at*: <https://www.inserm.fr/actualite/recherches-sur-embryon-ouvrage-pour-mieux-comprendre/> (last visited November 03, 2025).

[90] R. Lovell-Badge, E. Anthony, R.A. Barker, T. Bubela, A.H. Brivanlou, M. Carpenter, R.A. Charo, A. Clark, E. Clayton, Y. Cong, G.Q. Daley, J. Fu, M. Fujita, A. Greenfield, S.A. Goldman, L. Hill, I. Hyun, R. Isasi, J. Kahn, K.

In its 2018 input to the revision of the bioethics law, the CCNE argued that research on supernumerary embryos (those no longer subject to a parental project) should be permitted under strict conditions, possibly including genetic modification (so long as no transfer occurs) but maintaining the ban on creating embryos for research.[91] Although this proposal now dates a few years back, it may be picked up again in the future.

3.2.3. Germany

Germany is one of the most restrictive regulatory framework analysed in this report. Many of the ethical worries related to EmRe have traditionally received a lot of attention in German lawmaking, also due to the fact that embryos are assigned special protection according to the dominant interpretation of constitutional law. There is thus a blanket prohibition on research with embryos with criminal penalties. Research on hESC is permitted, but only with imported lines and under strict supervision of a special commission. A debate on the potential liberalization of the legislative framework is happening, but there is – at the moment – not enough political pressure for this to concretize in specific proposals for legal change. In the summary-box to the side, an overview of the main features of the German system are offered. In the following paragraphs, a more detailed overview of the regulatory framework is presented.

Restrictive law Criminal law provisions for EmRe, use of embryos prohibited	**Exception for hESC** Research on imported hESC is permitted under strict conditions
Special approval hESC research is monitored and approved by special committee	**Uncertain future** Strong opposition to liberalization, embryo covered by constitutional law

3.2.3.1 Historical context

A discussion around embryo research regulation commenced in the mid-80s in Germany with an interdisciplinary commission. This work was essential in that it anchored the topic of embryo research to Article 1 of the Constitution (Grundgesetz) in Germany, and thus on the ethical issue of dignity. The commission thus advised to prohibit instrumentalization of the embryo (ban on genetic engineering, surrogacy, embryo selection and creation of embryos for research), but opened the door for research with supernumerary embryos.[92]

Based (also) on the works of this commission, policymakers started the work on a law concerning embryo use in 1989.The discussion lasted two years and it produced what still remains nowadays a central piece of the regulatory framework in Germany for EmRe, the Embryo Protection Act.[93] This legislation was based on the concept of human dignity. At the same time, it diverted from the suggestions by the commission in respect to rules for the use of supernumerary embryos for research purposes, which was completely banned.

The regulatory framework largely remained intact over the years, apart from one change in 2002. Given the developments in hESC research, which showed the potential for various types of research (beyond the focus on MAR),[94] there was renewed discussion on whether these

Kato, J.-S. Kim, J. Kimmelman, J.A. Knoblich, D. Mathews, N. Montserrat, J. Mosher, M. Munsie, H. Nakauchi, L. Naldini, G. Naughton, K. Niakan, U. Ogbogu, R. Pedersen, N. Rivron, H. Rooke, J. Rossant, J. Round, M. Saitou, D. Sipp, J. Steffann, J. Sugarman, A. Surani, J. Takahashi, F. Tang, L. Turner, P.J. Zettler and X. Zhai, 'ISSCR Guidelines for Stem Cell Research and Clinical Translation: The 2021 Update', *Stem Cell Reports* 16, no. 6 (2021): 1398–408.

[91] Comité consultatif national d'éthique, supra note 57.

[92] V. Parfenchyk and A. Flos, 'Human Dignity in a Comparative Perspective: Embryo Protection Regimes in Italy and Germany', *Law, Innovation and Technology* 9, no. 1 (2017): 45–77.

[93] Gesetz zum Schutz von Embryonen (Embryonenschutzgesetz - ESchG), n.d., *available at*: <https://www.gesetze-im-internet.de/eschg/BJNR027460990.html> (last visited November 03, 2025).

[94] G.D. Wert, 'Human Embryonic Stem Cells: Research, Ethics and Policy', *Human Reproduction* 18, no. 4 (2003): 672–82.

discoveries should be considered for the EmRe regulatory framework. Whereas the possibility of passing laws allowing the derivation of hESC from embryos in Germany was not on the table, it was debated whether their import should be allowed and specifically regulated by law.[95] The solution was a compromise legislation passed in 2002 that allowed the import of hESC from abroad, but only when these were derived from supernumerary embryos and obtained before 2002.[96] This law was then amended in 2007 in order to allow the use of hESC derived before May of that year.[97]

One other core element to understand the historical developments of the EmRE regulation in Germany and its very restrictive stance is also the German approach to the Oviedo Convention. Germany was indeed one of the most critical countries of this Convention, albeit for very different and sometimes opposite reasons than other countries (like the UK). Indeed, German governments considered the provisions of the Oviedo Convention too permissive, in particular in regard to allowing in principle the performance of research with supernumerary embryos.[98] Therefore, after intense internal political debate and many criticisms addressed to different parts of the Convention, Germany decided to refrain from signing it. This means that for the regulation of EmRE, the Oviedo Convention provisions do not apply to Germany, since policymakers thought of them as contrary to the prohibitive stance set by national regulation (especially the Embryo Protection Act).

3.2.3.2 Core elements of the regulatory framework

The center of German legislation on EmRe is the fact that it is based on a prohibitive approach and that its rules are grounded in criminal law provisions. This means that – differently from the UK or the Belgian approach, which aim to provide a legal framework within which to exercise the freedom of research regarding EmRe – German law sets out penal provisions that apply whenever research with embryos is done and which limits very strictly even the use of embryos and gametes for MAR. Indeed, the Embryo Protection Act specifically states that the only legitimate use for embryos is that of bringing about a pregnancy through MAR (Art. 2 Embryo Protection Act). This means that in Germany there is a complete ban on embryo research of any kind. This approach is based on the conceptualization of the embryo as worthy of full legal protection, something which – in the German legal and constitutional system – is justified by reference to the inviable right to human dignity enshrined in article 1 of the Constitution.[99] As a consequence, any use of embryos that is not aimed at trying to bring about a pregnancy is considered – in the dominant view of constitutional lawyers – an illegal instrumentalization of the embryo as an entity worthy of protection. This anchoring of the regulation of embryo use in the principle of human dignity is one of the main obstacles to change the prohibitive stance towards embryo research enshrined in the German regulatory framework. Since dignity is considered inviolable in constitutional law, the argument that embryo research would violate this basic principle of the German Basic law is thus often used as a way to "end the debate"[100] about any different regulatory approaches.

The consequence of this is that "any use of an embryo for a purpose other than its preservation is a criminal offence" and it "also results in a ban on all research involving embryos, even if these embryos have been identified as genetically damaged in the course of PGD [preimplantation diagnosis, which is now allowed in Germany under very restricted conditions], for example, and therefore have no chance to survive because no woman would allow them

[95] Parfenchyk and Flos, supra note 92.

[96] Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen, n.d., *available at*: <https://www.gesetze-im-internet.de/stzg/index.html> (last visited November 03, 2025).

[97] Parfenchyk and Flos, supra note 92.

[98] M.A. de Wachter, 'The European Convention on Bioethics', *The Hastings Center Report* 27, no. 1 (1997): 13–23.

[99] Grundgesetz für die Bundesrepublik Deutschland, n.d., *available at*: <https://www.gesetze-im-internet.de/gg/BJNR000010949.html> (last visited November 03, 2025).

[100] Wapler Friederike, 'Research on human embryos: Constitutional perspectives', *Human Embryos in Medical Research. TABOO? JUSTIFIABLE? OPPORTUNITY? Proceedings of the Conference on 9th and 10th of October 2023*, (n.d.).

to be transferred".[101] This restrictive approach is also confirmed by other rules in the Embryo Protection Act, which – for example, set a "ban on creating more embryos than are to be transferred within one cycle [of IVF]" although "the limitation to as many embryos as are to be transferred rightly does not apply to legal PGD from the outset".[102]

The only exception concerns research with hESC. This is regulated by separate legislation, which – however – is based on a very similar prohibition approach. Indeed, "the research must pursue high-level objectives, and must be subsidiary and without alternative"; also "it is limited to stem cells from stem cell lines obtained before the cut-off date of 1 May 2007" and derived "from surplus embryos resulting from in vitro fertilisation (IVF) but not discarded for reasons of preimplantation genetic diagnosis (PGD)" which "have been provided free of charge and with consent."[103]

The only kind of EmRe research allowed in Germany is that with already derived hESC. Indeed, the Stem Cell Act of 2002 establishes that although "the import and use of embryonic stem cells (ES cells) is prohibited [in principles]" the "law contains exceptions to the prohibition."[104] This approach (prohibition with exceptions) has been defined as an "apodictic statement"[105] of the law, but it was adopted for political reasons to underscore the prohibitive stance of the regulation. In short, the Stem Cell Act provides for a "small window of liberty",[106] which is that of permitting research with hESC that have been derived abroad and are imported in Germany, but only as long as the research therewith conducted has an "high end purposes" («hochrangiges Forschungsziel) and the imported hESC were initially derived from supernumerary embryos.[107] This has allowed for research with hESC to develop, but not without obstacles. Research project requesting the use of imported hESC "can be approved by the Robert Koch Institute (RKI) after consultation with the Central Ethics Commission for Stem Cell Research (ZES)".[108] The whole procedure is described in a dedicated portal of the Robert Koch Institute.[109] Researchers have to document that hESC "were legally derived in the country of origin before 1 May 2007," a rule "based on the idea that any incentive to obtain ES cells emanating from Germany should be prevented" but that destructions of embryos to obtain hESC abroad in the past are simply "injustices [from the perspective of German law] committed abroad in the past", which "could not be made good and domestic researchers should not be completely excluded from promising research".[110] This limitation is problematic since "these stem cells […] were not produced and cultured according to today's standards, meaning that they are only of limited use for high-level research – a problem that is becoming increasingly serious with time."[111]

These limitations in the law are also echoed by the fact that there is a control by the Central Ethics Committee for Stem Cell Research on whether research projects asking for approval for the use of hESC satisfy the legal conditional that the study serves high-level research objectives for improving scientific gain of knowledge (§ 5 of the Stem Cell Act). It has been claimed that proving the fulfillment of this condition is hard for researchers since "there remains always a substantial risk that an agency may overstep its authority when it has to assess the scientific reasoning of a project, in particular if it is a highly specialized agency where scientific

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[101] Jochen Taupitz, 'Introduction to the topic: German law', *Human Embryos in Medical Research. TABOO? JUSTIFIABLE? OPPORTUNITY? Proceedings of the Conference on 9th and 10th of October 2023*, (n.d.).
[102] Ibid.
[103] Hans-Georg Dederer, 'Stem cells and derivatives – Scientific, ethical and legal implications – Legal contextualisation', *Human Embryos in Medical Research. TABOO? JUSTIFIABLE? OPPORTUNITY? Proceedings of the Conference on 9th and 10th of October 2023*, (n.d.).
[104] Jochen Taupitz, supra note 101.
[105] Ibid.
[106] Wapler Friederike, supra note 100.
[107] Ibid.
[108] Jochen Taupitz, supra note 101.
[109] Robert Koch-Institut, Genehmigungs-verfahren nach dem Stamm-zell-gesetz, n.d., *available at*: <https://www.rki.de/DE/Institut/Organisation/Stabsstellen/Leitungsstab/Stammzellgesetz/Stammzellen/stammzelle n-node.html> (last visited November 03, 2025).
[110] Jochen Taupitz, supra note 101.
[111] Ibid.

expertise is present."[112] Indeed, the responsible commissions for import and use of hESC is formed by 9 members, five of which with medical/biological expertise and 4 with ethico-legal background.[113] The absence of case law helping to define how to meet this criterion is also a symptom that "researchers are more likely to come to terms with their ethics committee out of necessity than to put pressure on it through the courts [by appealing against a refusal issued by the competent committees]."[114] At the same time, data from the Central Ethics Committee for Stem Cell Research shows that the greatest majority of projects submitted are approved. In 2024, a total of 9 new approvals have been issued and around 200 have been granted since the entry into force of the Stem Cell Act.[115] Approved projects are displayed online in a register.[116]

3.2.3.3 Other important elements

An important element to understand the German regulatory environment for EmRe are public attitudes towards the legal ban on the use of embryo for research. Some empirical evidence indicates that there is interest and availability of IVF couples to donate their embryos or gametes for research.[117] This seems to show some openness towards a more lenient regulation. At the same time, this survey also showed that medical ethicists and healthcare professionals are – on the contrary – quite contrary to a liberalization of the practices around embryo use and EmRe.[118] A more recent survey commissioned by the German stem cells network in 2023 indicated that a majority of the general public sees favorably research with embryonic stem cells and embryos.[119] It also showed that around half of the respondents would be supportive of a legal reform of the Embryo Act and Stem Cell Act, in particular because of the perceived contradiction that import of hESC is allowed, whereas local derivation is not. However, it also showed that there is a relevant minority (ca. 30%) that opposes liberalization. General results of the survey were similar in a sub-sample with a declared higher interest for biomedical research.

One final note to understand the regulatory environment in Germany and some of the contradictions that it entails are observable by considering data on the fate of embryos produced for reproductive purposes with MAR but left unused. Indeed, the total ban on use of German embryos for research does not mean that supernumerary embryos are not produced (and possibly even discarded at some point) in the country. Indeed, it "is estimated that in Germany there are already more than 50,000 surplus embryos in cryopreservation",[120] with the final fate of these embryos being unknown. This is also exacerbated by the fact that there are no limits to the time they can be cryopreserved.

3.2.3.4 Current debates and future challenges for the regulation

Many have highlighted a lot of contradictions in the current legal approach in Germany, and thus highlighted the importance to reconsider the regulation on this issue. As just highlighted, the Embryo Protection Act "does not prohibit leaving embryos to die or actively discarding

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[112] K.F. Gärditz, 'Work with Embryonic Stem Cells – Legal Considerations', *Journal of Perinatal Medicine* 51, no. 6 (2023): 763–8.

[113] Robert Koch-Institut, 22. Tätigkeitsbericht der ZES, n.d., *available at*: <https://www.rki.de/DE/Institut/Organisation/Stabsstellen/ZES/Taetigkeitsberichte/Download/22-taetigkeitsbericht.html> (last visited November 03, 2025).

[114] Gärditz, supra note 112.

[115] Robert Koch-Institut, RKI erteilt 200. Genehmigung für Forschungsprojekte nach dem Stammzellgesetz, n.d., *available at*: <https://www.rki.de/DE/Aktuelles/Neuigkeiten-und-Presse/Meldungen/Archiv/2024_11_25_Teaser_Stammzellregister.html> (last visited November 03, 2025).

[116] Robert Koch-Institut, Register nach § 11 Stammzellgesetz (StZG), n.d., *available at*: <https://www.rki.de/SiteGlobals/Forms/Suche/Stammzellenregister/Stammzellenregistersuche_Formular.html?nn=16931462> (last visited November 03, 2025).

[117] T. Krones, E. Neuwohner, K. Bock, K. Manolopoulos, H. Tinneberg and G. Richter, 'Attitudes of Patients, Healthcare Professionals and Ethicists towards Embryonic Stem Cell Research and Donation of Gametes and Embryos in Germany', *Reproductive BioMedicine Online* 13, no. 5 (2006): 607–17.

[118] Ibid.

[119] GSCN Civey survey on human embryo and human embryonic stem cell research, n.d., *available at*: <https://www.gscn.org/public-resources/gscn-umfrage-survey-2023> (last visited November 03, 2025).

[120] Jochen Taupitz, supra note 101.

them, i.e., killing them in vitro" which is "a strange contradiction - especially for an 'embryo protection law'"[121] This is one of the reasons why "the amendment of the Embryo Protection Act […] or its replacement by a broader Reproductive Medicine Act has been urged many times for years."[122] Some attempts to develop such legal reform where underway in the previous government (especially motivated by the desire to eliminate the ban on egg donation), but they were discontinued as government coalitions changed in 2025.

One venue to channel future developments in the regulatory framework towards more liberalization would have to reinforce the perspective of the right to freedom of research, including also research with embryos. Indeed, the German constitution "places the freedom of the individual at the centre of fundamental rights: fundamental rights guarantee entitlements to freedom and equal treatment. Restrictions on the development of individual freedom must therefore be justified. It therefore makes sense to begin constitutional considerations on research on human embryos with the fundamental right of freedom that is essential for this purpose: the freedom of science and research"[123]

However, for the moment there is not a lot of lobbying from scientists, physicians and other interested stakeholders to liberalise regulation. There are some complaints that regulatory limitations limit the possibility of conducting international research with partners from other countries with more liberal governance. On the contrary, there is still a lot of pressure from other stakeholders (e.g. religious communities) to try and maintain the current regulatory framework situation as is, or to even add further restrictions.[124]

Future reforms would need to reconsider the positions of many constitutional lawyers that still deem the embryo as worthy of full protection. Whereas this approach is slowly changing, the governance of EmRe remains a delicate topic, also because it is often connected with the discussions around the regulation of abortion. At the same time, it remains to be seen whether the pressure on the political claim that restrictions will lose international competitiveness on EmRe and compromise the knowledge-generation potential of this research will achieve more political agency.

3.2.4. Italy

Italy – like Germany – possesses a very prohibitive legal framework. The Government has traditionally been very cautious in enacting any laws regarding embryo usage, both in respect to MAR and research. When a law was passed in 2004, it completely prohibited research with embryos and remained silent in regard to research with hESC. Despite the legal vacuum, some researchers have attempted to import hESC for research, but this remains contested given the legal vacuum and the difficult in finding funding. Policies and research initiatives tend then to focus on research with iPSC. Some proposals have been advanced to liberalise EmRe, but they have not yet translated into concrete plans for legislative change. In the summary-box to the side, an overview of the main features of the

Prohibitive law Use of embryos for research completely prohibited	**Governmental abstention** Lawmaker very hesitant to make changes to rules on embryo use
Legal vacuum on hESC Import of hESC for research not explicitly regulated, but hard to fund	**Uncertain future** Some ideas on more liberal laws, but no concrete governmental plan.

[121] Ibid.
[122] Ibid.
[123] Wapler Friederike, supra note 100.
[124] T. Faltus, 'The Regulation of Human Germline Genome Modification in Germany', in A. Boggio, C.P.R. Romano and J. Almqvist, eds, *Human Germline Genome Modification and the Right to Science*, 1st edn, (Cambridge University Press, 2020): 241–65.

Italian system are offered. In the following paragraphs, a more detailed overview of the regulatory framework is presented.

3.2.4.1 Historical context

The debate around legislation on embryo usage started in Italy in the 1980s, as the first IVF treatments leading to the creation of embryos in vitro and then the use for MAR were made. In those years, a governmental commission (Santosuosso Commission) was created to provide advice on the matter.[125] This was advocating a very restrictive approach to the regulation of embryo use. Indeed, it proposed to define embryos as subjects of rights, including the right to life. However, the results of the policymaking advice of this commission were not implemented in explicit regulation or other soft law instruments. There were some directives from the Ministry for Health in respect to the use of embryos created as part of MAR, but they had limited scope (e.g. they were only applicable for public clinics) and they mainly advocated the need for explicit state regulation through law. There was however a situation of political stalemate in the lawmaking arena, with Christian democratic parties arguing for maximum restrictions to embryo use, and social democratic parties arguing that the law should only aim at protecting women from exploitation. No law was thus passed in the 1990s, since – when attempts were made to propose concrete laws (like the Bolognesi bill in 1998) – these were subject to many proposed amendments during parliamentary debates that a common ground could not be found.

There was a revival of the debate around the 2000s, when the potential of doing research with hESC reignited the debate on whether the law should explicitly regulate how embryos could be used to derive stem cells. Some governmental commissions (esp. the Dulbecco commission) were supportive of creating explicit regulations and liberalise embryo usage, but members of the commissions with a political orientation influenced by Christian democratic views were voicing strong oppositions to this proposal. The political debate was stirred by these stakeholders towards a discussion on why ethically divisive research with hESC should be facilitated, whilst less troubling research on adult stem cells could be promoted instead.[126] With the support of political actors from the catholic church, which plays an important role in Italy in affecting policymaking, the opposition to liberalizing embryo research was turned into an epistemological debate around the issue of which kind of research (hESC vs adult stem cells) has more potential to generate precious knowledge. Amongst this debate, a change of government and ministries happened, and the results of the Dulbecco commission were archived with a promise by the new government to institute a new commission to re-instate the debate in the future. This promise did not materialize and the commission was never instituted. Controversies continued also in terms of funding, with some debated decisions by the government to arbitrarily assign funding to research on adult stem cells only and excluding any proposals for projects involving hESC.[127]

Amongst this controversial political climate, a law regulating the use of embryos in the context of MAR was approved by the parliament in 2004 – law 40/2004.[128] This completely excluded the use of embryos for research purposes.[129] There were many aspects of this law that raised criticisms, and which – after several decisions by the constitutional court – led to amendments concerning the regulation of embryo usage within MAR.[130] Also the rules excluding the use of embryos for research were challenged by different stakeholders: a civic association supportive of the principle of freedom of research promoted an abrogative referendum. This is a

[125] Parfenchyk and Flos, supra note 92.

[126] L. Beltrame, 'The Italian Way to Stem Cell Research: Rethinking the Role of Catholic Religion in Shaping Italian Stem Cell Research Regulations', *Developing World Bioethics* 17, no. 3 (2017): 157–66.

[127] E. Cattaneo, E. Cerbai and S. Garagna, 'Italy's Stem-Cell Challenge Gaining Momentum', *Nature* 463, no. 7282 (2010): 729–729.

[128] LEGGE 19 febbraio 2004, n. 40 Norme in materia di procreazione medicalmente assistita., n.d., *available at*: <https://www.gazzettaufficiale.it/eli/id/2004/02/24/004G0062/sg> (last visited November 03, 2025).

[129] A. Boggio, 'Italy Enacts New Law on Medically Assisted Reproduction', *Human Reproduction* 20, no. 5 (2005): 1153–7.

[130] I. Riezzo, M. Neri, S. Bello, C. Pomara and E. Turillazzi, 'Italian Law on Medically Assisted Reproduction: Do Women's Autonomy and Health Matter?', *BMC Women's Health* 16, no. 1 (2016): 44.

democratic instrument, which in Italy allows to put to popular vote the elimination of specific norms of a published law.[131] However, stakeholders from the Catholic church started a strong campaign urging people not to vote (the message was "life cannot be put to vote"[132]). Indeed, Italian referenda need a minimum of 50% turnout to be valid and the objective of political forces next to the church was not to invite people to vote against the liberalization of research, but simply to invite them to abstain from voting. When results came out, it was revealed that turnout was less than 30%, thus rendering the referendum invalid and maintaining the total ban on embryo research.

The law in Italy remains silent on the issue of hESC import. As a consequence, some scientists started importing them from abroad to conduct research. However, the practice remains very controversial, since researchers act in a legal vacuum. Political actors affiliated to the catholic church press to close and accused researchers importing hESC to be committing criminal offenses.

As this historical overview shows, a characteristic feature of the Italian lawmaking process concerning EmRe is the resistance of the government to legislate on the issue and on changing controversial restrictive regulation. This is also demonstrated by how lawmakers handled the Oviedo Convention. Italy is one of the signing countries of the convention, but never actually applied its provisions (which technically allow for research on supernumerary embryos to be permitted). Although the process of passing the 2004 law on MAR was actually meant to align Italy with some of the requirements of the Convention,[133] the latter was never ratified. To be more precise, the Italian parliament authorized the government to implement laws to bring the legal system in line with the Convention, but the government never finished the ratification procedure according to national norms on procedural ratification.[134] As legal commentators have observed, "the Oviedo Convention is not currently binding for Italy. Although the Italian Government signed it, and authorization to ratification was given by the Parliament with Law 145/2001, it was never ratified."[135]

3.2.4.2 Core elements of the regulatory framework

In the 2004 law on MAR, article 13 contains a rule completely prohibiting of any kind of research on human embryos. This makes the situation quite clear cut, since it means that neither research on the embryos themselves, nor on the derivation of hESC is permitted – as this requires the destruction of embryos.[136] The situation is a bit different concerning research with already existing hESC that have been derived abroad. This can be described as a situation of legal vacuum, since – differently from the German approach, which explicitly regulates the import and use of hESC derived abroad for research conducted then in German – in Italy there is no law specifying whether import is allowed, under which conditions, and what procedure national researchers need to follow to get approval for research projects using these hESC.[137] There are thus some scientists that have exploited the legal loophole to work with stem cells from abroad. At the same time, this is made difficult by concrete governmental and administrative conditions. The most important of this is the decision to exclude research with existing (imported) hESC from national public funding. Funding regulations and decisions on this issue have generated a lot of controversies. The main funding agency responsible to finance stem cell research added a ban on hESC use in funded projects in an opaque way. Even if the scientific commissions in charge of preparing the call for funding for stem cell

[131] L. Palazzani, 'Embryo Research in Italy: The Bioethical and Biojuridical Debate', *Human Reproduction & Genetic Ethics* 17, no. 1 (2011): 28–39.
[132] Ibid.
[133] R.A. Fenton, 'Catholic Doctrine Versus Women's Rights: The New Italian Law on Assisted Reproduction', *Medical Law Review* 14, no. 1 (2005): 73–107.
[134] T. Goffin, P. Borry, K. Dierickx and H. Nys, 'Why Eight EU Member States Signed, but Not yet Ratified the Convention for Human Rights and Biomedicine', *Health Policy* 86, nos 2–3 (2008): 222–33.
[135] L. Poli, 'The Regulation of Human Germline Genome Modification in Italy', in A. Boggio, C.P.R. Romano and J. Almqvist, eds, *Human Germline Genome Modification and the Right to Science*, 1st edn, (Cambridge University Press, 2020): 335–57.
[136] https://doi.org/10.1017/9781108759083.013
[137] Beltrame, supra note 126.

research projects never instated an exclusion criterion for project proposals based on hESC use, this was added by governmental officials when the call was published.[138] This ban from public funding was challenged by scientists in front of several courts, but was eventually unsuccessful, leaving the issues of funding, import and approval of projects with hESC from abroad in a legal vacuum.

3.2.4.3 Other important elements

The fact that research on embryos is prohibited does not mean that stem cells research is absent. Indeed, there are centers of excellence also in Italy, but – in line with the national debate that favored the work with non-embryonic stem cells – they work primarily with stem cells derived from other bodily material. Examples of these centres include several research lines within the San Raffaele Research Hospitals in Milan.[139]

Another important contextual feature to understand the legislative framework for EmRe in Italy is the fact that there is not a lot of knowledge about stem cells amongst clinicians and researchers-clinicians, and there is, in any case, a preference to use non-embryonic stem cells – as empirical research on this matter showed.[140] At the same time, there is a substantial minority of clinicians that is open to the use of hESC and embryos in the research context. A small study with patients of a fertility clinic indicated that a great majority of them would prefer – if the options was legal – to donate surplus embryos for research.[141] Surveys with the general populations also point in this direction,[142] but the available evidence is rather preliminary and not always published in peer-reviewed journals. This raises the question whether legal prohibitions and the strict regulatory framework are related to political impasse rather than strong public opposition.

3.2.4.4 Current debates and future challenges for the regulation

At the moment, there is not a concrete debate on the legalization of embryo research, even though the 2004 law on MAR (which also contains the ban on use of embryos for research) has been modified several times since its approval. These modifications concerned mostly the use of gametes and embryos for reproduction, liberalising, for example, the use of donated oocytes in IVF treatment.[143]

In March 2024, SIRU (Italian Society for Human Reproduction) presented to one of the two parliamentary chambers an idea for a law proposal that would substantially change embryo legislation in Italy.[144] The proposal contained also specific rules on the use of embryos and gametes for research, in particular: it proposed to permit the donation of supernumerary embryos and gametes derived during MAR for research purposes; it tasked the Ministry for Health to be in charge of the approval process of research projects involving embryos.[145] However, there are no available news on whether the proposal is under concrete consideration by the lawmaker.

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[138] A. Abbott, 'Italians Sue over Stem Cells', *Nature* 460, no. 7251 (2009): 19–19.

[139] 'Italy', *Encyclopedia of Stem Cell Research*, (2455 Teller Road, Thousand Oaks California 91320 United States: SAGE Publications, Inc., 2008).

[140] P. Frati, M. Gulino, A. Pacchiarotti, S. D'Errico, L. Sicuro and V. Fineschi, 'A Survey of Italian Physicians' Opinion about Stem Cells Research: What Doctors Prefer and What the Law Requires', *BioMed Research International* 2014 (2014): 480304.

[141] F. Faustini, M. Forte, A. Capalbo, D. Cimadomo, F.M. Ubaldi and L. Rienzi, 'The Main Will of the Patients of a Private Italian IVF Clinic for Their Aneuploid/Affected Blastocysts Would Be Donation to Research: A Currently Forbidden Choice', *Journal of Assisted Reproduction and Genetics* 36, no. 8 (2019): 1555–60.

[142] Massimiano Bucchi and Federico Neresini, Fecondazione assistita e staminali: come la pensano gli italiani?, n.d., *available at*: <https://www.observa.it/fecondazione-assistita-e-staminali-come-la-pensano-gli-italiani/> (last visited November 03, 2025).

[143] G.M. Vergallo, S. Zaami, V. Bruti, F. Signore and E. Marinelli, 'How the Legislation on Medically Assisted Procreation Has Evolved in Italy', *Med. & L.* 36 (2017): 5.

[144] OLTRE LA LEGGE 40/2004 UNA PROPOSTA DI LEGGE SULLA SALUTE RIPRODUTTIVA E LA PMA, n.d., *available at*: <03.11.2025>.

[145] LEGGE SULLA TUTELA DEL DIRITTO ALLA SALUTE RIPRODUTTIVA E ALL'ACCESSO AI PERCORSI TERAPEUTICI DI RIPRODUZIONE MEDICALMENTE ASSISTITA, n.d., *available at*: <https://www.osservatoriomalattierare.it/documenti/category/7-documenti-vari?download=808:proposta-legge-siru-aprile-2024> (last visited November 03, 2025).

Recently, the government has expressed the intention of passing new laws to allow embryo donation, but only to other couples for reproductive purposes and not for research.[146] It is unknown whether this proposal (named emphatically "embryo adoption") is being considered for concrete implementation.

3.2.5. Netherlands

The Dutch regulatory framework is rather balanced, but cannot be described as permissive in the same ways as others (e.g. UK). A law on embryo research has existed for decades and it permits scientific projects with supernumerary embryos only. Moreover, other safeguards are in place, including the 14-day-rule. Oversight of research with embryos is performed by a specialize commission, which is in charge of examining several controversial types of research (including projects involving embryo use). There is specific interest for SCBEM, and many discussions are underway to try and define a regulatory pathway for research with embryo models. Moreover, there are other concrete legislative initiatives to update regulation, including considering an extension of the 14-day-rule. This is also due to the fact that the law on embryo research mandates periodical examination by expert committees to evaluate its functioning and the need of potential updates. In the summary-box to the side, an overview of the main features of the Dutch system are offered. In the following paragraphs, a more detailed overview of the regulatory framework is presented.

Balanced law EmRe permitted on supernumerary embryos, but with in-built revision rules	**Specific oversight** Embryo research requires approval from special committee
SCBEM interest Interest in SCBEM research and potential regulatory pathways	**Planned evolution** Several elements under discussions (e.g. extending the 14-day rule)

3.2.5.1 Historical background

The debate around the appropriate regulatory framework for EmRe developed in the 1980s and early 1990's in the Netherlands. At that time, MAR started to be used, oocytes being procured and embryo being created. In governmental agencies (such as the Health Council) and in the political sphere, a political debate started and centered on the question whether allowing research with embryo would violate their dignity and instrumentalize them.[147] However, since research with embryos at that time focused on matters related to MAR (e.g. research projects on how to improve cryopreservation techniques), support for allowing this type of research grew, given that it was seen as benefitting both women undergoing MAR (if IVF techniques could be improved, there was a chance to reduce the burden on women's health for gamete extraction and embryo implantation) and embryos themselves (if cryopreservation techniques improved, then less embryos needed to be created).
However, no explicit law on embryo use was published in the 1980s and 1990s. The final motivation to push the government to pass a law on embryo-use was the renewed attention to the topic of EmRe brought about by developments in hESC research at the end of the 90's.[148] At that time, it became evident that a law was needed, and there were two main doubts. First, it was debated whether research with embryos should be allowed only for projects aimed at improving MAR or also for projects planning to use hESC for research on broader issues. Second, it was discussed whether research should be allowed only with supernumerary embryos, or if also embryo creation should be permitted. In preparatory works for an EmRE

[146] Adozione embrioni congelati, Ministeri al lavoro su testo, n.d., *available at*: <https://www.ansa.it/canale_saluteebenessere/notizie/sanita/2025/04/22/adozione-embrioni-congelati-ministeri-al-lavoro-su-testo_f0de968e-f0fd-4b73-899c-53eba8ee22e8.html> (last visited November 03, 2025).
[147] M. Kirejczyk, 'On Women, Egg Cells and Embryos: Gender in the Regulatory Debates on Embryonic Research in the Netherlands', *European Journal of Women's Studies* 15, no. 4 (2008): 377–91.
[148] Ibid.

law, the ministry organized consultative meetings with different stakeholders, including church, civil society and science. In these public consultations, opinions were very split: some stakeholders were arguing for the banning of any research with embryos; others were in favor of a milder position (e.g. embryo research allowed only for very limited purposes, mainly linked to reproduction).

The draft bill proposed by the government was finally a compromise, with a temporary complete ban on the creation of embryos for research and a relatively open formulation ("increase of medical knowledge") of the purposes that EmRe projects should pursue to receive approval. The result of this process was the Embryo Act of 2002,[149] which sets out specific provisions for the use of embryos and gametes, both in the context of research and MAR. One specific feature of the act is that it also addresses its future evaluation and preemptively sets out potential future changes in the law itself. As to the first matter, the Act requires a commission to produce a yearly report on the functioning of the law to be examined by the parliament, and it requires that "within three years of the Act having entered into force, and every four years thereafter, the Minister must send a report to Parliament concerning the Act's effectiveness and impact in practice".[150] As to the second matter, the act already says that the ban on the creation of embryos for research is temporary, and already sets out the new rules concerning the creation of embryos for research to be implemented if the ban is eliminated.[151] As of 2025, however, the ban has not yet been removed.

During the historical development of EmRe research in the Netherlands, another central fact is the absence of a ratification of the Oviedo Convention. The government signed the treaty in the 1990s but has not ratified it since. The key reason why this did not happen is a contrast between the Convention – which completely prohibits the creation of embryos for research – and the Dutch Embryo Act – whose ban on the creation of embryo research is technically only limited in time, with the possibility of withdrawing it with a simplified procedure.[152] Although the lawmaker has – so far – not made use of this clause that could legalise the creation of embryo of research, the government continue to refuse initiating the ratification process for the Convention, in order not to 'tie their hands' for the future. As authors have highlighted, "relying heavily on two legislative evaluation reports, the government concluded that these prohibitions could hold back further advances in reproductive medicine, more specifically research into early embryonic development and preclinical research into safety of reproductive techniques".[153] As a consequence, the Convention is not directly applicable in the Netherlands.

3.2.5.2 Core legal sources and features

The core legal source for EmRe is the Embryo Act of 2002. This clearly sets out the conditions upon which research with embryos can proceed. These include several provisions, such as: the proposed project must be oriented towards the production of new knowledge related to medicine; only supernumerary embryos can be used; informed consent is required by embryo donors, and it should cover the prospected use of embryos ant their purpose; the 14-day limit of embryo development in-vitro must be respected.[154]

A key principle embodied by the act is "the legal doctrine of 'progressive legal protection' as a theoretical framework to explain the legal status of unborn life".[155] According to this doctrine, the embryo gets a different level of protection, which progressively increases at different stages (e.g. creation, implantation etc.). This is why the "the Embryo Act created different regimes of protection for embryos in vitro that are intended to be implanted for pregnancy and for those

[149] Embryowet, n.d., *available at*: <https://wetten.overheid.nl/BWBR0013797/2021-07-01> (last visited November 03, 2025).
[150] T.A.M.T. Braake, 'The Dutch 2002 Embryos Act and the Convention on Human Rights and Biomedicine: Some Issues', *European Journal of Health Law* 11, no. 2 (2004): 139–51.
[151] Ibid.
[152] Goffin, Borry, Dierickx and Nys, supra note 134.
[153] B. Van Beers, C. De Kluiver and R. Maas, 'The Regulation of Human Germline Genome Modification in the Netherlands', in A. Boggio, C.P.R. Romano and J. Almqvist, eds, *Human Germline Genome Modification and the Right to Science*, 1st edn, (Cambridge University Press, 2020): 309–34.
[154] Ibid.
[155] Ibid.

that are not" and "also distinguishes between embryos that are left over from IVF treatments [permitted] and embryos that were deliberately created for research purposes [prohibited]."[156]

3.2.5.3 Governance structure

The key institution for EmRe in the Netherlands is the Central Committee on Research Involving Human Subjects (CCMO – official acronym in Dutch).[157] This was a committee created already in 1998 after the Act on Medical research on Human Subjects was passed.[158] It is a governmental body tasked with operationalizing the Act on Medical research on Human Subjects (e.g. it supervises local ethics committees) as well as the Embryo Act of 2002.[159] According to regulation, the CCMO "is composed of up to 15 doctors and persons who are experts in the field of embryology, pharmacology, pharmacy, nursing, behavioural sciences, legal science, the methodology of scientific research and ethics, as well as a person who specifically assesses the scientific research from the perspective of the subject."[160] This special committee was developed to analyze, review and approve specific types of research projects that require special expertise and that can prove more controversial from a scientific or societal point of view. These include EmRe, but also other types of research, such as projects in the field of xenotransplantation or research with unauthorized prophylactic vaccines.[161]

This marks a contrast with other countries analysed in this report: research with gametes and embryos in the Netherlands does not need to be approved by 'normal' research ethics committees (like in Sweden) and – additionally – by a specialized institution (such as in Belgium), but has a separated and specialized authorization committee.

Concretely this means that the "managing board of an institution where embryos are created outside the human body, or other procedures involving embryos are carried out, is obliged to draw up a protocol regarding the use of gametes and embryos"[162] and obtain an evaluation by the CCMO. Changes to the protocol must equally be notified and communicated. Importantly, the CCMO "conducts a priori assessments to establish whether research [projects involving embryos submitted to it] can reasonably be expected to yield knowledge that is important for medical science and whether the research question cannot be addressed by other means (without using embryos)."[163]

A different set of stakeholders are the "officers of the Health Inspectorate" who "are charged with supervision of compliance with the provisions"[164] of the law on embryo research. Indeed, The Dutch Embryo Act includes a built-in evaluation clause: Article 32 requires periodic review of the law to ensure its aims are still being met and that it remains suited to scientific and societal developments. The Ministry of Health, Welfare and Sport commissions these evaluations, which are carried out under the ZonMw "Evaluatie Regelgeving" programme. ZonMw (Netherlands Organisation for Health Research and Development) is a national funding body that supports health research and innovation. Independent multidisciplinary research teams perform the evaluations, combining legal, ethical, and scientific analysis, and the findings are submitted to government and parliament to inform possible revisions of the Act.

Another institution that plays a role in Dutch embryo governance is the Health Council of the Netherlands. This is an independent scientific advisory body with a statutory duty under the Gezondheidswet (Health Act) and the Kaderwet adviescolleges (Advisory Bodies Framework

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156 Ibid.

157 The Central Committee on Research Involving Human Subjects (CCMO), n.d., *available at*: <https://english.ccmo.nl/about-ccmo> (last visited November 03, 2025).

158 Wet medisch-wetenschappelijk onderzoek met mensen, n.d., *available at*: <https://wetten.overheid.nl/BWBR0009408/2025-01-01> (last visited November 03, 2025).

159 Van Beers, De Kluiver and Maas, supra note 153.

160 Ibid.

161 Review by CCMO, n.d., *available at*: <https://english.ccmo.nl/investigators/primary-submission-to-the-review-committee/review-committee-accredited-mrec-or-ccmo/review-by-ccmo> (last visited November 03, 2025).

162 Braake, supra note 150.

163 *The 14-day rule in the Dutch Embryo Act To: the Minister of Health, Welfare and Sport* (The Hague: Health Council oft he Netherlands, 2023).

164 Braake, supra note 150.

Act). It provides government and parliament with evidence-based advice on complex medical and ethical questions. An example of this role is the Council's 2023 advisory report on the Embryo Act, in which, at the request of the Minister of Health, Welfare and Sport, it assessed whether the 14-day rule for embryo research should be extended and how developmental limits for SCBEMs should be defined, drawing on the expertise of a multidisciplinary committee. Indeed, the "committee consists of experts on human embryo research, bioethics, philosophy of law, health law, and science and technology studies".[165]

3.2.5.4 Key rules on the procurement of supernumerary embryos for research.

The only currently allowed source of embryos for research in the Netherlands are supernumerary embryos created during MAR. The Embryo Act sets the rules for the donation of embryos or gametes for research in articles 5-8. In brief, a central requirement is that supernumerary embryos can be used for research only if a written consent of those for whom the embryos were created is present. Before consent is obtained, donors must be provided with clear written information about the purpose and nature of the research-project that would be conducted with their embryos. Information must be given in a way that ensures comprehension, and donors must be granted sufficient time to reflect on the information before giving consent. Consent is revocable at any time without the need to provide a justification for the decision.

Professional bodies have elaborated detailed guidelines to support the implementation of the Embryo Act in terms of the donation of supernumerary embryos for research. The Modelreglement Embryowet, prepared by the Dutch Society of Obstetrics and Gynaecology and the Dutch Association of Clinical Embryologists, was first issued in 2003 and later updated, most recently in 2018/2020, following a request from the Ministry of Health to improve the practical applicability of the Act.[166] These guidelines include a set of model agreements that clinics can adopt or adapt in their practice. Among them is a model consent form for embryo storage and donation, which operationalises the legal criteria for embryo donation. This also recommends that a member of the treatment team reviews the agreement orally to ensure donor understanding before they sign.

Online[167] it is possible to see an example of a consent-form that reproductive clinic in the Netherlands give patients as part of their MAR treatment, which contains stipulations for the storage of embryos after fertility treatment. It says that couples can terminate the storage agreement either at the conclusion of the fertility treatment or after five years from the date of the last embryo storage. Upon expiry of this period, the clinic invites the couple in writing to indicate within three months what should happen to any remaining embryos. The options are either transfer to another licensed institution within the European Union for continued storage or treatment, or donation for legally permissible medical scientific research. If the couple does not communicate a decision within the three-month period, the embryos are thawed and discarded. In practice, this means that embryo donation for research only occurs when the couple explicitly provides written consent at the end of the storage agreement; otherwise, the default outcome is destruction. Extension of the preservation period beyond 5 years is possible upon specific request to the fertility center, given that the 5-year limit is not embedded directly in the law, but a matter of practice and it can be deviated.[168]

Some MAR clinics also offer the possibility to donate embryos to research biobanks and specify that reconsent is not required after the embryo has been transferred to the biobank and

[165] Supra note 163.

[166] Nederlandse Vereniging voor Obstetrie & Gynaecologie (NVOG) and Vereniging voor Klinische Embryologie (KLEM), Modelreglement Embryowet, n.d., *available at*: <https://www.nvog.nl/wp-content/uploads/2022/08/Modelreglement-Embryowet-NVOG-en-KLEM-definitief-augustus-2018-aanpassing-15-oktober-2020.pdf> (last visited November 03, 2025).

[167] Bewaarovereenkomst Embryo's, n.d., *available at*: <https://www.radboudumc.nl/getmedia/a658f1a1-bc52-4f5d-b7de-f5c643e19581/Bewaarovereenkomst-embryo.aspx> (last visited November 03, 2025).

[168] Nederlandse Vereniging voor Obstetrie & Gynaecologie (NVOG) and Vereniging voor Klinische Embryologie (KLEM), supra note 166.

approval has been obtained by the CCMO.[169] At the same time, it is not clear whether this can be qualified as a broad consent. The regulation of biobanking embryos and fetal tissues obtained after a medical termination of pregnancy (and not after IVF) follow under a different regulatory framework and – in this case – donation to biobanks with use for several research projects is performed.[170]

3.2.5.5 Note on the creation of embryos for research.

The creation of embryos for research is currently not permitted, since Article 24.a of the Embryo Act bans both the creation of embryos specifically for research and also the use of such embryos – if created elsewhere. This means that the "ban is phrased in such a way that Dutch scientists are also not allowed to import and use embryos that have been created for research purposes abroad."[171] What is special about the Dutch system is – however – that the law already permits a simplified procedure for lifting this ban, given that scientific and societal developments may require it. As a consequence, the Embryo Act say that "the ban can be lifted by mere Royal Decree, an act of the government that does not require a parliamentary vote."[172]

3.2.5.6 Other important features

To better understand the application and context of the Dutch regulatory framework, it is important to understand that scientific research is generally supported in the Netherlands, and that there is a broad scientific community and research infrastructure for EmRe. For example, there is a society for stem cells research with annual meetings and an established network.[173] Moreover, there is a long tradition in research around these matters, including also rather generous funding at a national level[174] and centers of excellence (such as the Hubrecht institute).[175]

In the public attitudes of the Dutch population towards EmRe policy, there is a certain level of ambiguity. A large population survey published in 2020 confirmed this issue.[176] It showed, for example that people have mixed feelings about embryo research and that – whilst there is relatively high support for research with supernumerary embryos (around 65% of the surveyed sample claimed to support or somewhat support it) – there is relatively low approval of permitting the creation of embryos for research purposes (around 51% has negative feeling towards it).

3.2.5.7 Current debates and future challenges for the regulation

There are three main issues that dominate the political and legal debate around current and future potential amendments to the Dutch regulatory framework on EmRe. The first one concerns the potential amendments to allow for the creation of embryos for research. The second concerns the potential extension of the 14-day limit beyond which embryos use for research cannot be developed. The third one concerns the regulation of SCBEMs.

Regarding the potential elimination of the ban to the creation of embryos for research purposes, debates have been going on for a longer time, since the Embryo Act of 2002 already

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169 Meedoen aan onderzoek Voortplantingsgeneeskunde, n.d., *available at*: <https://www.amsterdamumc.nl/nl/voortplantingsgeneeskunde/meedoen-aan-onderzoek.htm> (last visited November 03, 2025).

170 Y. Dawood, M.F.J. Buijtendijk, D. Bohly, Q.D. Gunst, D. Docter, E. Pajkrt, R.-J. Oostra, R.C. Hennekam, M.J.B. Van Den Hoff and B.S. De Bakker, 'Human Embryonic and Fetal Biobanking: Establishing the Dutch Fetal Biobank and a Framework for Standardization', *Developmental Cell* 58, no. 24 (2023): 2826–35.

171 Van Beers, De Kluiver and Maas, supra note 153.

172 Dawood, Buijtendijk, Bohly, Gunst, Docter, Pajkrt, Oostra, Hennekam, Van Den Hoff and De Bakker, supra note 170.

173 Dutch Society for Stem Cell Research, n.d., *available at*: <https://www.dsscr.nl/> (last visited November 03, 2025).

174 'Netherlands', *Encyclopedia of Stem Cell Research*, (2455 Teller Road, Thousand Oaks California 91320 United States: SAGE Publications, Inc., 2008).

175 Hubrecht Institute - About us, n.d., *available at*: <https://www.hubrecht.eu/about-us/> (last visited November 03, 2025).

176 Gouman, J., S. Vogelezang, and P. Verhoef, *Resultatenbijlage bij onderzoeksrapport 'Gewicht in de Schaal'* (Den Haag: Rathenau Instituut, 2020).

contained a clause on this potential change. This modification was very close to being implemented in the late 2010s when a concrete proposal was put forward by the Minister of Health, which suggested to eliminate both the ban on research with surplus embryos and with genome modifications of embryos.[177] This move was supported also by a joint statement of the Health Council of the Netherlands and the COGEM (Commission on Genetic Modification, a scientific advisory body tasked by law with advising the government on the ethical and societal aspects of genetic modification) that recommended to implement such changes.[178] Also the results of the second evaluation of the Embryo Act had pointed in a similar direction.[179] At the same time, the Council of State (another governmental advisory body) opposed the changes, finding insufficient factual basis to lift the general ban on creating embryos for research.[180] Eventually, also due to a change of government, the proposal was abandoned and the new government only supported the promotion of a public debate on these issues.[181] This issue is recently come back to the fore of the discussion, and there is now (September 2025) a proposal being discussed to allow the creation of embryos for research.[182] This is also in line with the recommendations of the third evaluation of the Embryo Act published in 2021.[183]
The second key issue being debated is whether the limit of culturing embryos for research only for 14 days should be extended until the 28th day of development. This change is suggested both by the third evaluation of the Embryo Act,[184] and also by another report of the Health Council of 2023.[185] This recommends extending the legal limit for in-vitro embryo research from 14 to 28 days. The Council argues that lifting the limit would close a major knowledge gap relevant to miscarriage, infertility, and congenital disease. Ethical safeguards should remain unchanged, meaning that research planning to develop embryos beyond the 14th day should still receive prior review by the CCMO, and meet the criteria of necessity, proportionality, and lack of alternatives. This proposal has received attention the academic literature,[186] but the government has recently communicated that – for the moment – it does not intend to change the 14-day rule.[187]
The third issue concerns the regulation of SCBEMs. The Netherlands is at the forefront of international discussion for various reasons. First, several reports from advisory institutions to the government have suggested to produce explicit regulation on SCBEMs.[188] Both reports recognize that new stem cell technologies allow creation of SCBEMs, which sometimes mimic the integrated development of a whole embryo. They stress the need to clarify whether and how SCBEMs fall under the Embryo Act's protections. The Health Council recommends distinguishing between integrated SCBEMs (which resemble entire embryos) and non-integrated SCBEMs (which model only parts, e.g. organs). Integrated SCBEMs are considered morally equivalent to "classic" embryos and should therefore be subject to the same developmental research limit – either 14 or 28 days. Non-integrated SCBEMs, while lacking the potential to become a human being, may still raise ethical issues (e.g. if they develop brain

[177] Van Beers, De Kluiver and Maas, supra note 153.
[178] COGEM, *Editing Human DNA. Moral and social implications of germline genetic modification.Policy reports | 21.09.2017 | CGM/170328-01* (n.d.).
[179] *Evaluatie Embryowet en Wet donorgegevens kunstmatige bevruchting* (n.d.).
[180] *Advies Raad van State inzake het voorstel van wet, houdende wijziging van de Embryowet in verband met de aanpassing van het verbod op het speciaal tot stand brengen van embryo's voor onderzoek en enkele andere wijzigingen naar aanleiding van de tweede wetsevaluatie* (2017).
[181] Van Beers, De Kluiver and Maas, supra note 153.
[182] Voorstel van wet van de leden Paternotte en Bevers tot wijziging van de Embryowet in verband met de afschaffing van het tijdelijk verbod op het doen ontstaan van embryo's voor wetenschappelijk onderzoek (36416) (1e TK), n.d., *available at*: <https://www.tweedekamer.nl/debat_en_vergadering/plenaire_vergaderingen/details/activiteit?id=2025A05392> (last visited November 03, 2025).
[183] *Derde evaluatie Embryowet (2021)* (n.d.).
[184] Ibid.
[185] Health Council of the Netherlands, *The 14-day rule in the Dutch Embryo Act* (The Hague, 2023).
[186] H.I. M'hamdi and G. De Wert, 'Reconsidering the 14-Day Rule in Human Embryo Research: Advice from the Dutch Health Council', *Cell Stem Cell* 31, no. 11 (2024): 1560–2.
[187] Wijziging van de Embryowet naar aanleiding van de derde wetsevaluatie, n.d., *available at*: <https://zoek.officielebekendmakingen.nl/kst-36677-6.html> (last visited November 03, 2025).
[188] Supra note 183; Health Council of the Netherlands, supra note 185.

tissue). The Council suggests regulating them not through the Embryo Act but under the forthcoming Control of Body Materials Act. This proposal would entail that such structures - once created would not fall under Embryo Act/Foetal Tissue Act, but have a separate legal regime requiring explicit consent when the bodily material is procured, enhanced information duties, and ethics review.[189] Regarding integrated SCBEMs, there is currently a legal proposal to explicitly regulate them by amending the Embryo Act. It introduces a new legal definition of "embryo," ensuring that SCBEMs fully mimicking an intact human embryo fall under the Embryo Act, with the same protections and the 14-day growth limit.[190]

3.2.6. Sweden

Sweden, together with Belgium and the UK, offers one of the most permissive and supportive regulatory frameworks for EmRe. It has well-established legislation on research with embryos dating back decades and permitting these types of scientific studies for a long time. Oversight of EmRe is performed by regular ethics committees and not by a specialized commission like in many other countries. At the same time, there is a complex interplay with biobanking regulation, given that the latter tends to govern hESC and research with other types of human material. There is an ethical and regulatory debate regarding SCBEM, and the possibility of developing special legal pathways for this kind of research is under discussion. In the summary-box to the side, an overview of the main features of the Swedish system are offered. In the following paragraphs, a more detailed overview of the regulatory framework is presented.

Permissive law EmRe explicitly allowed for many decades, very liberal regulation	**Regular oversight** 'Normal' ethics committees examine research proposals on EmRe
Interplay with biobanks Regulatory approach (e.g. on withdrawal of consent) differs for biobanks	**SCBEM regulation** Plans to adapt regulation for embryo models

3.2.6.1 Historical background

Sweden was one of the first countries in Europe to start passing regulation on EmRe, and it has always been considered as one of the most permissive countries in Europe. Indeed, observers noticed that Sweden "has a tradition of encouraging and nurturing research and innovation."[191] Moreover, differently from other countries like Germany and Italy, where religious stakeholders have had an influence on restrictive policymaking, in Sweden "religion has not played a decisive role in steering scientific research in any particular direction."[192]
Research on embryos was already permitted and explicitly regulated with a law dating back to 1991, when the government passed the "Law on measures for research or treatment purposes with human eggs."[193] One peculiar fact of this regulation is that it focused on gametes and fertilized eggs, and refrained from trying to define the embryo. This marks a special feature of the Swedish legal framework. This law was already very liberal, in that it permitted research with embryos, it allowed cultivation until the 14th day, and it also did not ban the creation of embryos for research.

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189 Wet zeggenschap lichaamsmateriaal, n.d., *available at*: <https://wetgevingskalender.overheid.nl/Regeling/WGK004470> (last visited November 03, 2025).
190 Supra note 187.
191 S. Slokenberga and H.C. Howard, 'The Regulation of Human Germline Genome Modification in Sweden', in A. Boggio, C.P.R. Romano and J. Almqvist, eds, *Human Germline Genome Modification and the Right to Science*, 1st edn, (Cambridge University Press, 2020): 281–308.
192 Ibid.
193 Lag (1991:115) om åtgärder i forsknings- eller behandlingssyfte med ägg från människa, n.d., *available at*: <https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/lag-1991115-om-atgarder-i-forsknings-eller_sfs-1991-115/> (last visited November 03, 2025).

When in the late 1990s the first hESC were derived, there was a debate whether the regulatory framework should be updated. Indeed, the Swedish National Council on Medical Ethics (SMER) published two opinions on this matter, in 2002[194] and in 2003.[195] The first one was an advisory opinion self-initiated by SMER within its advisory role to the Government and it argued that new reflections on EmRe were needed, given that research with hESC changes the purposes of embryo research, which earlier was mainly focused on improving MAR and not on exploring treatment for diseases – like research with hESC permits. It concluded that hESC research should be permissible under strict safeguards (such as ethics review and informed consent) and protection from unethical commercialization. The second document was in direct response to an request to advise on a potential regulation of hESC and the SMER argued that: 1) it would be problematic to impose a blanket ban on creating embryos for research and supported case-by-case assessment through ethics review; 2) at the same time, it warned that there was no clarity on how embryo research should be evaluated by ethics committees; 3) it underlined that egg, sperm, and embryo donation must always rely on explicit consent, but highlighted unresolved issues around withdrawal of consent, especially after stem cell lines are already derived.

Two other pieces of legislation were adopted that also shaped the governance of embryo research. The Biobank Act of 2002[196] introduced a general framework for the collection, storage and use of human biological material, which also covered fertilised eggs and stem cells as "tissue samples", thereby linking embryo research to rules on consent, withdrawal and traceability. However, the law did not contain any rules specifically targeted at embryos. This act was then updated in 2023, but – once again – it contained no rules specific to EmRe and – on the contrary – it referred to the fact that the rules established in the specific regulation for fertilized eggs prevail.[197] In 2004, the Ethics Review Act was passed, and it established mandatory ethical review for all research involving humans and human tissue, ensuring that also projects using embryos or human embryonic stem cells were subject to legally regulated ethics oversight.[198] Even in this case, the law did not list explicit special conditions for the ethics review of embryo research.

In 2006, Sweden passed the Genetic Integrity Act (2006:351), which superseded the 1991 law and more explicitly regulated embryo and fertilised-egg research. In essence, this Act marked a legal consolidation of prior fragmented rules, and specifically also allowed somatic cell nuclear transfer (therapeutic cloning) under strict oversight.[199]

What is also interesting to note for the evolution of the regulatory framework is that Sweden is one of the few countries that signed, but did not ratify the Oviedo convention.[200] Signing a treaty is not making it binding for the state, it simply expresses the intention of the state to approve it, and it creates a loose obligation to submit the treaty to the national legislative body for examination. Ratification, on the contrary, is the process by which the legislative body (usually the parliament) of a country expresses the consent to be officially bound by the threat, thus making its provision enforceable in the state. There were many reasons for Sweden not to ratify the Oviedo convention after signature in 1997, not only concerning research on

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[194] Statens medicinsk-etiska råd (Smer), Yttrande om embryonal stamcellsforskning, 2022., *available at*: <https://smer.se/2002/01/17/yttrande-om-embryonal-stamcellsforskning/> (last visited November 03, 2025).

[195] Statens medicinsk-etiska råd (Smer), Remissyttrande angående SOU 2002:119, "Rättslig reglering av stamcellsforskning, 2003., *available at*: <https://smer.se/2003/05/20/remissyttrande-angaende-sou-2002119-rattslig-reglering-av-stamcellsforskning/> (last visited November 03, 2025).

[196] Lag (2002:297) om biobanker i hälso- och sjukvården m.m., n.d., *available at*: <https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/lag-2002297-om-biobanker-i-halso-och_sfs-2002-297/> (last visited November 03, 2025).

[197] Biobankslag (2023:38), n.d., *available at*: <https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/biobankslag-202338_sfs-2023-38/> (last visited November 03, 2025).

[198] Lag (2003:460) om etikprövning av forskning som avser människor, n.d., *available at*: <https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/lag-2003460-om-etikprovning-av-forskning-som_sfs-2003-460/> (last visited November 03, 2025).

[199] Lag (2006:351) om genetisk integritet m.m., n.d., *available at*: <https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/lag-2006351-om-genetisk-integritet-m-m_sfs-2006-351/> (last visited November 03, 2025).

[200] Slokenberga and Howard, supra note 191.

embryos. However, this was certainly one of them, given that national legislation is in explicit contrast with the convention (e.g. concerning the creation of embryos for research).

3.2.6.2 Core legal sources and features

The main piece of legislation on EmRe in Sweden is the Genetic Integrity Act of 2006. One particular feature of the act is that a definition of embryos is absent. Instead, the act applies to eggs and fertilized eggs. The choice to avoid using the term "embryo" in this context was due to the idea is that embryo starts only from the moment of implantation and – since implantation is not a part of EmRe – it was better to speak of fertilized eggs.[201] Indeed, a core element of the regulations is also that the introduction of a fertilized egg used for research into a woman's body is completely forbidden.[202] This rule ensures that – as far as the law is concerned – embryos used for research have no chance to develop into a human being, as their implantation cannot be performed.

The Genetic Integrity Act requires informed consent from all donors of eggs, sperm, or somatic cells (Ch. 5, §§ 1–2), and limits experiments on fertilised eggs and embryos created by somatic cell nuclear transfer to 14 days in vitro (Ch. 5, § 3). Embryos used in research must be destroyed and may never be reimplanted (Ch. 5, § 5). The Act also regulates storage periods (up to ten years for fertilised eggs, five for Somatic Cell Nuclear Transfer embryos, Ch. 5, § 4) and prohibits reproductive cloning.

3.2.6.3 Governance structure

One central institution for the governance of EmRe are ethics review committees (the departments listed below). Indeed, research involving embryos – like any other types of research in Sweden – must be authorized by an ethics committee. Since 2019, this process is managed by a centralized commission, the Swedish Ethical Review Authority.[203] This has 6 regional subsidiaries and 21 departments. A total of 15 of such departments are dedicated to reviewing medical research specifically – whereas 6 focus on other types of research. Each department has different members representing different types of expertise. Specifically, it is established that, for each department the "department chair must be or have been a permanent judge in a Swedish court, while ten members must have research expertise and five represent the public interest."[204] Once a project is submitted to the Swedish Ethical Review Authority, it is assigned to a department, which then examines it. So, differently from other states (e.g. Belgium, Netherlands) where research on embryos also receives a specific approval from a specialized committee, in Sweden the procedure for approval is the same as that for any other scientific project.

In addition to the Ethical Review Authority, two other institutions participate in the governance of embryo research in Sweden. The National Board of Health and Welfare[205] plays a regulatory role under the Genetic Integrity Act. For example, it may grant exemptions such as extending the permitted storage period for fertilised eggs or embryos beyond the statutory limits. Alongside this regulatory function, the Swedish National Council on Medical Ethics (SMER) acts as an advisory body to the government and parliament. While it does not decide on individual projects, SMER has had a significant influence on the national framework by issuing policy opinions on ethically sensitive issues such as embryonic stem cell research (notably in 2002 and 2003, as mentioned above).

3.2.6.4 Key rules on the procurement of supernumerary embryos for research.

Patients undergoing MAR can preserve their embryos for 10 years, a limit that can be extended exceptionally. During this period, storage costs are covered by the health system, if the MAR

[201] L. Walin, 'Ambiguity of the Embryo Protection in the Human Rights and Biomedicine Convention: Experiences from the Nordic Countries', *European Journal of Health Law* 14, no. 2 (2007): 131–48.
[202] Slokenberga and Howard, supra note 191.
[203] Swedish Ethical Review Authority - About the Authority, n.d., *available at*: <https://etikprovningsmyndigheten.se/en/about-the-authority/> (last visited November 03, 2025).
[204] Ibid.
[205] About the National Board of Health and Welfare, n.d., *available at*: <https://www.socialstyrelsen.se/en/about-us/> (last visited November 03, 2025).

treatment was performed in a public hospital according to access rules (e.g. maximum age for aspiring parents).[206] Patients with supernumerary embryos can decide to donate embryos to other couples, to destroy, or to donate for research. An interesting fact is that the embryo donation to other couples for reproductive purposes was prohibited. Indeed, until 2019, the law was permitting the donation of embryos to research, but donation to other couples was forbidden.[207] Donation for research requires the consent of both the provider of the oocyte and of the sperm that lead to creation of the fertilized egg.[208]
The consent is normally collected by physicians-investigators pertaining to the IVF clinic where the embryos are procured, since ethics the Ethical Review Authority "demands that the [research] team includes at least one clinician who can take the clinical responsibility for the health and safety of the research persons (in this case the embryo donors)."[209] Consent can be revoked by the donors for embryo research, whereas the situation is more complicated when embryos are used to derive stem-cells. In this case, before the Biobank Act of 2002 was passed "the donors could in principle revoke their consent and have stem cell lines derived from their donated embryos terminated".[210] This situation also happened in practice, since in "2001, one of the lines established by the researchers at Cell Therapeutics in Göteborg was destroyed because the donating couple withdrew their consent."[211] Since the passing of the Biobank Act (2002 and then revised in 2023), the situation is still not completely clear, even if this law says that the Genetic Integrity Act has precedence. Indeed, it "is still not quite clear when a human embryonic stem cell line changes from donated material (which could be revoked) to research material under the control of the research group (and eventually a company)."[212]

3.2.6.5 Note on the creation of embryos for research.

The creation of fertilized eggs for research is not explicitly prohibited and thus it is considered allowed, even if no specific rules define the condition to be met for this procedure – differently from other countries, like Belgium. This situation is quite unique and it also differentiates Sweden from all other Nordic countries, where – on the contrary – the production of embryos for research purposes is outlawed.[213] At the same time, the absence of explicit rules on this matter can create some confusion. Indeed, there is also a scientific publication claiming the creation of embryos for research is forbidden.[214]
Evidence that creation of embryos is allowed is present in several forms. For example, the EuroStemCell network explicitly lists Sweden as a country where embryo creation is possible.[215] Moreover, the preparator works for the Genetic Integrity Act also explicitly state that a reason why the ratification of the Oviedo Convention is not possible in Sweden is that

[206] Debitering vid frysförvaring av könsceller/embryon, n.d., *available at*: <https://www.karolinska.se/vard/tema/tema-kvinnohalsa-och-halsoprofessioner/gynekologi-och-reproduktionsmedicin/mottagning-reproduktionsmedicin-huddinge/debitering-vid-frysforvaring-av-konscellerembryon/> (last visited November 03, 2025).
[207] K.S. Bywall, J. Holte, T. Brodin, M. Hansson and J. Drevin, 'Would You Consider Donating Your Left-over Embryos to Treat Parkinson's Disease? Interviews with Individuals That Underwent IVF in Sweden', *BMC Medical Ethics* 23, no. 1 (2022): 124.
[208] 'Sweden', *Encyclopedia of Stem Cell Research*, (2455 Teller Road, Thousand Oaks California 91320 United States: SAGE Publications, Inc., 2008).
[209] A. Persson, S. Hemlin and S. Welin, 'Profitable Exchanges for Scientists: The Case of Swedish Human Embryonic Stem Cell Research', *Health Care Analysis* 15, no. 4 (2007): 291–304.
[210] Ibid.
[211] Ibid.
[212] Ibid.
[213] Legislation on biotechnology in the Nordic countries – an overview 2022, n.d., *available at*: <https://norden.diva-portal.org/smash/get/diva2:1653137/FULLTEXT02.pdf> (last visited November 03, 2025).
[214] Å. Grauman, M. Hansson, D. Nyholm, E. Jiltsova, H. Widner, T. Van Vliet and J. Drevin, 'Attitudes and Values among the Swedish General Public to Using Human Embryonic Stem Cells for Medical Treatment', *BMC Medical Ethics* 23, no. 1 (2022): 138.
[215] EuroStemCell, Regulation of stem cell research in Sweden, n.d., *available at*: <https://www.eurostemcell.org/regulation-stem-cell-research-sweden> (last visited November 03, 2025).

national regulation is in contrast with art. 18.2 of the convention, which prohibits the creation of embryos for research.[216]

3.2.6.6 Other important features

In order to understand the Swedish liberal regulatory framework, it is also important to underline how active the country is in supporting and performing EmRe. Indeed, Sweden is very active on stem cell research, with at least "three centers are active in hESC research and derivation of hESC lines. Cellartis AB in Gothenborg has derived 37 hESC lines, the Karolinska Institute in Stockholm, 30. Another research institute is the Stem Cell Center Lund."[217] There are also scientific publications outlining the performance of big hESC banks in the countries, for example in Stockholm.[218]

In Sweden – beyond the rather permissive legislation – there are also additional supportive framework conditions for EmRe. These includes "government support with appropriate legislation and funding, a strong scientific research foundation, public support—including willingness to participate in clinical trials of biomedical research, and international cooperative relationships and partnerships."[219]

In general, it is also important to know that the use of embryos for research is relatively supported in Sweden by the public. A survey from 2013 interrogating both women and men also showed that 51% of the respondents approved of research being conducted with embryos.[220] A more recent study asking respondents if leftover embryos should be used to investigate the development of treatment for specific diseases showed much higher approval rates.[221] Although public attitudes on this matter are difficult to measure and can vary with time, these studies indicate that the public is rather supportive of EmRe.

3.2.6.7 Current debates and future challenges for the regulation

For the future evolution of the Swedish regulatory framework, there are currently debates on two issues in particular: the possibility of extending research beyond the 14th day to the 28th day; and the necessity to modify regulations to that it also covers SCBEMs. This debate is also promoted by SMER, which has recently published both ethical reflections and policy recommendations on these topics.[222]

In a letter to the government, SMER proposed several recommendations concerning the time limit and the regulation of SCBEMS. First, the Council proposes extending the current 14-day rule in the Genetic Integrity Act to 28 days, arguing that this period offers the greatest potential for scientific insights while remaining ethically acceptable, since no nervous system or capacity for pain exists. Research on embryos should also be subjected to ethical review based on explicit, embryo-specific criteria (e.g. lack of alternatives, scientific necessity, minimal number of embryos, and limited culture time) – like it happens in Belgium or the Netherlands. However, a recent proposal to modify the Ethics Review Act does not follow up on this recommendation.[223] The SMER also recommends that embryo research should be registered in an open international register to ensure transparency and public trust.

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[216] Genetik, integritet och etik SOU 2004:20, n.d., *available at*: <https://www.regeringen.se/rattsliga-dokument/statens-offentliga-utredningar/2004/03/sou-200420/> (last visited November 03, 2025).

[217] A. Elstner, A. Damaschun, A. Kurtz, G. Stacey, B. Arán, A. Veiga and J. Borstlap, 'The Changing Landscape of European and International Regulation on Embryonic Stem Cell Research', *Stem Cell Research* 2, no. 2 (2009): 101–7.

[218] H. Main, M. Hedenskog, G. Acharya, O. Hovatta and F. Lanner, 'Karolinska Institutet Human Embryonic Stem Cell Bank', *Stem Cell Research* 45 (2020): 101810.

[219] Supra note 208.

[220] K. Wånggren, F. Prag and A. Skoog Svanberg, 'Attitudes towards Embryo Donation in Swedish Women and Men of Reproductive Age', *Upsala Journal of Medical Sciences* 118, no. 3 (2013): 187–95.

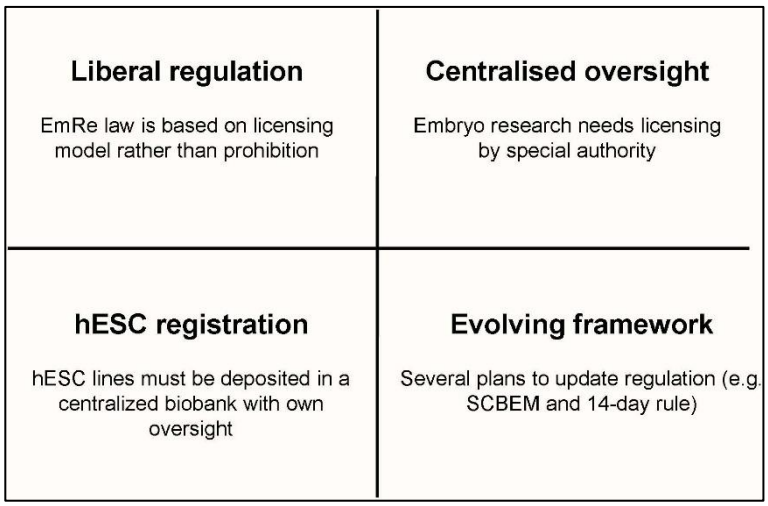
[221] Grauman, Hansson, Nyholm, Jiltsova, Widner, Van Vliet and Drevin, supra note 214.

[222] Statens medicinsk-etiska råd (Smer), Letter to the Swedish Government: Embryos and embryo models – the need for an updated regulatory framework for research on early human development, n.d., *available at*: <https://smer.se/en/2024/05/17/letter-to-the-swedish-government-embryos-and-embryo-models-the-need-for-an-updated-regulatory-framework-for-research-on-early-human-development/> (last visited November 03, 2025).

[223] En ny lag om forskningsetiska krav på och etikprövning av forskning som avser människor, n.d., *available at*: <https://www.regeringen.se/rattsliga-dokument/departementsserien-och-promemorior/2024/10/ds-202421/> (last visited November 03, 2025).

For human SCBEMs, SMER stresses that protection should not depend on the method of creation. Models that represent the embryo as a whole and whose developmental capacity cannot be excluded should be regulated similarly to embryos, with a development limit – potentially also 28 days – and subject to strict ethical review. Models that mimic only certain structures (e.g. the developing nervous system) may also require special ethical review, though regulation could be targeted to more advanced models. SMER further advises expanding the existing ban on implantation of embryos to cover SCBEMs and other embryo-like structures, including implantation in non-human primates or artificial wombs.

3.2.7. United Kingdom



The United Kingdom was a pioneer in both EmRe and on the ethico-legal discussion about the most appropriate regulation for this research. It developed permissive legislation on this matter, based on the principle of robust oversight rather than blanket prohibition. A special authority was created in the 1990s for overseeing the use of embryos in MAR and research. This centralized authority issues permission for EmRe after accurate examination, which concerns both material factors (e.g. the preparedness of labs requiring permits) and legal ones (e.g. the respect of the 14-day rule). A different legal regime (with separate supervision authority) concerns hESC, which also need to be deposited on a centralized biobank. Some concrete plans exist to potentially revise regulation, both with respect to SCBEM and a potential extension of the 14-day-rule. In the summary-box to the side, an overview of the main features of the United Kingdom system are offered. In the following paragraphs, a more detailed overview of the regulatory framework is presented.

3.2.7.1 Historical background

The UK was one of the first countries to put in place explicit regulatory governance for EmRe, also because it has always been at the forefront of this research, which made the need of clear governance even more pressing. The most significant steps in the development of the UK regulatory landscape was the work of a Committee established in 1982 and named “Committee of Inquiry into Human Fertilisation and Embryology’, but usually referred to as “Warnock” Committee – from its chair, Baroness Mary Warnock. This Committee was tasked to develop principles of governance for the use of embryos, both in research or in clinical use (MAR). After two years of work, the Committee “proposed a regulatory system that is constrained by law, rather than one based entirely on legal prohibition.”[224] Already from the start, the UK choose to take a very different regulatory path to states like Germany, where criminal law and blanket prohibitions characterize the legislation of embryos. As commentators noted, the Committee “recommended that the use of embryos and gametes in treatment and the use of embryos in research be subject to statutory regulation and licensing, and that a new statutory regulator be established to perform these functions”[225] – which are still key features of the UK approach to EmRe today.

[224] R. Lovell-Badge, ‘The Regulation of Human Embryo and Stem-Cell Research in the United Kingdom’, *Nature Reviews Molecular Cell Biology* 9, no. 12 (2008): 998–1003.
[225] J.L. Davies, ‘The Regulation of Human Germline Genome Modification in the United Kingdom’, in A. Boggio, C.P.R. Romano and J. Almqvist, eds, *Human Germline Genome Modification and the Right to Science*, 1st edn, (Cambridge University Press, 2020): 217–40.

After a few years of political inactivity by the lawmaker, motivated by some contrast within political parties, Parliament passed the Human Fertilisation and Embryology Act (HFE Act) in 1990.[226] This law set the fundamental rules for the use of embryos and it also designated a specific institutional authority for implementing governance on this issue, the Human Fertilization and Embryology Authority (HFEA).[227]

An important modification of the legislative framework occurred at 2001, where – after the revolutionary developments in hESC – lawmakers felt there was a need to update regulation. The "Human Fertilisation and Embryology (Research Purposes) Regulations"[228] of 2001 modified the HFE Act, especially in order to expand the list of allowed purposes towards which a license to conduct EmRe could be granted. Since then, research is allowed not only for purposes such as "promoting advances in the treatment of infertility", but also for "increasing knowledge about serious disease" – which is a very common purpose in case of the use of embryos to derive hESC.

A further substantial revision of the 1990 HFE Act was passed in 2008.[229] A key aspect of the reform was the expansion of the legal definition of an embryo. Under the 1990 Act, the law was primarily framed around embryos created through fertilisation. By 2008, however, developments in reproductive and stem cell research meant that embryos could also be generated by other means, such as cell nuclear transfer, and even using combinations of human and animal material, often referred to as "admixed embryos." To address this, Parliament broadened Section 1 of the Act so that the definition of an embryo was no longer restricted to fertilisation. The amended wording made clear that "references to an embryo include an egg that is in the process of fertilisation or is undergoing any process capable of resulting in an embryo." Moreover, the updated regulation also opened up the possibility of allowing mitochondrial donation. [230]

Commentators have observed two main trends in the evolution of the legislative framework in the UK.[231] First, the fact that the regulatory system has been becoming increasingly research friendly. The political discourse around EmRe has been "escaping the tyranny of the embryo",[232] meaning that it has evolved "toward making a clearer distinction between two kinds of embryos: the IVF embryo designed to become a child and the research embryo designed for destruction."[233] Policy and legal discussions about EmRe governance have thus grown closer to general debates on the appropriate limits of science and research/innovation, rather preserving an exceptional status related to the embryo as entity. Second, there has been an increasing emphasis on the importance of public consultation on this topic, before any new changes to governance are passed in the future.

Alongside the revisions of the HFE Act, another important development in the UK's regulatory framework was the introduction of the Human Tissue Act 2004[234] and the Human Tissue (Scotland) Act 2006.[235] Their scope covers the removal, storage, and use of human material including human cells and they establish another governance authority (the Human Tissue

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[226] Human Fertilisation and Embryology Act 1990, n.d., *available at*: <https://www.legislation.gov.uk/ukpga/1990/37/contents/enacted> (last visited November 03, 2025).

[227] Human Fertilisation and Embryology Authority (HFEA), Modernising fertility law, n.d., *available at*: <https://www.hfea.gov.uk/about-us/modernising-the-regulation-of-fertility-treatment-and-research-involving-human-embryos/modernising-fertility-law> (last visited November 03, 2025).

[228] The Human Fertilisation and Embryology (Research Purposes) Regulations 2001, n.d., *available at*: <https://www.legislation.gov.uk/uksi/2001/188/contents/made> (last visited November 03, 2025).

[229] Human Fertilisation and Embryology Act 2008, n.d., *available at*: <https://www.legislation.gov.uk/ukpga/2008/22/contents/enacted> (last visited November 03, 2025).

[230] Davies, supra note 225.

[231] J. Gillott, 'The Changing Governance of Embryo Research?', *New Genetics and Society* 32, no. 2 (2013): 190–206.

[232] M.H. Johnson, 'Escaping the Tyranny of the Embryo? A New Approach to ART Regulation Based on UK and Australian Experiences', *Human Reproduction* 21, no. 11 (2006): 2756–65.

[233] Gillott, supra note 231.

[234] Human Tissue Act 2004, n.d., *available at*: <https://www.legislation.gov.uk/ukpga/2004/30/contents> (last visited November 03, 2025).

[235] Human Tissue (Scotland) Act 2006, n.d., *available at*: <https://www.legislation.gov.uk/asp/2006/4/contents> (last visited November 03, 2025).

Authority) to supervise these practices. Although gametes, embryos and the process of deriving hESC from embryos continue to be regulated under the HFE Act, once hESC are derived and deposited in the UK Stem Cell bank (an obligation for researcher)[236], they are then considered human material and thus follow the rules of the Human Tissue Act.[237]
During the historical development of EmRe research in the United Kingdom, another central fact is the absence of a ratification of the Oviedo Convention. The UK was among the states that actively participated in drafting the Convention but has not signed or ratified it. The main reason lies in the clear contrast between the Convention – which prohibits the creation of embryos for research – and the HFE Act, which permits such research under a licensing system overseen by the HFEA. For this reason, the UK is amongst the states that did not join the convention due to the fear that it would impose a too restrictive regulatory framework for embryo usage.[238]

3.2.7.2 Core legal sources and features

The principal statute governing embryo research in the United Kingdom is the HFE Act 1990 (as amended). Under this regime, embryos may only be used in vitro for research under a licence issued by the HFEA. The notion of a licence is central: any clinic or laboratory wishing to create, maintain, or use embryos must satisfy the HFEA that its procedures meet strict criteria, including ethical review, donor consent, traceability, and scientific justification. A key constraint is the 14-day rule: embryos must not be cultured beyond 14 days from fertilisation or beyond the appearance of the primitive streak, whichever occurs first.
Embryo research is only permitted for a limited set of statutory purposes. These include increasing knowledge about embryo development and research related to infertility and contraception, but also increasing knowledge about serious disease (more typical for hESC). The Act also includes an explicit definition of embryo designed to capture early stages of development “embryo means a live human embryo [and] references to an embryo include an egg in the process of fertilisation”. Further regulatory constraints ensure that embryos used in research cannot be reimplanted, and that a licence to conduct research on embryos is allowed only when it can be demonstrated that the use of embryos is necessary.

3.2.7.3 Governance structure

The main institution responsible for governing embryo research in the UK is the HFEA. This is a central committee that is responsible for several issues in respect to embryo research and also MAR. The most important one for EmRe is the licensing power that it has. This means that clinics and research centers willing to perform EmRe need to obtain a specific authorization from the HFEA for each project, on top of ethics committee approval (see below). The conditions to get this license are that the research project serves on the purposes set out in the legislation.
The process to obtain a research license are clearly outlined online.[239] The HFEA examines requests to obtain a license for EmRe only with the payment of a fee and only after ethics approval has already been obtained from a local ethics committee. Once this is done, the HFEA organizes visit to the premises of the requesting research institution, to ensure that the necessary standards are upheld. External peer review of the license request is also performed. The results of these processes are then submitted as a dossier to the licensing committee within the HFEA. The normal processing time for the request is up to four months but the process can last longer especially in cases of new and more controversial research projects.[240]

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[236] Regulating human embryonic stem cell lines for human application, n.d., *available at*: <https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/regulating-human-embryonic-stem-cell> (last visited November 03, 2025).
[237] EuroStemCell, Regulation of stem cell research in the United Kingdom, n.d., *available at*: <https://www.eurostemcell.org/regulation-stem-cell-research-united-kingdom> (last visited November 03, 2025).
[238] J. Almqvist and C. P.R. Romano, ‘The Regulation of Human Germline Genome Modification in Europe’, in A. Boggio, C.P.R. Romano and J. Almqvist, eds, *Human Germline Genome Modification and the Right to Science*, 1st edn, (Cambridge University Press, 2020): 155–216.
[239] Applying for a research licence, n.d., *available at*: <https://www.hfea.gov.uk/about-us/applying-for-a-research-licence> (last visited November 03, 2025).
[240] Davies, supra note 225.

Another task of the authority is that of "producing and maintaining a code of practice, which sets out quality and safety standards for treatment and research".[241] The HFEA also provides information on the main research lines with embryos in the UK.[242] To get an idea of the importance of this agency, it suffices to say that it employs 76 staff, and has an expert board of 14 members.

Another important role is played by the local research ethics committees.[243] These are created at the local level and based on the Health Research Authority under the Care Act 2014. There are around 80 such committees in the UK and they are normally established locally by the National Health System and its subsidiaries. They are responsible to examine and approve all human and health related research, including those on embryos – which require then also a license from the HFEA. Research ethics committees have up to 15 members, a third of which must be lay people, and they deliver a response within 40 days on average.

A third level of governance is constituted by the Nuffield Council on Bioethics. This is a non-governmental institution supported by donations, but it has a similar status as the National Advisory Commission on Biomedical Ethics in Switzerland. It is responsible for publishing general guidance, opinion papers, and expert reports on matters of bioethical relevance, thus including also embryo research. It has also an important role in policy advice on such matter, as elucidated below in the last section of this chapter.

The aforementioned Human Tissue Act also created the Human Tissue Authority. This is not responsible for the governance of embryos or the derivation of hESC, but for other bodily human material. However, given the blurring lines between hESC, iPSCs and embryos (esp. due to SCEMBs), this is also an agency that is involved in the EmRe governance – as highlighted by a recent report.[244] At the moment, it is tasked to grant licenses for the storage of such material and to act as oversight authority.

3.2.7.3 Key rules on the procurement of supernumerary embryos for research.

Like in other countries, the majority of embryos are procured through donation from couples that – after IVF – have some leftover embryos that they are willing to donate. This is the reason why consent of the couple is a cornerstone of the EmRe regulation. In the HFE Act, it is specified that "all donors of embryos (or gametes or human cells used to create embryos in vitro) provide their written, signed consent to the use of such material in a licensed research project."[245] Along the process of donating embryos couple must also receive counselling, in order to ensure that their decision is well-informed. The HFEA also helps to set guidelines for this process and to establish appropriate inform consent forms for couples. This is done through a constantly updated code of practice, which has now reached the 9th edition,[246] which has been updated after some changes to the length of the storage duration of embryos (up to 55 years, with re-consent every 10 years) have been made in 2022.[247]

Conditions for providing consent are interpreted quite strictly, to the extent that the donation of embryos for general research purposes or classes of research (so-called broad consent) is not considered possible. This means that – at the moment of donation – it needs already to be known what specific project the embryos will be needed for. This is considered particularly critical, and it is indeed one of the areas of potential reform in the future – as explained below.

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[241] UK Government, *Independent review of the Human Fertilisation and Embryology Authority (HFEA): final report and recommendations* (2023).

[242] Embryo research project summaries, n.d., *available at*: <https://www.hfea.gov.uk/donation/donors/donating-to-research/embryo-research-project-summaries/> (last visited November 03, 2025).

[243] Research Ethics Committees overview, n.d., *available at*: <https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committees-overview/> (last visited November 03, 2025).

[244] Human stem cell-based embryo models: A review of ethical and governance questions, n.d., *available at*: <https://www.nuffieldbioethics.org/publication/human-stem-cell-based-embryo-models-a-review-of-ethical-and-governance-questions/> (last visited November 03, 2025).

[245] Davies, supra note 225.

[246] Read the Code of Practice, n.d., *available at*: <https://portal.hfea.gov.uk/knowledge-base/read-the-code-of-practice/> (last visited November 03, 2025).

[247] New law comes into force giving greater flexibility for fertility patients, n.d., *available at*: <https://www.hfea.gov.uk/about-us/news-and-press-releases/2022/new-law-comes-into-force-giving-greater-flexibility-for-fertility-patients/> (last visited November 03, 2025).

Moreover, there are strong withdrawal rights for the couple donating the embryos, given that "consent may be withdrawn at any time until the embryos or gametes have been used for the purposes of the research project".[248]
In practical terms, the consent-process (and consent form) for the creation of embryos within a MAR treatment and the consent-process (and form) for donating to a research project are kept separate. Online it is possible to recover examples consent forms for the creation of embryos for MAR treatments: they contain mainly provisions on the storage of embryos, and hint at the fact that donors may be contacted for the provisions of embryos for research.[249] At this link, on the contrary, it is possible to find an example of a consent form for the provision of embryos for a specific research project.[250]

3.2.7.4 Note on the creation of embryos for research.

The general regulatory approach in the UK is based on a rather liberal principle of research, which also entails that all what is not forbidden, is also allowed. In consequence, also the creation of embryos specifically for research is allowed, since it is not explicitly forbidden. This is confirmed by analysis of national regulation.[251] It is also clearly outlined by international legal analysis, which describes the UK as a very permissive regulatory framework also because of the possibility to create embryos for research.[252]
The creation of embryos requires a licensing process from the HFEA, just like any other procedure involving reproductive material. Also the general requirements required for the granting of a license listed above remain valid. Since the creation of embryos specifically for research requires eggs and sperms, these must also be procured from the individual fertility and research centers. For this process, they need to abide by the general rules on informed consent as specified in schedule 3 of the HFE Act. Information on donating gametes for research purposes is also provided by the HFEA.[253]

3.2.7.5 Other important features

The clear regulatory environment is one of the features that lead to the development of many research activities in the field of EmRe in the UK. Indeed, the country has placed itself at the forefront of this research, with government support, appropriate legislation and funding, strong scientific research foundation, public support of biomedical research, and international cooperative relationships and partnerships."[254]
A key role is played by the UK Stem Cell bank. This is not just a repository where all nationally derived hESC must be deposited, but also a regulatory, symbolic, and infrastructural institution to confirm UK commitment to stem cell research. It was the first stem cell bank of this type in the world, and it does also facilitate international collaboration by allowing access to international researchers. The bank is a custodian of all hESC, it has an approval process for the deposit of biological material, and releases codes of practices that must be followed by

[248] Ibid.
[249] Your consent to your eggs and embryos created using your eggs being used in treatment (IVF and ICSI) or stored, n.d., *available at*: <https://www.uhcw.nhs.uk/download/clientfiles/files/Attachment%201%20hfea-wt-form-v12-your-consent-to-your-eggs-and-embryos-created-using-your-eggs-being-used-in-treatment-ivf-and-icsi-or-stored.pdf> (last visited November 03, 2025).
[250] Patient Information and Consent Document, n.d., *available at*: <https://www.babraham.ac.uk/sites/default/files/2023-08/v_2.2%20Patient%20Information%20Document_Consent%20form%2017-07-2023.pdf> (last visited November 03, 2025).
[251] Davies, supra note 225.
[252] M. Popovic, C. Scarica, S.M. Chuva De Sousa Lopes and M.N. Shahbazi, 'Frozen Potential: Embryo Research at the Crossroads of Ethics, Regulation and Scientific Opportunity', *Development* 152, no. 17 (2025): dev205133; K.R. Matthews and D. Moralí, 'National Human Embryo and Embryoid Research Policies: A Survey of 22 Top Research-Intensive Countries', *Regenerative Medicine* 15, no. 7 (2020): 1905–17.
[253] Donating to research, n.d., *available at*: <https://www.hfea.gov.uk/donation/donors/donating-to-research/> (last visited November 03, 2025).
[254] 'United Kingdom', *Encyclopedia of Stem Cell Research*, (2455 Teller Road, Thousand Oaks California 91320 United States: SAGE Publications, Inc., 2008).

scientists working with hESC in the UK.[255] It holds around 150 hESC and it has made more than 300 shipments around the world.[256] As a consequence, the UK scores second to the US alone in terms of scientific output based on research with hESC.[257]
It is also important to underline that – according to HFEA data recently analysed in a scientific publication[258] – the UK has accumulated a very large reserve of frozen surplus embryos. By 2019, around 500,000 embryos were stored nationally, reflecting the rapid expansion of cryopreservation in IVF. Each year, far more embryos enter storage than are used: for example, in 2019 approximately 90,000 embryos were newly frozen, while only 40,000 were thawed for treatment and less than 700 donated to research. The number of embryos donated to research in the UK peaked in 2004 and 2007, but declined thereafter. The peaks likely reflect the surge of interest following the discovery of human embryonic stem cells in 1998, while the subsequent drop from 2007 onwards may be linked to the advent of induced pluripotent stem cells (iPSCs) in 2006, which offered a widely accessible alternative and reduced demand for embryos in research.
The public is generally supportive of EmRe in the UK. Comparative survey data show that in the UK respondents expressed support for regenerative medicine and stem cell research, but with relatively low knowledge about hESC and iPSCs.[259] This has also been confirmed by national surveys, which have highlighted a majority of the UK public does not feel very informed about stem cell research.[260] There are also public dialogues that have been organized to both improve public knowledge and get inputs on public policy changes. For example, the Human Developmental Biology Initiative commissioned a public dialogue project to explore public hopes and concerns around embryo research regulation. Funded by Wellcome Trust and Sciencewise. The project engaged 70 diverse participants and revealed citizens' hopes, concerns, and priorities, providing an initial evidence base to guide future consultations and inform both policy and scientific practice.[261]

3.2.7.6 Current debates and future challenges for the regulation

The UK regulation of EmRe has been regularly updated, in order to both adapt to the changing scientific landscape and responsive to emerging societal needs. Therefore, also now there are discussions about potential future developments. These efforts are brought forward in particular by institutions involved in the governance of EmRe, like the Nuffield Council of Bioethics and the HFEA.
The first issue currently under debate concerns whether it is appropriate to maintain the current consent system for the donation of embryos, which allows research institutions to collect consent for embryo research only for specific projects. A publication by the HFEA[262] proposed a complete overhaul of the consent regime in the HFE Act, to simplify and modernise how consent is given. Rather than requiring patients to "opt in" to every single element of treatment, the HFEA suggests structuring consent in a few "standard consent packages" that patients can select or tailor to their preferences, while still preserving the principle of informed consent. This would be a situation similar to the one currently in action in Belgium. The law should allow

[255] Policies and guidelines, n.d., *available at*: <https://nibsc.org/science_and_research/advanced_therapies/uk_stem_cell_bank/policies_guidelines_and_due_diligence.aspx> (last visited November 03, 2025).
[256] UK Stem Cell Bank Repository Statistics, n.d., *available at*: <https://nibsc.org/asset.ashx?assetid=d761992f-89ab-4865-a1ea-09fa27e81043> (last visited November 03, 2025).
[257] P. Löser, J. Schirm, A. Guhr, A.M. Wobus and A. Kurtz, 'Human Embryonic Stem Cell Lines and Their Use in International Research', *Stem Cells* 28, no. 2 (2010): 240–6.
[258] Z. Yue and C. MacKellar, 'A Quantitative Analysis of Stored Frozen Surplus Embryos in the UK', *The New Bioethics* 30, no. 3 (2024): 173–90.
[259] R. Shineha, Y. Inoue and Y. Yashiro, 'A Comparative Analysis of Attitudes toward Stem Cell Research and Regenerative Medicine between Six Countries – A Pilot Study', *Regenerative Therapy* 20 (2022): 187–93.
[260] Cambridge Stem Cell Institute - Reaching beyond Cambridge, n.d., *available at*: <https://www.stemcells.cam.ac.uk/about-us/engage/beyond-cambridge> (last visited November 03, 2025).
[261] Public support for extending the 14-day rule on human embryo research indicated by foundational dialogue project, n.d., *available at*: <https://www.babraham.ac.uk/news/2023/10/public-support-extending-14-day-rule> (last visited November 03, 2025).
[262] Human Fertilisation and Embryology Authority (HFEA), supra note 227.

patients to donate embryos for 'research (bio)banking', so that embryos donated for research can be stored in a central research bank and allocated later to research projects – rather than being tied only to specific named projects at the time of donation. Any revised consent system should uphold core principles, including dynamic consent (allowing parties to change their mind).

The second issue under debate concerns how research with SCBEMs should be regulated.[263] The UK is at the forefront of the discussion of this matter, although a final decision for the regulatory framework has not been reached yet. In 2024, the first code of practice for creating good practice and ethical standard in the creation and use of SCBEMs was published by the University of Cambridge, but it is not a binding document.[264] A working group within a project promoted by the Nuffield council of bioethics published a report in November 2024 to try and guide policymaking in this area.[265] It recommended the official adoption by the law of the aforementioned code of practice, and especially the funding of an oversight committee and register for research involving SCBEMs. The report also proposed to add a reference to SCBEMs in the HFE Act, but to regulate them differently to normal embryos, and create a temporary regulatory sandbox, in order to provide a good compromise between regulatory certainty and free innovation. Finally, the report recommended that the experiences collected within the regulatory sandbox should then be used to create separate approval procedures for research with low risk and high-risk SCBEMs. This is, however, mainly a proposal, and many doubts remain. One of them concerns the remit of the expert committee, and especially which institution should be mostly involved with the new regulatory framework. These could be The UK Stem Cell Biobank, the Human Tissue Authority or the HFEA.

The third issue under debate concerns the potential expansion of the 14-day limit for the cultivation of embryos in vitro for research purposes. The Nuffield Council on Bioethics announced in February 2025 the launch of a project aimed at producing recommendations concerning the 14-day-rule.[266] The project has recently started and it includes different phases, including both a review of the medical and ethical literature, a public engagement module to collect citizens' views on the issue and then the issuing of policy recommendations.

[263] E. Cave, 'Advocating Distinct Regulatory Paths for Embryos and Embryo-like Structures', *Journal of Law and the Biosciences* 12, no. 1 (2025): lsaf008.

[264] The SCBEM Code of Practice, n.d., *available at*: <https://www.repro.cam.ac.uk/scbemcode> (last visited November 03, 2025).

[265] Supra note 244.

[266] Nuffield Council on Bioethics begin major review of the 14-day rule for research on human embryos, n.d., *available at*: <https://www.nuffieldbioethics.org/news-blog/nuffield-council-on-bioethics-begin-major-review-of-the-14-day-rule-for-research-on-human-embryos/> (last visited November 03, 2025).

4. Critical discussion of results

As emerged in the overview of ethical issues and the country reports, EmRe is still characterized by ethical and legal controversies. In this chapter, some general comments on issues emerging across different parts of the report and at the crossroad between ethics and regulatory implementation are discussed.

First, it becomes clear that all countries that permit EmRe are aware of the ethical issues generated by this kind of research and they therefore create appropriate institutional bodies to examine single projects involving the use of embryo and provide general oversight. In this sense, the difference between more permissive and more prohibitive countries does not consist the appreciation (or lack thereof) of ethical issues. It consists in how such issues are resolved. In prohibitive countries, they are solved by blanket bans on whole categories of research (e.g. research with embryos). In more permissive countries, they are solved by creating institutions with the duty to examine whether the ethical risks that individual projects entail are counterbalanced by the advances that they can achieve. However, many different exists how this form of institutional oversight can be concretely organized. One possibility is to delegate this to general research ethics committees, like it is done in Sweden. If this is implemented in Switzerland, it would mean that cantonal ethics committees would be assigned this task. Another possibility is to design specific authorities that have the duty to examine research with embryos. This is the case, for example, in the Netherlands, where research with embryos is evaluated by an especially designed committee that has competence only over controversial types of research. If this was implemented in Switzerland, a new committee (not the cantonal ethics committees) would have to be designed. A third option is to require that research with embryos is examined both by regular ethics committees and a specialized commission, as in Belgium. Under this model, Switzerland would likewise have to design a second type of committee – in addition to the cantonal ethics committee -to provide the second layer of specialized ethical examination of EmRe. It would then need to be determined how and with what kind of experts concretely this special committee would be composed, and it requires the presence of both scientists with specific expertise on EmRe, but also ethicists and lawyers, maybe members from the public, patient representatives etc. Finding committee members with sufficient expertise to understand what complex scientific EmRe projects have planned and the respective ethical consequences is considered difficult by some authors and interviewees.

A second key issue concerns what consent model should be used for the donation of embryos, embryonic material and – in the case of iPSCs/SCBEMs created by those – even of other body cells - for research purposes. Considerations around the right type of consent, and its outreach (e.g. the possibility to withdraw it) are central to the ethical debate, as highlighted in chapter on the cross cutting ethical issues. Given the rapid pace of developments, it is often difficult to anticipate what types of research could be conducted with the donated material in just a few years' time. Most countries have implemented a consent model based on the necessity to require consent for specific research projects. This means that if e.g. supernumerary embryos from IVF treatment want to be used for research, researchers must ask patients to provide explicit consent for each distinct project. In Belgium, on the contrary, it is also possible for patients to donate embryos for broader categories of research, which are pre-defined on the consent form. Implementing this system is also under consideration in the United Kingdom. If Switzerland were to legalize research with embryos, it would have to decide what kind of consent model to implement. It would also be important to clearly define rules on withdrawal of consent, i.e. until which point this is considered legitimate. In Sweden, for example, some unclarity on this issue has created problems in the past, when donors sought to withdraw of consent after an embryo had already been used to derive hESC.

Third, this report showed how the regulation of SCBEMs remains filled with significant uncertainties. To begin with, the review of the ethical literature revealed persistent doubts regarding the appropriate terminology and the appropriate differentiation of different types of SCBEMs (see Chapter 3.1.4). This fundamental uncertainty – together with the very rapid developments in this field -– has contributed to the fact that there are still many regulatory

vacuums around SCBEMs. At presence, only France (see chapter 3.2.2) amongst the examined countries addresses SCBEMs directly in the regulation, but even there debates continue as to whether the current approach is satisfactory or whether new regulatory pathways should be created. The United Kingdom is currently considering whether to create temporary regulatory sandboxes for SCBEMs (see Chapter 3.2.7). The aim would be to allow research to proceed more freely in the short term while establishing stricter regulation (e.g. in terms of the determination of appropriate regulatory pathways) at a later stage. If Switzerland were to explicitly regulate SCBEMs, it would be important to debate whether to follow a similar approach – which would, however, require close coordination between regulatory authorities and researchers operating within the regulatory sandboxes. A further open question concerns how to integrate the continuously evolving ethical debate into the evolving regulation and how to involve the public in deliberations. Calls and initiatives for finding compromises in increasingly pluralistic societies by broader societal debates on the ethical debates regarding EmRe (e.g. regarding research time limits) are widely announced, however it often remains unclear to how such public engagement can be meaningfully implemented in practice.

Fourth, an ongoing ethical debate concerns the exact definition of the embryo and whether the law should explicitly embrace such a definition at all. From the ethical point of view, there are many potential ways to define an embryo for the purpose of EmRe governance. Some of the countries examined endorsed a specific definition in the law (e.g. Belgium or Netherlands, see respective chapters), while others refrained from doing so (e.g. Sweden, see Chapter 3.2.6). If Switzerland were to decide in favour of a concrete definition, it would be important to decide on a definition that is both future-proof – so that one that does not have to redefine the embryo whenever a new technology arises (like SCBEMs) – but that also is compatible with the definitions already existing in other pieces of regulation. Careful considerations of exact definitions are particularly important also to avoid conflict of laws. Many states have different regulatory regimes for bodily material (e.g. in terms of donation rules, preservation, ethics approval, oversight authority etc.) and embryos, which have concrete consequences. For example, the UK gives the Human Tissue Authority oversight over research with bodily material (including also hESC once derived), whereas the HFEA governs the use of embryos. Consequently, determining the point at which an entity ceases to qualify as an embryo is also essential to define applicable law and regulatory oversight.

One final note concerns the coordination of legislation on research with embryos with that regarding MAR. Given that a great deal of the embryos used in research are supernumerary ones donated from couples who have undergone MAR, it is important that rules in legislation on this matter are closely coordinated. This includes issues such as the length of storage periods for embryos, or also the definition of the exact number of choices MAR patients have. With respect to this issue, it would be very important to define – for example – whether embryos can be donated only for research or also to other couples for them to be used for further reproductive purposes.

5. Limitations

This report has several limitations that should be acknowledged. First, the broad thematic scope agreed upon with the FOPH team – covering a wide range of ethical, legal, and regulatory aspects as well as multiple entities of EmRe – combined with the short project duration, meant that many topics could only be addressed in brief. Several of the issues raised, such as the moral status of the embryo or the categorization of SCBEMs, are extensive debates in their own right and could each warrant a dedicated report. Methodologically, therefore, the review conducted for the identification of ethical issues does not claim to be exhaustive. Nevertheless, we believe that it provides a concise synthesis of the key aspects of the ethical debate. Moreover, the interviews conducted under WP3 served as an important validation to ensure that the most essential points were captured in the analysis.

Second, there are numerous adjacent topics that could not be covered within the scope of this short project. These include, for example, debates surrounding genetic modification and cloning. This exclusion reflects both the breadth of these discussions, which could each again constitute a separate research projects, but also because although these topics are closely related to EmRe, it remains important to keep them disentangled. There may be reason, for instance, to support embryo research in general, while opposing research involving germline gene editing. The same is the case for debates related to specific organoids that can be created using stem cell technologies. Some of these (esp. brain organoids) raise ethical specific issues (e.g. because of the possibility to achieve consciousness), but these are still quite separate to the debate on EmRe in general and a thorough examination of the related ethical aspects would have exceeded the scope of this project.

Finally, there exists a gap between law in the books and law in action. Investigating the practical application of legal frameworks proved challenging in some cases, as detailed information on the procedures for approving EmRe was not always accessible. We addressed this by considering not only legal texts but also reports of the agencies in charge of implementing them and also by interviewing experts that are members of the committees in charge of the application of the law. However, even they confirmed that some issues remain quite moot, as none of the analyzed legal systems is characterized by complete clarity. Indeed, insights into how certain legal criteria are interpreted and applied in practice remain limited, and knowledge is often shared amongst many stakeholders (e.g. some issues about legal interpretation may be better known by scientists who apply for permissions to conduct embryo research, whereas other by legal experts and other by public official working in the governmental agencies supervising EmRe).

6. Conclusions

This report encapsulates an overview of the ethical and legal issues related to EmRe that was produced as part of a short-term project consisting of three different WPs. Given the rapidly evolving field of EmRe, this overview aimed to provide the necessary knowledge base – in terms of ethical and legal debate – for informing the upcoming discussion at the Swiss policymaking level. With its mixed-method approach, combining both desk-research with also interviews with expert – we attempted to cover both the breadth of issues that are related to the complicated field of EmRe, but also respect the limited timeline of the project itself. We combined depth of the exploration of the ethical issues and legal landscape, with also summary tables to help identify the more distinctive issues in each chapter. Finally, we also provided a final critical discussion of the results, to highlight some of the cross-cutting themes that concern both the theoretical ethical discussion around EmRe, but also its practical operationalisation in legal rules.

7. Additional material

In the next pages, we included three files for the additional material. First, a copy of the interview agenda we used for WP3. Second, the list of interviewed experts for WP3. We thank them for their time and sharing their expertise. They provided very valuable information and we hope that our report relates it in an accurate way – we assume responsibility in the content of the report. Third, a list of the literature consulted for WP2 and indicated in the tables of Chapter 3.1.

Interview agenda for WP3

Notes: There is also room to note things that emerge in each interview and which are relevant to potentially improve/adapt the agenda. As it is an unstructured interview, all questions are very open, and they mainly contain the issues we think are important to investigate with each expert, rather than a 'structured/fixed' question to be asked in the same way (and with the same words) each time. Expected length of the interview is 60 minutes.

Topic to explore	**Open questions**
PERSONAL EXP. Involvement and field of expertise of the interviewee	Can you please summarise shortly your work in relation to the ethics/law of embryo research, embryonic stem cells, or embryo models → adapt based on the interview
HISTORICAL PERSPECTIVE: Identifying the major traditional ethical issues characterizing research with embryos/stemcells and/or embryo models	In your view, what are the crucial ethical controversies and dilemma that have dominated the debate around embryo research **in the past**? - Internationally - In your specific country/context of work?
HISTORICAL PERSPECTIVE: Explore how policy/law on embryo research has evolved in the country of expertise	In your view, what were the crucial moments in the past development of legal rules and policies around embryo and stem cells research in your own country? Rather liberal or rather conservative?
CURRENT SITUATION: Identifying	What about the present? Are there ethical issues/controversies that you believe are particularly important **at the moment**? - Internationally - In your specific country context of work
CURRENT SITUATION: Identifying the major features of the law/policy around embryo research in your country	If you had to summarise, what do you think are the distinctive features of current law/policy around embryo research in your country? - main institutions in the governance structure - conditions/aims for embryo research to be legal - supernumerary embryos: how they are procured? Rules on consent, role of hospitals

	- institution/governance structures for frozen embryo storage facilities (“biobanks” for embryos/ stored at IVF-labs)? Who finances those? - embryo created for research: possible? Rules for creation? Donation of gametes? - Bans/prohibitions? - Differences in embryo research vs research with embryonic stem cells? - Import of embryos?
Public Attitudes toward the topic	Can you assess the public attitude toward the topic? - What majority/minority opinions can you identify? - Which institutions/groups are particularly involved? - What are their main arguments?
FUTURE: Identifying the major ethical issues looking forward	What about the future? Are there ethical issues/controversies that you believe are particularly important looking ahead? - Internationally - In your specific country context of work
FUTURE: Grey areas in the law and open questions for future regulation	Are there any controversial aspects about the current regulation that lead to debate? If so which, and how? Is there a policy debate about potential future changes in the law? - E.g. around 14-day limit - E.g. around embryo-models - Are there any reasons to expect the law will (or will not change)?--> drivers of change
Final thoughts	Anything else important that we forgot to talk about?

	Name	Institutional Affiliation	Short bio
1	Prof. Dr. Dr. Sabine Salloch	Hannover Medical School, Germany	A globally renowned bioethicist who is also a member of the Central Ethics Commission for Stem Cell Research at the Robert Koch Institute in Germany (the commission with the legal mandate to decide on all stem cell research in Germany).
2	Prof. Dr. Christiane Druml	UNESCO Professorship für Bioethics, Medical University of Vienna, Austria	President of the bioethics commission of Austria and expert in the field of regulation of embryo research and its underlying ethical debates.
3	Dr. Kirstin Matthews	Rice University, USA	Kirstin Matthews is a fellow in science and technology policy at Rice University's Baker Institute for Public Policy. She has published extensively on the topic of regulating embryo and embryo-models research.
4	Prof. Guido Pennings	Ghent University, Belgium	Guido Pennings is a renowned expert in the ethics and law of embryo research. In Belgium, he is a long-standing member of the Federal Commission for medical and scientific research on embryos in vitro.
5	Prof. Giulia Giovannini	Pompeu Fabra University, Barcellona, Spain.	Professor Giovannini is an expert on the legislation on Medically Assisted Reproduction and embryo use in several jurisdictions. She is also the author of a recent study on the reform of EmRe legislation in France.
6	Prof. Emma Cave	Durham University, United Kingdom	Professor Cave is one of the leading experts in the ethics and law of EmRe in the UK. Moreover, she has just led a project by the Nuffield Council to inform the potential changes in the regulation of SCBEMs.
7	Dr. Nienke de Graeff	Leiden University Medical Center, the Netherlands	Dr. de Graeff is assistant professor for bioethics and the ethics of emerging technologies, with a particular expertise in EmRe. She is involved in a project on reforming regulation for SCBEMs in the Netherlands and is also part of a large international consortium on stem cell research.
8	Prof. Friederike Wapler	Johannes Gutenberg-Universität Mainz, Germany	Prof. Wapler is a renowned Constitutional lawyer in Germany. She was involved in a recent expert commission for the government to propose reform on Medically Assisted Reproduction use and was also involved in a recent international conference by the Federal Ministry for research to discuss potential future reforms on embryo research law.
9	Dr. Alessandro Blasimme	Health Ethics & Policy Lab Department of Health ETH Zurich, Switzerland	Senior researcher focusing on ethical and policy issues in biomedical innovation and biotechnology. He has published widely in leading bioethics and medical journals on stem cell research.

Bibliographical information of analysed publications for WP1

No.	Publication
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