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Issue **REVISION OF DECLARATION OF HELSINKI**

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 also 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 would like to thank for the possibility to comment on the new version of the DoH.

TUKIJA is pleased to note the structural changes of the text, which make the text easier to read. Most of the substantial amendments proposed by the workgroup are supportable. Especially important is the inclusion of the new paragraph 15 on adequate compensation in case of harm.

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

Para 11 and 21 last sentence: It is unclear why in a Declaration concerning human subjects there are provisions on environment and animals. These are important topics but not the core of the DoH. Therefore, we propose to delete these references, or, if this is not considered possible, for the sake of consistency of the text, to have them in the same paragraph. For example the last sentence from paragraph 21 could be transferred to paragraph 11, after which the text would read as follows: "Appropriate caution must be exercised in the conduct of medical research that may harm the environment. The welfare of the animals used for the research must be respected."

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Para 19: In our view, the strengthening of the protection of vulnerable people is very welcome. However, there might be some room for additional clarity in the proposed text. E.g. it is not clear what is meant by additional and greater harm. It can also be asked does the text limit unnecessarily the group of vulnerable research population if additional and greater harm is required in order to be included in this group. TUKIJA proposes therefore to add "may" to the first sentence: Some research populations are particularly vulnerable and may have an increased likelihood of incurring additional and greater harm.

Para 20: In our opinion, the last sentence raises some concerns. It is not clear what is meant by "a fair level of additional benefits"? Does this mean monetary compensation to the community of whose members have participated in the research? Or what kind of benefits does the text envisage? According to TUKIJA´s view it should be clear that any kind of additional benefits should be put into practice in an ethically sound way.

Para 22: The last words of this paragraph have been deleted. The reasoning of the amendments does not explain the deletion. The access to other appropriate care or benefits is not explicitly mentioned in the new paragraph 34 on post-trial access.

Para 23: TUKIJA supports the amendments on paragraph on Research Ethics Committees. However, the issue of transparency is somewhat unclear. What does transparency mean in this context? Public meetings? Public applications? Public minutes of the meetings of the REC? TUKIJA hopes this will be clarified in the final version.

Para 34: The first sentence of this paragraph requires that in advance of a clinical trial… host country governments should make provisions for post-trial access… In practice, government´s role may be e.g. in approving the level of reimbursement for the medicinal product. This cannot be evaluated prior to the clinical trial but only after the safety and efficiency of the medicinal product has been tested. Therefore, the mentioning of host country governments is somewhat odd in this context.

TUKIJA agrees that all study participants should be informed about the outcome of the study. The text is not clear on what kind of informing it stands for. Does the text mean individual information to each research subject? This may not be appropriate in all situations. It should be sufficient to make the outcome available e.g. on the website of the company or research institution.

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Para 37: In TUKIJA´s view it is of paramount importance to avoid situations where unproven interventions are used (deliberately) too broadly and for a too long time. The text should be very clear on the ethical principle that unproven interventions cannot be applied generally and for a long time to patients without conducting an appropriate medical research. The proposed text is a step to the right direction, but it could be even stricter and more precise. The use of unproven interventions should be limited by time and by the amount of patients. Therefore TUKIJA proposes to add the following text to the paragraph: Any systematic use of a particular unproven intervention to patients should be made the object of research without undue delay.

Yours sincerely,

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