| Procedure description 02 | Page: | 1 of 6 |
|---|---|---|
| | Version: | 3 |
| | Valid from: | 15.10.2014 |

**Responsibilities and tasks of the Principal Investigator (Project Manager), pursuant to the Health Research Act**

Translated at Biotechnology Centre of Oslo / Centre for Molecular Medicine Norway 5.12.12

**MEDICAL AND HEALTH RESEARCH**
Research activity conducted using scientific methodology to generate new knowledge about health and disease.

**PRINCIPAL INVESTIGATOR (PROJECT MANAGER)**
A physical person who is responsible for the day-to-day operation of the research project, and who has the necessary research qualifications and experience to be able to fulfill the Principal Investigators' duties pursuant to the Health Research Act.

## 1. Purpose

The purpose of this procedure is to ensure that research projects are planned, organized, initiated, implemented and completed, including management both during and after completion and mediation of the results, appropriately and in accordance with applicable law, including a sound internal evaluation and determination of which legislation applies. Furthermore, the procedure must ensure that necessary agreements, notifications and approvals are in place before the project starts and that these are adhered to throughout the project period up to reporting and, in the event of any publication.

## 2. Scope

This procedure applies to all research at UiO covered by the Health Research Act and which should be conducted in accordance with the UiO's quality system. It must be correlated to other legislation which may apply to medical and health research, cf. Chapter 5 of this procedure. Clinical trials of medicinal products and / or medical devices are subjected to special procedures. Cf. Procedure Description 3 and 4.
Health research conducted in collaboration with other institutions may be conducted in accordance with the other institution`s QA system if so agreed in international, collaborative or project agreements.

## 3. Responsibilities

**The Principal Investigator is responsible for:**

- preparing a project description
- carrying out an independent assessment of the project's soundness and feasibility
- presenting the project to the representative of the institution or person responsible for research ("forskningsansvarlige"), in accordance with the unit's procedures and UiO's routines for submission of external funding, when relevant.
- obtaining the necessary external approvals
- posting in Clinicaltrials.gov if required
- the daily operation of the research project
- communication with the representative of the institution or person responsible for research at the unit
- communication with public authorities
- carrying out the research in accordance with approved conditions
- ensuring that the project participants give informed consent
- ensuring that amendments in the research protocol are approved before implementation.
- appropriate delegation of tasks within the research team
- ensuring research data are processed and stored according to UiO procedures
- archiving of project documentation according to UiO procedures
- monitoring of the project's finances according to UiO procedures
- making sure that the project participants are insured
- providing information to research subject if harm is inflicted or complications occur
- notification of adverse medical events according to UiO procedures
- a final report and any reports to REK (Regional Committees for Medical and Health Research Ethics)

Cf. Appendix 2.1 Form for project planning

## 4. Description of tasks

### 4.1. Clarification of responsibility in collaborative projects

In collaborative projects with other institutions, the research responsibilities must be agreed upon in advance and a written consent must be obtained before the project is initiated. The institution or person responsible for research and the Principal Investigator shall be named in the Project Agreement. The Principal Investigator must have the necessary research competence and experience for the current project. Students with a lower degree than PhD may not be Principal Investigators.

A multicentre study has one single Principal Investigator, but several institutions responsible for research.

**4.2. Internal presentation of project**
Before initiation of the project, it must be presented to the representative of the institution or person responsible for research, in accordance with the procedures at the faculty / department / unit and UiO's routines for presentation of projects with external funding, when this is relevant. This presentation and the evaluation from the representative of the institution or person responsible for research must be documented (c.f. Appendix 2.1 *Form for project planning)*, and **records of the projects must be continuously updated**.
The assessment must include the following:

- Principal Investigator's qualifications
- Resources
- Compliance with the unit's research strategy
- Review of the Principal Investigator's independent justifiability-assessment, see section 4.3

**4.3. Principal Investigator's assessment of soundness/ justifiability**
Before the project is submitted to REK and any other authorities for approval, the Principal Investigator must make an independent assessment of whether the ethical, medical, health, scientific, privacy- and information security issues are taken care of in the project. Similar evaluation should be made continuously during project implementation, particularly when considering amendments of plans.

**4.4. Principal Investigator's delegation of tasks**
Tasks to be performed in the project can be delegated from the Principal Investigator to the research team. Each member of the project team must have qualifications relevant to the tasks he / she has been delegated. The Principal Investigator cannot delegate his own assessment of the project's soundness.

**4.5. Preparation of research protocol**
The research protocol with attachments must be prepared in accordance with *Appendix 2.2 Checklist research protocol.* All documents must have version control, i.e., the version number and dates. Where governmental authorities accept the project description in an application-form or a copy of another application to replace the protocol, the preparation of a separate research protocol can be omitted.

### 4.6. Application for approval from public authorities

Before the project is commenced, the necessary authorization must be obtained from the REK. Applications for approval must be complete and accompanied by the final, signed version of the research protocol and a final, updated version of other attachments.

### 4.7. Registration in Clinicaltrials.gov

After the project is approved by REK and any other external authorities, it must be considered whether there is a requirement for registration of the project in the international database Clinicaltrials.gov. Such registration may be a prerequisite for future publication.

### 4.8. Information and obtaining consent

All research participants must receive information about the research project and be asked about consent for participation in accordance with the approval from REK, unless otherwise is provided by law. Information and consent must be prepared in accordance with the template from REK. Cf. Appendix 2.3 *REK's template for information and consent.* Where consent is required, this should be documented with the date and signature of the research subject who also must receive a copy of the signed consent. In the event of any changes in the project's implementation or utilization of data, one should consider acquiring a new consent. New consent must be obtained if these changes are likely to affect the research subjects' consent. New consent must be submitted to REK along with the changed proposal (ref. Section 4.9) and must be approved by REK before being utilized.

In cases of research on human biological material or health information, one may acquire consent for more broadly defined research purposes, if this is approved by REK.

Research subjects have the right to access their personal data. Research subjects who have given broad consent are entitled to information at regular intervals about the project from the Principal Investigator.

### 4.9. Seeking approval of planned amendments

In accordance with Appendix 2.4 REK's procedures for project amendments with checklist, any changes made to the research plan may require new approval from the same authority that gave its preapproval. The amendments must be approved before being implemented. It may also be necessary to inform the representative of the institution responsible for research

about the amendments if this is part of the regular procedures of the department / group. You will find an overview of the type of amendments that require new approval on REK's website: http://helseforskning.etikkom.no/ikbViewer/page/reglerogrutiner/endringograpport?p_dim=35021&_ikbLanguageCode=us

**4.10. Information**

The Principal Investigator must establish a subject identity list for research subjects who have given consent to participation in the research project. The subject identity list contains unique personal identification connected to the serial number / research subjects numbers in trials, look at Procedure Description 6 *Storage and processing of research data*, Appendix 6.3 *Form for subject identity list*. According to *Procedure Description 6 Storage and Processing of Research Data*, sensitive research data such as the subject identity list and all other documents containing names or other personal information about the research subjects, such as consent forms and source documentation (raw data), must be stored in UiO's *Services for sensitive data (Tjenester for sensitive data – TSD)*. On the registration form and other documents given from Principal Investigator for internal or external data processing, the research subjects should only be identified by serial number / research subject`s number.

**4.11. Submission of final reports and other reports**

The final report must be sent to REK as soon as the project results are available.

**4.12. Filing of project documentation**

In accordance with Appendix 2.5 *Checklist for filing project documentation*, key project documents must be filed in a an appropriate manner while the project is running, in a way that serves completion of the project. After completion of the project, the documentation should be filed collectively, in formats and locations as prescribed by department procedures. For storage of research data, please confer Procedure Description 6 *Storage and Handling of Data (Information Security).*

**4.13 • Notification of adverse events**

Adverse events must be documented by the Project Manager/Principal Investigator in Appendix 2.6 *Form for reporting adverse events*. If the project manager considers the incident to be serious, a completed form must be submitted to the Health Inspectorate (Helsetilsynet) within five (5) working days. A copy of the letter must be sent to the representative of the institution responsible for research.

### 4.14. Information to participants/subjects in the event of injuries

If harm is inflicted on a research subject or a complication has occurred that may have been caused by the research project, the Principal Investigator must immediately inform the research subject of the harm and his/her rights to seek redress/ claim damages. Furthermore, the representative of the institution responsible for research must be informed immediately.

## 5. Legal basis

| | |
|---|---|
| ACT 2oo8-o6-44 to 2o | Act on medical and health research (Health Research Act) REG |
| 2009-07-01-955 | Regulations of the organization of medical and health research |
| ACT 2000-04-14-31 | Act relating to the processing of personal data (Personal Data Act) |
| REG 2000-12-15-1265 | Personal Data Regulations |
| ACT-2003-12-05-100 | Biotechnology Law |
| ACT-2001-05-18-24 | Personal Health Data Filing System Act |
| ACT-2001-o6-15-53 | Patient Injury Act |

## 6. Appendix

Appendix 2.1 Forms for project planning
Appendix 2.2 Checklist research protocol
Appendix 2.3 REK templates for information and consent
Appendix 2.4 REK's procedures for project amendments with checklist
Appendix 2.5 Checklist for archiving of project documentation
Appendix 2.6 Form for notification of adverse events
Appendix 6.3 Form for key connector and a list of research participants
Look at Procedure Description 6

See also UiO templates for contracts