

Executive summary

1. Background and objective

In a referendum on 7 March 2010, the Swiss electorate voted in favour of Article 118b of the Federal Constitution, which prescribes the creation of a legal framework for research on humans. As a result of this, on 1 January 2014 the Federal Act on Research involving Human Beings (Human Research Act or HRA for short; SR 810.30) ultimately entered into force along with the accompanying implementing ordinances.

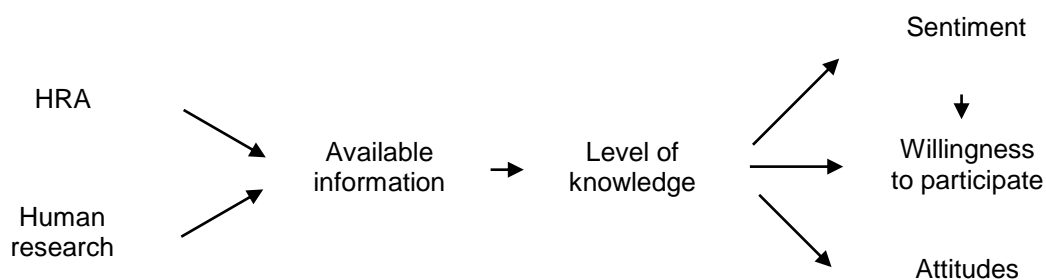
The legislation is designed primarily to safeguard the dignity, privacy and health of people involved in research. The law also creates a favourable framework for research involving humans, among other things by laying down uniform administrative requirements throughout the whole of Switzerland. In addition, the legislation helps assure the quality and transparency of research involving humans (the dispatch on the federal law on research involving humans of 21 October 2009 and Art. 1 HRA).

To evaluate the efficacy and appropriateness of the legislation, among other measures the Federal Office of Public Health (FOPH) commissioned the Swiss Centre of Expertise in the Social Sciences (FORS) to conduct a population-based survey. Essentially the FOPH wants to find out whether members of the public feel adequately protected by the Human Research Act and the statutory regulations derived from it. It also intends to investigate the degree to which members of the public are informed about research involving humans and whether they are able to make informed decisions in connection with the Human Research Act and human research projects. The concrete goal of the population-based survey is to gauge public sentiment, the level to which people are informed and their attitudes with regard to research involving humans and the Human Research Act, as well as their willingness to take part in a project related to human research.

2. Themes, interdependencies and methodology

By way of working hypotheses, on the basis of our own deliberations and discussions with the commissioning client, we have created the following diagram representing the overall interdependencies we assume to exist between the different themes:

Connections between themes and concepts of interest



We assume that the information made available on human research by the federal authorities and the statutory regulations will tend to increase the level of knowledge among

members of the public, and that this knowledge will influence sentiment, attitudes and willingness to take part in a study (see Chapter 2). However, we also assume that sentiment and attitudes among members of the public will influence their willingness to take part in a study, regardless of their level of knowledge.

On the basis of theoretical considerations and literature research, we identified the various dimensions of the four basic concepts of interest (level of knowledge, sentiment, attitudes and willingness to participate) and formulated concrete questions to be put to members of the public so that their responses would in turn allow the underlying research questions to be answered (see questionnaire in the annex).

To allow assertions to be made about the population in Switzerland, a random sample of the resident Swiss population aged 18 and over was taken. The sample was taken by the Federal Statistical Office from the sampling frame for person and household surveys. All necessary precautionary measures were taken to assure data privacy at all times. The people surveyed were sent a letter asking them to complete the questionnaire online or on paper. A total of 1,983 people took part in the survey between March and May 2018. This corresponds to 53% of the people addressed – a very high response rate by comparison with other population-based surveys. Questionnaires were completed in full or almost in full, and those surveyed were a good representation of the Swiss population. In other words, the quality of the data is very good, and it was possible to improve it even further by means of weighting. This involved giving the responses of people who were underrepresented among those surveyed (for example foreigners) a somewhat higher weighting than those of other people to enable the findings to be transferred even more effectively to the overall population in Switzerland.

3. Summary and interpretation of findings

In the course of designing the questionnaire and evaluating the data it emerged that there are overlaps between the various concepts, with sentiment and attitudes in particular very close together. For this reason the results for these two concepts are presented together in the following summary of the findings.

Level of knowledge

The findings of a population-based survey following the referendum on the article of the constitution on research involving humans in 2010 suggest that the level of knowledge of human research in Switzerland is fairly low, and that only a small section of the population has already come into contact with research involving humans and the relevant legislation. The main aim in our case was therefore to find out the extent to which members of the public are even interested in health issues and how they get their information, how many people have even heard of research involving humans and the Human Research Act, and how they rate their own level of knowledge of these matters. We were also interested in finding out whether people have a need for information, and whether the public is aware of the information provided by the FOPH.

The following findings emerge:

- 74% of the population are interested in health issues, women somewhat more than men. People's most important source of information is discussion with professionals.
- 43% of the population have engaged with or heard of research involving humans, and 24% have engaged with or heard of the statutory regulations on human research in Switzerland – most via the media.
- 40% of the population rate their knowledge in terms of human research as average or above-average compared with the average person in Switzerland; 28% make this assertion with respect of the Swiss regulations on research involving humans. People who have completed tertiary education or work in healthcare gauge their level of knowledge to be higher than the rest of the population.
- More than half the population would in general like more information on research involving humans (61%) and the relevant statutory regulations (50%).
- 51% of those surveyed were familiar with the general website of the FOPH, while the website of the Coordination Office for Human Research (www.kofam.ch) is familiar to 4% of those polled.

These findings suggest that as anticipated, the level of knowledge among members of the public is fairly low, but that around half of people have nevertheless heard something about human research at some point. There is interest in the topic, and there is a need for information. However, given that so few people know about the information already available, the need for information does not seem to be so great that people actively seek information themselves.

Sentiment and attitudes

The concepts of *sentiment* and *attitudes* are connected and were therefore addressed together. Public sentiment is measured by way of the emotions people have with regard to research into humans and the relevant legal framework. In this context the relevant emotions were identified as general interest in these topics¹, trust in the relevant actors and legislation, and fears in connection with human research in general and in relation to people participating in a human research study; the emotions identified were surveyed accordingly. Attitudes cover people's views and opinions on human research and the Human Research Act.

The survey yielded the following findings:

- 89% of those surveyed trust that people participating in human research studies in Switzerland are well protected by the law.
- Trust in researchers at universities is higher than trust in researchers in industry and business and in the pharmaceutical industry in general.
- 28% of the population thinks that patients are sometimes part of a research project without their knowledge, and 38% are unsure on this point.
- 95% believe that medical research is necessary.

¹ On a purely conceptual level, general interest is assigned to the dimension of "sentiment". However, when it comes to summarising the findings it makes more sense to address this indicator along with the level of knowledge.

- 49% of the population are sometimes scared by medical progress, and 58% believe that the development of new technologies should be halted if there are unknown risks; women somewhat more frequently than men.
- 28% believe that human research should investigate everything without restriction.
- 32% believe that the Human Research Act gives rise to unnecessary bureaucracy and impedes progress. This view is held considerably more frequently by older people who position themselves to the right of the political scale than by younger, better educated people to the left of the political spectrum.

This suggests that members of the Swiss public are convinced of the necessity of medical research, and basically trust the actors and legislation when it comes to research involving humans. On the other hand, a considerable portion of the public appears to doubt that people taking part in research are always informed. For around half the population, research involving humans is also associated with fear, and legal restrictions are welcomed by a majority of people.

Willingness to take part in a human research study

Finally we wanted to show how many people had already taken part in a human research study, and how many would be prepared to take part in various types of human research study. We also wanted to be able to say something about whether people are more likely to take part in studies of this sort if they know that a law exists and are informed about what the law contains. The latter point could not be clarified, because very few people are informed about what the law contains. On the other hand people's general reasons for or against taking part in a human research study were surveyed in somewhat more detail.

The following findings emerge:

- Overall 22% of the population have already taken part in a human research study. 3% have taken part in drug trials, while the remaining 19% have taken part in other types of human research study.
- Basically 66% of the population would be generally prepared, within the framework of a human research study, to answer questions about their health, 50% to undergo medical examinations, 49% to provide biological material, and 10% to take trial drugs.
- Whether someone is prepared to take part in a drug trial depends to a large extent on the actual scenario. The most frequently cited reasons for taking part are for the participant's own benefit, and because other people might benefit from the findings. The most frequently cited reasons for not taking part are the fear of risks, and because people do not wish to be a test object.
- For 50% of the population, the knowledge that the Human Research Act exists increases their willingness to take part in a human research study themselves.
- The conditions for taking part mentioned by those surveyed show what is important to them, even if they are not familiar with the statutory regulations. For example most (70%) would only take part if there was no risk to health, and more than half the population believe it is crucial for participants to be able to leave a study (61%), be informed about the details of the projects and their personal results (57% each), and for data privacy to be assured (51%).

These findings can be interpreted to suggest that a significant proportion of the Swiss population would be perfectly willing to take part in a human research study under certain conditions, and that the existence of the Human Research Act increases willingness to take part. When deciding whether to take part in a study or not, people weigh the personal benefits and altruistic motives against the feared risks and the aversion to being a test object. This is probably one of the reasons why the willingness to take part in a study declines the more the study affects the person taking part; in other words, people are more willing to provide biological material than to take a trial drug.

4. Conclusions

All in all, the population-based survey shows that while a significant proportion of the population has heard of human research and the Human Research Act, the level of knowledge is low. Even without precise knowledge, people generally trust the Human Research Act to protect them, and many do not categorically reject the idea of taking part in a human research study. Nevertheless, there also appear to be prejudices among members of the public, such as the belief that patients are not always informed if they are part of a human research study. Targeted information could allay such prejudices and build trust in human research and the statutory regulations.

In general there seems to be a need for information among members of the public, and the information already on offer is not very well known. This means that the public could be better informed primarily by publicising the information already on offer, and that additional information does not necessarily need to be provided.