Regional Medical Research Ethics Committee of Wellbeing Service County of North Savo 5.3.2024

Guidance for an Assessment on the Ethical Aspects of Research

(unofficial translation)

Background

This guidance describes the elements that should be included in an assessment on the ethical aspects of medical research. The Regional Medical Research Ethics Committee of Wellbeing Service County of North Savo ("the Committee") recommends preparing an assessment taking the guidelines into account.

The assessment must be attached to the application to the Committee to obtain an opinion on medical research under the Medical Research Act (488/1999, "Research Act").

The principal investigator acts as the responsible head of the team of investigators conducting medical research at the research site. If there is only one investigator in the research or at the research site, he or she acts also as the principal investigator. An assessment must be provided regarding the ethical aspects of the research, especially the appropriateness of its objectives and design, and of the assessment of risks and benefits. If a separate ethical assessment is missing, the application will not be processed.

Assessment

The assessment should include the date, the name of the sponsor/principal investigator, contact details and signature.

In the ethical assessment, considerations related to the research must be taken into account, including but not limited to the following:

Patient care-related studies

- It must be described how to make sure that the research subjects understand the difference between participation in the research and normal patient care.
- It is necessary to evaluate the balance between the potential benefits of the research to the harms and risks for the research subjects and society. Physical risks (e.g. procedures, side effects, pain), psychological harms and discomforts (worry, fear, uncertainty) and harms to everyday life (e.g. special diet, effects on normal life) must be taken into account in the assessment.
- If a placebo is used in a disease for which an effective treatment exists, the use of the placebo must be justified.
- The provision of care for the research subjects after the completion of the research must be described.
- If the research is emergency research (research according to section 10a of the Research Act), it must be demonstrated that the research subject’s involvement in the

research immediately benefits their health, whether the research is directly related to the research subject's illness, injury, or change in health condition, and why the research can only be conducted in emergency situations. It must be demonstrated that the risk and burden to the research subject from the research are very small compared to the standard treatment for the research subject's disease, injury, or health condition. Additionally, it must be clarified how the process of informed consent is implemented afterwards.

- If the research is emergency research (research according to section 10a of the Research Act), the following should be clarified:
    - whether there are scientifically justified reasons to assume that the research subject's participation in the research can direct benefit their health.
    - whether the research is directly related to the research subject's illness, injury, or change in health condition, making it impossible to provide information and obtain informed consent from the research subject or someone authorized to consent on their behalf.
    - whether the investigator is aware that the research subject or someone authorized to consent on the research subject's behalf has objected to participation in the research.
    - why the nature of the research is such that it can only be conducted in emergency situations.
    - that the risk and burden to the research subject from the research are very small compared to the standard treatment for the research subject's disease, injury, or health condition.

Additionally, it must be clarified how the process of informed consent is implemented afterwards.

Questions related to the informed consent process

- It must be described how the research subject's autonomy and voluntary participation are ensured during the recruitment of research subjects and obtaining informed consent (e.g. the opportunity to read the information sheet in peace, and talk with the investigator).
- If consent for the research is obtained remotely, it must be described how data protection and the identification of research subject are ensured, and how the information is provided to the research subject in a way that allows for discussion, including genuine opportunities for interaction, asking questions, and receiving answers, as well as how informed consent is documented.
- If the investigator or a member of the research team does not inform the research subject or obtain informed consent (e.g., research related to emergency care), it must be explained how the informed consent process is carried out.

Generally, informed consent to participate in the research should be in writing. The requirement for written consent can be waived in situations specified in section 6(2) of the Research Act, in which case the deviation must be justified in an assessment.
If the research is to be carried out as a cluster research, reasons for choosing the type of study must be presented and why informed consent is obtained using a simplified procedure, and the

extent of information given to the subject and the methods of informing must be described.

Justification for the use of vulnerable subjects in research

The Research Act sets specific requirements for studies involving research subjects with reduced decision-making capacity (i.e. incapacitated subjects), minors, pregnant or breastfeeding women, prisoners, forensic psychiatric patients. Sections 7-10 of the Research Act specify the specific conditions for each vulnerable subjects.

- The use of vulnerable subjects as research subjects must be justified (why the research cannot be conducted with other research subjects) and evaluated in terms of its relevance to the research subjects, whether participation in the research has immediate benefits for the research subjects' health, or whether participation in the research benefits the health of the population group in question, as well as whether the research is directly related to the research subjects' disability or illness.
- Additionally, attention must be paid to groups of individuals whose voluntariness may be questioned (e.g., conscripts, investigators' subordinates/students).
- It must be clarified how informed consent is obtained, who obtains it, and how the information is provided.
- If informed consent is obtained remotely, it is requested to explain how data protection of personal data is ensured.
- It must be clarified how research subjects belonging to vulnerable subject are consulted, how their will, wishes and interests are taken into account, and how their informed consent is documented.
- If the research subjects' decision-making capacity is reduced, it must be clarified how the research subject is consulted and provided with the information required by the Research Act in an understandable manner. Additionally, it must be clarified who gives informed consent on behalf of the research subject, how the eligibility for giving informed consent is determined, and how the research subject's expressed will and best interests are taken into account.
- If the research subjects are minors, it must be clarified how they are consulted and given the opportunity to give informed consent according to their age and level of development. Additionally, it must be clarified who gives informed consent on behalf of the minor and how the eligibility for giving informed consent is determined. Additionally, if necessary, it must be clarified how, when the minor research subject reaches the conditions for giving independent consent (age), he is told about his right to withdraw from research.

Aspects related to payments and compensation from sponsors

- The reasonableness of the payments and compensation provided by sponsors and other external funders must be evaluated.
- The impact of financial interests related to funding on the research must be assessed.

Use of radiation in research

- If ionizing or other potentially harmful radiation is used in the research, the use of radiation must be justified and its effects on the research subjects must be evaluated.

Ensuring data protection and processing of personal data

- The purpose and necessity of processing the collected personal data of research subject for the research must be justified.
- It must be described how the safety and rights of the research subjects are ensured in the processing and protection of personal data (including samples), as well as how the confidentiality, disclosure, and destruction of personal data are guaranteed.

Other ethical aspects related to the research

An overall view must be presented on how ethical aspects have been taken into account in the research and how potential ethical problems have been resolved.

Points to consider in the ethical assessment

- The qualifications of the principal investigator, investigators, and other research staff of the research.
- The necessity and significance of the research in terms of science, healthcare, or education.
- The appropriateness of the research, considering statistical aspects, the research design, and methods.
- The appropriateness of the assessment of benefits and risks and the justification for the conclusions drawn.
- The consent process and the material for informed consent.
- Why the research is conducted on vulnerable subjects, why it is emergency research or cluster research.
- The recruitment method of research subjects and its ethical considerations.
- Compensation provided to the research subjects, the amount, and the criteria for determining the compensation.
- The appropriateness of the facilities and equipment used in the research.
- Insurance coverage for the research subjects.

Other Considerations

- Whether the research hypothesis could be answered in another way.
- Whether the harm or inconvenience caused by the research is acceptable in relation to the knowledge gained from the research.
- Whether the resources used for the research are acceptable in relation to the benefits obtained from the research.
- Justification for the sample size.