What does the Regional Medical Research Ethics Committee pay attention to when evaluating applications for an opinion

(unofficial translation)

The guide is intended as a checklist for investigators and members of the Regional Medical Research Ethics Committee. Where applicable, it can be used in preparing and/or evaluating an application for an opinion.

Research Plan

1. Scientific value and validity of the clinical research
   - whether the investigation is scientifically/clinically necessary; whether a scientific question raised is justified
   - previous studies and the significance of the results obtained from them in terms of current research, does the investigator demonstrate familiarity with previous literature
   - whether the primary and secondary outcome variables are valid for assessing clinical effectiveness
   - whether the methods are appropriate
   - whether the investigation can provide an answer to the scientific question presented
   - the sample size and evaluation methods of the clinical research
   - statistical methods used in the research
   - research design with justification (possible placebo comparison or other comparison group use, randomization, blinding, etc.)
   - the research schedule and its eligibility for implementation in relation to resources

2. Selection criteria for the research subjects
   - the main selection and exclusion criteria of the research subjects
   - the appropriateness of the selection criteria
   - justifications for the inclusion of vulnerable populations (incapacitated subjects (i.e. subjects with reduced decision-making capacity), minors, pregnant or breastfeeding women, prisoners, forensic psychiatric patients)
   - recruitment procedures (e.g. newspaper advertisements, contacting the attending physician, use of social media)

3. Description of the informed consect process
   - how to ensure that the research subject can give voluntary, knowledge-based consent to the investigation
   - consent procedures for vulnerable populations

4. Research implementation, quality assurance and publication
   - description of the implementation of the research and related measures, use of biological samples (genetic studies in particular)
   - monitoring of adverse events and reporting of adverse effects
   - research monitoring plan
   - principles of publication of research results
   - transparency and possible future use of research materials

5. Analytical methods and their validation

6. Assessment of benefits and risks
   - expected health benefits/harms and risks for research subjects and their estimated probability (physical and psychological risks and practical harms)
   - burden caused by laboratory and/or imaging studies
   - risks and discomforts related to the investigational treatment and the placebo
   - monitoring of side effects
   - ensuring the safety of the research subjects after the research
   - preparing for unexpected risks
   - consideration and treatment of clinically significant coincidental findings in the research

7. Data confidentiality, material management plan
   - the necessity and sources of information to be collected in the research
   - data processing (including who processes sensitive data), storage and disposal
   - coding of data and storage of the code key
   - the right to information of the research subjects
   - the principles to be followed in the disclosure and transfer of data

8. Financial aspects: compensation for the investigators and other research personnel and insurance cover for the research subject, compensation, and any acknowledgement for the research subject

9. Research staff and research location
   - the qualifications of the person responsible for the research and the research site (training, experience, field of specialization, investigator's curriculum vitae)
   - affiliations of investigators and their declaration
   - appropriateness of research site instruments and equipment, complication and emergency preparedness, storage, and handling of dangerous substances

Information and informed consent form

See models and guidelines of Regional Medical Research Ethics Committee of North Savo web-pages.

Ethical evaluation

The principal investigator and investigator must be professionally and scientifically qualified and familiar with the research in question, and ready to take responsibility for the performance of the research to the extent required by the Medical Research Act. The ethical evaluation must present an overall view of how ethical aspects have been considered in the research and how potential ethical problems have been resolved. Where applicable, the following should be taken into account:

1. Necessity and justification of the research (benefit-risk analysis)
   - the risks associated with research and how to take them into account in research
   - compliance with current treatment recommendations in the research
   - suitability of research methods
   - justification for the research setting

2. Form, content, scope, and comprehensibility of knowledge-based consent
   - especially vulnerable population whose request for research may be ethically questionable (e.g. those related to disability, vulnerability, or limited voluntariness reasons)

3. Data protection and processing of personal data
   - the necessity of the data to be collected in terms of the research
   - processing of personal data and samples

4. Emergency and complication preparedness, other factors related to the safety of research subjects

5. Questions related to the financial resources of research and the compensation of investigators and other research personnel

6. Other ethical concerns related to the research

Other material to be given to the research subject

All material given to the research subjects must be submitted to the committee for evaluation, incl. questionnaires and diaries.

Recruitment announcement

Information about the research for the research subjects.

Bulletin of research staff / staff to be recruited

Instructions for the research personnel regarding the conduct of the research.

More information on preparing a research plan:

http://www.spirit-statement.org/