Framework for patient / participant representation in ethical review processes in clinical research

1. Introduction and background:

Ethics committees shall assess whether research projects and the conduct thereof comply with the ethical, legal and scientific requirements of national and international regulations and Swiss law, in particular the Human Research Act and its ordinances(1). In particular, they shall assess whether the protection of those, participating in these research projects, is guaranteed.

Ethics committees must be composed in such a way that they have the professional skills and experience required to fulfil their duties. The members must include experts in various disciplines, in particular medicine, ethics and law; and at least one person representing patients[1]. The need to better define the role of those persons representing patients and study participants in Ethics committees, resulted in drafting this framework.

The framework is in general based on previous work from EUPATI (EUPATI and Patients in Medicines Research and Development: Guidance for Patient Involvement in Ethical Review of Clinical Trials[2]) and was adapted to the Swiss context by a working group mandated by swissethics[3]. This working group proposes to broaden the scope and to represent not only patients, but any study participant. The framework therefore applies analogously to all participants in research projects.

The aim of this framework is providing a national standard for patient / study participant representation in ethical review processes, to be used and adapted for local Ethics Committee's (EC) purposes. After adoption, the framework will be periodically reviewed and revised, reflecting evolution and input from users.

The framework is based on the following values(2) as regards patients / participants

Relevance: they have knowledge, perspectives and experiences that are unique and contribute to ethical deliberations.

Fairness: they have the same rights to contribute to the ethical review of clinical trials as other stakeholders and have access to knowledge and experiences that enable effective engagement.

Equity: their involvement in the ethical review process contributes to equity by seeking to understand the specific needs of study participants with particular health issues, balanced against the requirements of industry and academic sponsors.

Capacity building: Patients / study participants involvement processes address barriers to involving them in ethical reviews and build capacity for them and ethics committees to work together.

[1] https://www.fedlex.admin.ch/eli/cc/2013/617/en
[2] https://pubmed.ncbi.nlm.nih.gov/30246010/
[3] swissethics working group for patient representation in Swiss ethical review processes in clinical research

2. Defining "patient" [(2)] and participant:

The term "patient" and "participant" does not reflect the different types of input and experience required from patients and participants in different collaborative processes. We therefore propose the following definitions. For this framework, we use "patient / participant representative" as an overarching term as appropriate.

"Individual Patients" are persons with personal experience of living with a disease. They may or may not have technical knowledge in research and development (R&D) or regulatory processes, but their main role is to contribute with their subjective disease and treatment experience.

"Carers" are persons supporting individual patients such as family members, as well as paid or volunteer helpers.

"**Patient Experts**" in addition to disease-specific expertise, have the technical knowledge in R&D and/or regulatory affairs through recognised/documented training or experience.

"**Participant**" those participating in clinical research are not always patients. Examples; early drug development trials recruiting healthy volunteers; vaccination / prevention studies etc. Their specific needs and rights need to be protected as well.

These definitions should guide the profile and related tasks of individual patient / participant representatives in ECs. Furthermore, different roles for patient / participant representatives in ECs are conceivable:

- Full member of an ethics committee with equal rights and obligations as all other members
- External peer reviewer giving advice to the ethics committee members before their review meeting

The individual role and profile of each patient / participant representative in an EC should whenever possible, be agreed on in advance.

3. General focus of patient / participant representation in ethical review processes in clinical research[(2)]:

The following list outlines, what patient / participant representatives should review as a priority (however, always depending on their individual profiles and local ECs needs).

- Assessment of the benefit/risk balance
- Fairness of inclusion and exclusion criteria
- Study participant burden
- Patient relevant clinical endpoints
- Suitability of participant liability coverage (insurance)
- Data protection measures
- Potential conflicts of interest

- Readability and acceptability of the informed consent documentation and study participant information material
- Avoidance of inducement, for example ensuring that participant fees or travel expenses are appropriate
- How patient organizations can contribute to the patient information and recruitment processes

4. Conditions for patient involvement in ECs[(2)]:

In addition to the above-mentioned, general aspects, the following specific conditions should be considered when involving patient representatives in ethical review processes in clinical research.

Furthermore, local / cantonal law and procedures always need to be considered. All conditions and aspects have to be adapted accordingly.

The resulting, individual conditions have to be negotiated with concerned patient representatives, as well as communicated to other local EC members, to ensure smooth and efficient collaboration.

4.1. Job Profile and/or Written Agreement ("the document")

To ensure clarity about the collaboration between ethics committees and patient / participant representatives, a job profile and/or written agreement may be agreed on as needed, containing a clear description of the role of the patient / participant representative in the ethical review process (see e.g. 3. General focus….).

As appropriate, following local circumstances, the document may specify the legal and regulatory conditions, working procedures, ground rules, and conflict resolution procedures, frequencies of interaction, mutual obligations including confidentiality, liability (insurance) protection, resource requirements, and timelines as well as the mechanism for payment/reimbursement of expenses and any other benefits.

4.2. Transparency

As with all members of an ethics committee, patient / participant representatives in ethics committees should ensure they are transparent about their own (and/or their patient organization's) professional interests and financial support and sign the same declaration of interest as the other ethics committee members.

4.3. Representativeness

Representativeness of the patient /participant representatives' advice is an important aspect for both the ethics committee and the group of patients / participants represented. This point should be addressed in advance and be mentioned in the job profile (see also 2. Defining "patient").

4.4. Appointment, Introduction, and Training

The appointment process and introduction of patient / participant representatives should follow the standard rules of the respective ethics committee. To support real involvement, patient / participant representatives should bring a basic knowledge and training in public health and clinical research (e.g.: https://dkf.unibas.ch/en/news/new-course-for-patient-experts/; https://eupati.eu/ etc.). Participating in the ethical review in an ethics committee is for many

patient / participant representatives a new experience. Debating with experts in their field might be intimidating and can lead to a lack of contributions: it is important that the mere presence of patient / participant representation is not seen as a given endorsement to committee decisions. A thorough introduction into the work of an EC member and continuous professional development initiatives is a prerequisite, even if their involvement focuses on specific tasks (e.g. as listed under 3. above).

4.5. Compensation

As mentioned, patient / participant representatives being full members of an ethics committee (with equal rights and obligations as all other members) should get the same compensation. However, some of them may be involved as experts in additional activities, not as part of their principal occupation. In this specific situation and following prior agreement, the following may apply, respecting existing guidance[4]:

• Compensate for time invested plus expenses (if not covered anyway).

• Help organize the logistics of patient representation as appropriate depending on the individual situation.

All parties should be transparent about any compensation arrangements.

5. Impact of, and feedback on patient / participant representation in ethical review processes in clinical research

Presidents of ECs and the swissethics steering board should be asked for feedback as regards their impression of the impact and added value of patient / participant representation in ethical review processes. Patient / participant representatives in Swiss ECs should exchange experience at least once a year, addressing major common issues they encounter as well as taking into account feedback from EC leadership / swissethics steering board.

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[4] https://www.scto.ch/en/patient-and-public-involvement/ppi-resources.html, SCTO Remuneration Policy for PPI Activities