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Informed Consent and Comprehensibility Issues

**Summary of the research project
“Comprehensibility – A Requirement of the
Human Research Act and its
Implementation”**

**On behalf of the Federal Office of Public Health FOPH
Human Research and Ethics section**

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Informed Consent in an Intelligible Form: Summary

The Federal Office for Public Health has commissioned a project to investigate a key requisite for research with humans: Any person who consents to participate in health-related research must have understood the purpose, the risks and the course of the study in question. This principle for research with humans is known in the literature as ‘Informed Consent’. The Human Research Act (HRA) in Art. 16 para. 2 and in agreement with international Standards specifies that the person concerned “must receive comprehensible oral and written information”. This project answers the question, in the context of a possible revision of the HRA, of the problems that arise from a linguistic and communication perspective of the HRA legislation, and which recommendations may be derived from the results.

Independently of the research context, the *informed consent* also refers to one of the fundamental principles of modern medicine, namely in order to empower lay persons to decide, preferably independently, on their medical care (keyword “empowered patient”). The *Informed Consent Principle* replaces the historical paternalistic relational model between medical doctors and patients. In human research the requirements for informed consent gained in importance as a reaction to cases of abuse. Understanding the basics of the clarification is the key for patients to take on more responsibility. Subsequently, the principle of autonomous decision-making of the patients has been strongly emphasised in the ethically oriented literature. In the last ten years the fundamental principle of shared decision making (SDM) has increasingly replaced autonomy. A precondition for communicating this is greater than that of the previous dialogue between experts/physicians and lay persons/patients which on the one hand implies an adequate knowledge transfer and on the other hand aims for a mutual understanding procedure.

The following stakeholders were particularly relevant for the implementation of the specified comprehensibility of the HRA for this project: the cantonal Ethics Committees, their umbrella organisation swissethics, the Swiss Academy of Medical Sciences (SAMS) and researchers. The four research reports on the problems associated with the understanding of Informed Consent focus on the following aspects:

1. A literature review of Informed Consent and a model-based analysis of the problems associated with the understanding of Informed Consent
2. The comprehensibility of the General Consent
3. The concept and studies of comprehensibility by the ethics committees
4. The concepts of Informed Consent by researchers.

Building on the research reports, the present summary is intended to separately illustrate each of the following three levels of the problems associated with the understanding of Informed Consent, namely the results and the recommendations relating thereto. We forego any detailed derivation and discussion of the results that are contained in the four research reports.

1. Intelligibility of the written Informed Consent explanation
2. Intelligibility of the oral Informed Consent explanation
3. Combination of the oral and written Informed Consent explanation

1 Intelligibility of the written Informed Consent explanation

From the viewpoint of linguistics intelligibility in written texts is a multi-dimensional phenomenon with structural, content-related and linguistically stylised requirements (keyword “plain language”) that should enable the text to be read as easily as possible. This model-supported view of intelligibility is the basis for the analytical results of the IC explanatory documents as presently used in Switzerland (1.1). The concepts of intelligibility which the cantonal Ethics committees advocate, and which are applied for the examination of intelligibility, are subsequently summarised (1.2). The effective difficulties while reading are the subject of the empirical intelligibility examination of the General Consent (1.3).

1.1 Intelligibility of the IC explanatory documents

In the last three decades the difficulty in understanding IC explanatory documents has been extensively described in the literature and proposals for optimisation have been suggested. In this regard intelligibility is often explained with simple communication models (Results and Recommendation 1). Aspects of the explanatory documents, such as text length or technical complexity, may be overwhelming and are described as barriers to intelligibility (results 2 and 3) and are supplemented by recommendations (recommendations 2 and 3).

Result 1: Multi-dimensionality of IC Intelligibility

In the IC literature a written explanation is modelled as an information transfer between a sender and a receiver. From the linguistic viewpoint it is essential to consider the reading of written texts as not precisely a transfer of information, but rather as an individual reconstruction of the meaning by using competences and knowledge requirements. Intelligibility in this sense is a multi-dimensional construct that allows or hinders this individual reconstruction of meaning, i.e. makes texts more or less intelligible to particular readers. The following intelligibility dimensions are particularly crucial for IC explanatory documents:

1. Structure: Stepwise explanations in the context of the central theme from the general to the specific. The individual meaning should also be selectively creatable.
2. Simplicity: Reduce complexity at the content level. Use generally understandable vocabulary at the word level (avoid specialist vocabulary). Use simple sentence constructions at the sentence level.
3. Explain framework concepts such as research, studies, experiments.
4. Readability: Typographical design of the texts in the sense of a problem-free readability (sectional organisation, clear subsections, legible print, reader guidance by highlighting).

Analysis of the body of IC explanatory documents shows that barriers to intelligibility are not limited to a single dimension. The texts exhibit a high degree of specialist knowledge, highly complex contents, unexplained framework concepts, unexplained technical terms, density of information comparable to a scientific “ abstract style”, and in the main, few reader-friendly text layouts.

Recommendation 1: Instruction of model dimensions for the production of intelligible IC explanatory documents

Intelligibility is to be taught as a multi-dimensional phenomenon, and a model-supported Good Practice is to be developed.

Result 2: Text functions in conflict: Agreement function versus explanatory function

The relationship between the quantity of information and intelligibility has been extensively examined in the IC literature. The (historically increasing) length of IC explanatory documents is largely due to the fact that they not only have to fulfil the ethical requirements of the explanation, but as contractual documents they also have to fulfil legal requirements. The recognition that the text length hinders the intelligibility has led to a summary being presented before the IC explanations. Separating the summary, as the templates of swissethics indicate for IC explanatory documents in Switzerland, is functional from the linguistic viewpoint because it thereby enables and encourages selective reading. However, the density of information in the style of scientific abstracts is problematic for the intelligibility of the IC summary.

Recommendation 2: Consistent orientation of the abstract to lay persons

From the linguistic viewpoint the IC explanatory document cannot simultaneously involve the requirement of a contract and that of an intelligible explanation for a layperson. These requirements are more difficult to separate than previously and are to be allotted to the abstract and the full version: Consequently, the abstract has also to be geared towards the linguistic and knowledge horizons of lay persons (also poor readers). Specific proposals from swissethics and the ethics committees are to be considered for the separation of the abstract and full version.

Result 3: IC-simplification: simple language and further solutions orientated to lay persons

An important research finding relates to the obvious assumption that linguistic simplification increases the intelligibility of the IC-explanatory documents: In practice, plain language is often equated to participation, as the complexity of the linguistic surface is regarded as the main obstacle to intelligibility. Although simplified documents certainly have positive effects (greater satisfaction, fewer doubts about consent, greater willingness to participate in studies), they do not lead to a significant improvement in intelligibility (Davis et al. 1998; Coyne et al. 2003; Flory/Emanuel 2004; Breese et al. 2007; Cortés et al. 2010; Paris et al. 2015). Especially for recipients, who are less educated or poor readers, the lack of familiarity with the research context leads to hurdles for intelligibility. The explanation of framework concepts (e.g. studies, research, experiments) and the chance to be able to pose questions help these stakeholder groups to overcome such hurdles. Such explanations would also help to recognise the distinction between research participation and therapy (therapeutic misconception) as is so strongly emphasised in the specialised literature on Informed Consent.

Recommendation 3: Explaining the framework concepts

A fundamental requirement for intelligibility is the explanation of framework concepts such as studies, research and experiments. This enables an increased understanding of the specific contents. From the linguistic viewpoint purely stylistic interventions at the formulation level lead nowhere in regard to intelligibility. The effort that is made for the intelligibility elaboration by the researchers and the ethics committees in regard to the simplification of the linguistic surface is to be reviewed in view of the expected return.

1.2 Test of intelligibility by the Ethics committees

The ethics committees (ECs) are responsible inter alia for examining the intelligibility of IC explanatory documents. The investigation of the fundamental concepts of illegibility shows that the three investigated ECs (CCER, EKOS, KEK ZH) have different opinions and that within the ECs the opinions also diverge in the sense of a differentiated problem awareness.

Result 4: Lack of uniform criteria for the IC intelligibility test

Orientation for common criteria for the intelligibility examination is lacking. In the investigation a well constructed awareness of the intelligibility problem of the IC explanatory documents will indeed become visible. However, the ethics committees lack a uniform concept that structures and renders transparent the process and criteria for the examination of intelligibility. In regard to the examination of intelligibility a high degree of contingency is expected. Practically, this means: For applicants the editorial comments in the explanatory texts remain linked to the individual opinion of the assigned personnel who give feedback.

Recommendation 4: Criteria-based intelligibility test

The professionalisation of the intelligibility test should be sought by introducing a manageable catalogue of test criteria (similar to the structural guidelines by the template of swissethics). The introduction of guidelines for criteria offers the advantage that it promotes the sustainable learning effect in regard to the production of texts. Mandating the intelligibility concerns to experts in the ECs in regard to the understanding by lay persons may also be considered as a further measure.

1.3 General Consent (GK) intelligibility

Preliminary remarks: The consent of the greatest possible number of persons for medically/quantitatively oriented research paradigms (research with data and samples, research with biobanks etc.) is a prerequisite for future research in this field. The research paradigm at present strongly depends on the intelligibility of a text that is called “General Consent” by swissethics/SAMS and differs from the format of Informed Consent in the explanatory and consent parts (GC 1/2017). Even though the swissethics/SAMS version has scarcely been directly adopted by the Swiss research institutes, there exists, however, an agreement for the adoption of the “contractual format”.

Result 5: Difficult intelligibility of the scope of the consent

The empirical examination of the intelligibility problems of the General Consent GC 1/2017 shows that significant aspects of the explanation for research with data and samples are not understood by test persons of above average reading competence. An alternative version, drafted for test purposes, shows an improved comprehension. However, significant problems of comprehension also exist with the alternative text. All in all, the consent occurs without clarification, rather at best as an *Empty Performative* (Conley et al. 2016) in the sense of a scarcely informed ceremonial) comparable with the acceptance of terms and conditions in the Internet.

The concept of an open consent of the content for an unlimited time for research with data and samples in the sense of the contractual character (General Consent) is rarely part of the common knowledge of lay persons. The GC text cannot presuppose any prior knowledge for the corresponding research paradigm. Internationally, solutions exist for this problem which do not rely exclusively on a written text. For the General Consent process communication strategies are favoured which structure the relationship between participants and research institutes differently from a contract: e.g. the concept of dynamic consent; participation model (e.g. UK Biobank); trade secret model (compensation).

Recommendation 5: Develop a communication concept for General Consent

Text intelligibility is not considered to be the sole communicative solution to improve intelligibility of the General Consent. Based on the findings, we recommend that a communication concept for this purpose be drawn up, which means in particular to redesign the relationship between consenting patients and researchers, and to move away from a purely contractual “assignment solution”.

2 Intelligibility of the oral explanation: Approaches for researchers

In the investigation researchers who have experience in clarification techniques focus on approaches for intelligibility in the clinical context. Data were collected by means of interviews. All in all, the investigation shows that the clarification-practitioners regard the oral explanation to be a key aspect in the IC process. Accordingly, the researchers assign a secondary function to the written explanation. The importance attributed to the oral explanation is in clear contradiction to the existing instructions that are largely silent for the oral sector.

Result 6: Organisation of the discussion for the IC explanation

The concept of the oral explanation, as illustrated in the interviews, is based on the asymmetric exchange of the required information. The oral IC explanation is conceived as a monologue. The organisation of the discussion in the sense of awareness of the object of the discussion, the role of the discussion and the discussion format appear unplanned in the mind of the researcher (“we simply do it”). The orientation to e.g. a list of key words with (common) topics for the discussion is absent. We assume therefore, that IC explanatory discussions generally avoid or gloss over the clarification of the purpose of the discussion, the notification of sub-topics and the explicit counselling to fully and clearly explain the point of view of the expert.

Recommendation 6: Establish quality standards for the oral IC explanation

At the present time, in the absence of instructions for the oral IC explanation, the researchers charged with the explanation have to draw on their own expertise. We recommend that minimum quality standards for the explanatory discussion be defined and that these standards are then taught: e.g. for moderating the discussion, structuring the content, and the transparency of the expert’s viewpoint.

3 Combining the oral and written explanation

In the literature relatively few investigations have been reported on the typical sequence for written and oral explanatory information and their effectiveness as required by HRA Art. 16 for the informed consent. However, there are strong indications that this combination - and in particular the possibility to be able to pose questions by referring to a written pre-information notice - is very effective for IC intelligibility. In order to improve the comprehension of persons with limited reading ability discussions have proved to be the most effective intervention (cf the overview of this in Tamariz et al. 2013).

In the current practice of the ethics committees the written part of the IC explanation is considered to be the legally binding section, whereas the oral IC explanation is entrusted to the individual competence of the researchers, who are involved in the explanation. The investigation of the researchers' concept of IC showed that they considered the oral part to be the absolute centre of the explanation.

Result 7: Oral-written intelligibility model for informed consent

In the current IC explanatory practice the written and oral explanations are carried out sequentially and are thereby split up. The ZHAW draft model envisages a more effective combination of oral and written explanation. The following repeatable textual actions (oral, written or their combination) are vital for the IC process: Framing by meta-explanations (procedural agenda items, framework concepts, obligation features); Clarification of participation in the research (information on sub-activities, summarising, illustrating); Questions (to address the topic of individual understanding); Answers (as a confirmation of the knowledge base); the mutual, dialogically arranged understanding (as a result of a repeatable IC process); the agreement or retraction (as the result of understanding).

Recommendation 7: Interlinking the oral and written IC explanations

The organisation of the Informed Consent procedure as an intended interlocking of oral and written explanations is important for the success of the IC communication: A timely and locationally staged organisation should be favoured. For example, announcing that questions can be posed at a later date encourages the involvement of the participants in the IC procedure (cf Quinn et al. 2012).

Customarily today the IC summaries are formulated in an abstract and considerably condensed manner. At the same time the IC explanatory discussions are based on an intuitive concept of knowledge transfer. We recommend that the existing attributions of functions for the oral and written explanations be revised:

- To bring the IC summary much closer to the oral explanation (e.g. question-answer structure).
- To use the IC summary to pre-structure the IC explanatory discussion in the sense of a selection of topics (agenda items).

At the level of the communication concept the oral and written explanatory parts can be integrated in this way in the meaning of the HRA regulation.