Guidelines for the Local Ethical Evaluation of Human Medical Research with US Federal Funding (translated version)

No. 1-309/2021

Valid from 2021-03-23

Diarienummer: 1-309/2021	**Dnr för föregående version:** -	**Beslutsdatum:** 2021-03-23	**Giltighetstid:** Fr.o.m. och tills vidare
Beslut: Rektor		**Dokumenttyp:** Riktlinjer	
Handläggs av avdelning/enhet: Avdelningen för forskarstöd		**Beredning med:** Vetenskapligt ombud och juridiska avdelningen	
Revidering med avseende på: Nytt styrdokument			

Introduction

For research projects with humans that are financed by American funders, and for which the provisions of "the Federal Policy for the Protection of Human Subjects" ("Common rule") apply, an organizational Federal Wide Assurance (FWA) is required. To be able to apply for an FWA at the Office for Human Research Protections (OHRP), United States Department of Health and Human Services (HHS), it requires that the project has been evaluated by a local ethics review body at Karolinska Institutet (internal review board, IRB).

Affected research projects will, as before, need ethics approval according to Swedish legislation before the research begins, but now there will also be an internal review process by the local body.

Purpose

The guidelines are aimed at all those who participate in human research projects with US federal funding that are regulated according to the "Common rule" and which thus require a local ethics assessment and where, more specifically, the regulation of human research according to the U.S. Code of Federal Regulations (CFR) Title 45 (public welfare), part 46 (protection of human subjects) (45 CFR part 46).

The review must ensure that no projects start without ethics approval and that the projects also comply with relevant requirements in 45 CFR part 46.

Committee for review

At KI, there must be a Committee for ethical evaluation of medical human research with US federal funding. The committee shall consist of at least five (5) members with broad scientific competence and integrity of which;

- at least one (1) member must focus on scientific issues and at least one (1) member must focus on non-scientific issues;
- at least one (1) member must be external and must not be a (close) family member of any employee at or affiliated with KI; and
- it must not consist only of men or only of women.

No conflicts of interest must occur. The person who is in a bad mood may not participate in the handling of the case.

The president appoints the members, one of whom is the chairman, of the Committee for a period of three years at a time.

The committee must be assisted by an administrator appointed by the head of the department for research support (RSO).

The committee must meet/convenes at least four times per semester and minutes must be kept of the meetings.

Review process

A project must be reviewed before the project starts. In the future, according to the American rules, an annual review must be carried out.

Initial/Introductory review

Before the start of the project, the researcher in charge sends in a completed form for the initial review prepared for the purpose to the Committee at compliance@ki.se.

The following must be attached to the form:
complete ethics application and approval, including any amendments
copy of research application or Statement of Work (SoW)

- The committee reviews the documentation and, if necessary, obtains additional information from the responsible researcher.
- The committee reviews and decides whether the review is approved or not.

Annual review

Prior to the annual review, which usually takes place in connection with the renewal of the annual agreements, the responsible researcher sends in a completed form for the annual review prepared for the purpose to the Committee at the address compliance@ki.se.

- The committee reviews the documentation and, if necessary, obtains additional information from the responsible researcher.
- The committee decides whether the annual review is approved or not, which is reflected in a certificate in English signed by the chairman of the committee.

Reporting

Unapproved projects are reported by the manager of the Committee to the financier.

Changes in the Committee's composition are reported by the Committee's administrator to OHRP, HHS.

Responsibility

The responsible researcher is responsible for submitting documentation to the Committee before the start of the project and that the relevant research is not started before the Committee has given its approval. Deviations from the project plan and/or ethics permit must be reported to the Committee.

The committee issues a certificate of approved research project in English. The chairman signs the certificate.

The university administration, via the RSO, is responsible for keeping the IRB registration of the Committee up to date with OHRP, HHS, and for notifying the concerned funder of unapproved projects if necessary. The RSO sends a copy of the signed certificate to the responsible researcher and, if necessary, to the prime/pass-through-entity (PTE).