Guidelines for the AU Research Ethics Committee

Background

The background to the formation of the AU Research Ethics Committee is that researchers are increasingly required to obtain ethical approval for projects not regulated by the law on Research Ethics Review of Health Research Projects (Consolidated Act no. 1083 of 15 September 2017) from the relevant university department. This requirement is imposed by, for example, international journals and the EU’s framework programme for research (EU Regulation 1291/2013, EU Regulation 1290/2013 and H2020 Grant Agreement, article 34), and the EU recommends a central interdisciplinary approval committee. The AU Research Ethics Committee will ensure a professional, consistent and responsible framework for the approval of these projects and make it easier for AU researchers to obtain EU grants and publish.

Purpose

- The AU Research Ethics Committee (hereinafter ‘the Committee’) is a service provided to AU researchers whose projects are required, by funders or journals, to document ethical approval, but which are not regulated by the regional research ethics committees.
- The Committee shall ensure that research conducted at AU complies with the university’s guidelines for responsible conduct of research, and with the Helsinki Declaration and other research ethics guidelines relevant to the project in question, e.g. the American Psychological Association's (APA) code of conduct regarding the handling of study participants.

Projects assessed (limitations)

- The Committee exclusively approves projects requiring ethical approval which fall outside of the existing research ethics committee system, and which are headed by researchers employed at AU.
- The Committee only approves empirical projects that collect data from volunteer study participants, including observation studies and questionnaire-based studies that involve the collection of data from individuals.

Composition of the Committee

The Committee has nine members: eight ordinary members and one chair. The deans appoint two ordinary members, each based on the recommendations of the Academic Council. The chair is appointed by the rector and must have a legal background. The Committee members are appointed for a term of three years. The Committee constitutes a quorum when five of its members are present. In cases where the Committee requires a more detailed understanding of the scientific characteristics of a project, it may seek the support of an independent researcher with insight into the project methodologies.

Specific tasks

Based on descriptions of the studies planned, the Committee assesses the studies on the basis of the following three considerations.

1) Informed consent:

The study subjects’ participation in research projects must take place on the background of informed consent. The informed consent should include the following information:
• The name of the primary investigator
• The purpose of the research project
• The research project’s funding sources
• The process for recruiting study participants
• The methodology/methodologies of the research project
• Expected risks/adverse effects
• Who will benefit from the results of the research project
• How the project results will be communicated (including participant feedback)
• How personal data will be protected
• Opportunities for leaving the study
• Opportunities to view and, if applicable, comment on transcriptions of interviews and quotes, if relevant
• Debriefing opportunities, if relevant

2) **Purpose and risks:**

The purpose declaration must demonstrate that the beneficial outcome of the project is balanced against the human resources involved in the project and the risks/adverse effects that they may be exposed to in connection with recruitment, study and reporting. The declaration must also demonstrate that the social group represented by the study participants will benefit from the outcome of the project.

3) **Anonymised data collection and publication:**

Methods for the anonymisation of data and publication of results must be outlined in the project description.

**Approval process and authority**

The Committee should make every effort to meet six times a year. The Committee’s administrative support staff will notify the responsible researcher of the assessment outcome as soon as the project has been reviewed by the Committee. The Committee must draft a statement explaining the grounds for approval/rejection. The Committee may grant conditional approval in cases in which additional information is required in order to be able to grant final approval.

The Committee is not responsible for ensuring that individual projects comply with research ethics or data protection regulations. Responsibility for this lies with the researcher/researcher group in question. Nor is the Committee authorised to stop a project from being conducted. However, it may advise that projects that do not comply with AU’s guidelines, or which have not applied for the requisite approval, be stopped.

Projects that are approved will be awarded an approval number, and the researcher may elect to state in a later publication that: "the project was approved by the Institutional Review Board at Aarhus University, approval #: [approval number]."

**Appeals procedure**

Researchers whose applications for approval are rejected may contact the Committee to submit an appeal, stating the grounds for appeal, within 14 days of receiving notification of the application’s rejection. The Committee will then reassess the application.

**Reporting**
The Committee must prepare an annual report on the applications processed for the AU Committee for Research and External Cooperation and for the senior management team.