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Council of Europe
Human Rights Policy and Development
The Committee on Bioethics (DH-BIO)
Secretariat General
dgl.consultation@coe.int

Ref. DG1/BIO/

**Issue WORKING DOCUMENT ON RESEARCH ON BIOLOGICAL MATERIALS
OF HUMAN ORIGIN**

National Committee on Medical Research Ethics (TUKIJA) is an independent agency on medical research ethics in Finland. TUKIJA's primary roles are to advise and coordinate regional ethics committees in matters of ethical principle related to medical research, and to issue opinions on the ethics of clinical drug trials unless this task is delegated to a regional ethics committee. TUKIJA's duty is also to evaluate the ethical acceptability of the establishment of the new biobanks in Finland. TUKIJA provides training on medical research issues, and acts as a "second-opinion" organ to applications which have previously received negative opinion from regional ethics committee.

TUKIJA is grateful for the opportunity to comment on working document on research on biological materials of human origin.

There are few issues TUKIJA would like to comment in more detail.

Article 3 part ii: TUKIJA is not certain whether "do not allow with reasonable efforts the identification of the persons" means the same as "anonymised". In TUKIJA's opinion it rather means hard-identifiable or difficult to identify than non-identifiable or anonymised. TUKIJA further encourages contemplating whether the concept of anonymisation is still relevant in modern scientific world where the means to identify practically any sample exist. Still, TUKIJA notes that some kind of protection is warranted even though anonymisation is no longer possible and, thus, TUKIJA finds the distinction of the article itself relevant.

Article 12 section 4: The proposal is to require a new consent of the person after the possible change in the capacity to give a consent, e.g. in case of minors. However the obligation to obtain a written informed consent may not be appropriate in all situations. In our opinion, individual participant can be respected also by providing him/her

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relevant information on the research project and by giving him/her a possibility to opt-out from the research project.

Article 13 section 3: TUKIJA is uneasy about the usage of anonymised biological materials for research. Besides the above mentioned restrictions about the term anonymised, TUKIJA feels that the possibility to use the so called anonymised materials for research does not adequately respect the wishes of the persons they were collected from. Hence, TUKIJA wants to raise the question whether data protection is enough to respect a person's autonomy or should it also require respect for the person's value choices. The right to live according to one's own values is very important feature of being a person, and it should not be offside by mere data protection.

Article 16 section 1: Based on TUKIJAs experience in issuing opinions on the research on biological materials, it seems not always feasible to storage biological materials in case one wishes to alter the scope of the consent. Therefore TUKIJA proposes to add "when feasible" or "when appropriate" in the first sentence, between the words "or" and "alter".

Article 19 section 1: TUKIJA does not see the point in submitting reports or summaries to the ethics committees since as a general rule the ethics committees do not oversee research practice. It is more evident that the report or summary of the results may be helpful to biobanks and it also needs to be published.

Article 21: TUKIJA finds the document a bit contradictory in that in some parts of it the persons cannot be identified and in others they can, for example, in this article. Section 2: TUKIJA supports that feedback should take place within a framework of health care or counselling. However, it is not clear what follows from it and how it is accommodated.

Article 23 section 2 is beautifully put but does not give much guidance of how it is achieved.

Yours sincerely,

Professor, chair

General Secretary


Heikki Ruskoaho


Outi Konttinen