

Mal for samarbeidsavtale i forskning - engelsk versjon

Gjelder for: Hele SiV
Dokumenttype: []
Sist endret: 14.10.2024

Agreement

between

<Institution>

and

<Institution>

Regarding the research project:

<Title>

Name of Party and Name of Party may be referred to herein individually as a “Party” or collectively as the “Parties.”

1. Purpose

This agreement (“this Agreement”) regulates the responsibilities of the involved Parties. This includes the roles and the rights of the Parties, regarding the implementation of research projects in accordance with the research protocol, (see appendix 1) in this Agreement (hereafter referred to as “the study”). A copy of the REC approval (Regional Ethical Committee in Norway) and other mandatory approvals have been presented and are included in this agreement (see appendix X, Y).

This agreement shall ensure that the study is conducted and documented in accordance with relevant legislation and recognized ethical norms for good and reliable research.

The Parties have an independent responsibility for organizing and executing the part of the study that falls within their own institution, and that this is done in accordance with relevant legislation and based upon formal approval.

If the study is funded by external funding sources, the Parties have jointly a responsibility to ensure that the funds are used and reported in accordance with the current guidelines and conditions set by the external sources.

2. Contact information

Name of the Chief Investigator (CI): <Name and affiliated institution>

Contact information: <adresse, telephone no., e-mail>

Local responsible Principal Investigator (PI): <Name and affiliated institution>

Contact information: <adresse, telephone no., e-mail>

3. Chief investigators responsibilities

The chief investigator has the daily responsibility for overseeing the project. The chief investigator is also responsible for fulfilling the conditions in this agreement.

The chief investigator has the responsibility for making sure that the local responsible PI's within the project, has access to the latest version of the study protocol, consent forms and other important documentation and approvals.

The chief investigator must facilitate a good organization and flow of information between the participating institutions via the locally responsible PI's. A project meeting/coordinating plan should be drafted if this is considered necessary.

4. The responsibilities of the local responsible PI

The local responsible PI has the daily responsibility for overseeing the project within their affiliated institution and make sure that the study is conducted within this agreement, including the appendix. The local responsible PI also has a responsibility of abiding by local internal routines within their institution.

The locally responsible PI is required to report any discrepancies or unwanted adverse medical events or medical side effects. This is in accordance with section 10 of this agreement and in accordance with relevant legislation.

5. Data management and data access

Personal data collected for the purpose of the Study shall be processed in accordance with all relevant rules and regulations, decisions by public bodies, the Study protocol, this Agreement, as well as the informed consent of the research subjects to the extent that the Study relies upon participant consent.

The responsibility for ensuring that the data processing has a legal basis lies with the data controller. Any data controller confirms, upon the conclusion of this Collaboration Agreement, that the Study's legal basis for processing has been considered sufficient. There is also a requirement that the data controller perform similar assessment for the technical solutions that will be used for the collection of personal and health information.

The Parties are responsible for ensuring that all processing of research data (health information and human biological material) that will takes place in their own institution is carried out in accordance

with the purpose, legal basis for processing, REK approval with associated approved research protocol, and other applicable regulations, including the GDPR.

Transfers of research data between the Parties shall be regulated separately in a separate agreement.

At the end of the project period, each of the Parties has an independent responsibility for ensuring that research data in their possession under this Collaboration Agreement, are handled in accordance with the legal basis for processing, REK approval with the associated approved research protocol, and other applicable regulations, including the Privacy Regulation.

If one of the Parties becomes aware of a breach of the security of personal data as defined in Art. 4 No. 12 of the GDPR, that Party must immediately inform the other Party. The Parties agree to cooperate to ensure that breaches of personal data security are followed up and that the notification obligation in Art. 33 and 34 in GDPR are taken care of.

7. Finances

The Parties are required to work out a budget plan for the research study. The budget plan must address the finance plan of the study, which costs will apply and in what way income and costs will be divided between the Parties. The budget plan is part of this agreement.

If the study is partly/fully externally funded and there exists a payment plan between the Parties, then both Parties are responsible for making sure that the funds are used and that the results from the study are administered in accordance with the guidelines (or agreements) that follow the funds.

The Party that is responsible towards the funding body also has the main responsibility for managing the fundings and for ensuring that necessary internal routines are set up in order to report on the projects academic and administrative progress to the funding body.

8. Publication

The Parties involved in this agreement shall secure openness regarding the research project. Both positive and negative research results from the study must be published. The Parties may agree upon making a plan for publication based upon the criteria set by the latest version of the Vancouver convention on co-authorship on scientific publications.

Unless otherwise is stated, the Parties have the right to publish results from data collected within their institution unless such a publication will damaged or in other ways weaken the potential presentation of the other involved Parties' results, or where such a publication will weaken the scientific fundament of the study significantly, see the Agreements paragraph 9.

9. Ownership of the research results

Results are owned by the Party that generates them.

The Parties own results jointly if they have jointly generated them and it is not possible to establish the respective contribution of each Party, or separate them for the purpose of applying for, obtaining or maintaining their protection.

All involved Parties have the right to commercially take advantage of their own research results. If the results have been produced in collaboration, then an agreement must be made stating which of the Parties is in charge of ensuring the commercial utilization - including the distribution of rights.

Any Party, who wants to commercialize the research results by applying for patenting, may ask to postpone the publications for a maximum of 90 days.

10. Processing of discrepancies

Any unwanted adverse medical events or serious side effects must be reported to the Chief Investigator without delay.

11. Duration and survival clauses

This agreement is valid from the date of the last signature, and the duration of the agreement runs until the research study has ended. After the study end date – sections 8 and 9 in this agreement are still valid between the involved Parties.

12. Legal matters

The involved Parties rights and obligations in this agreement are based upon Norwegian law. Any legal disputes from this agreement will be settled in court. Oslo District Court is set as the legal venue.

13. Signature

This agreement is signed on 2 –two- copies, and each Party keeps 1 –one- copy.

On behalf of <Institution>

On behalf of <Institution>

<Responsible person>

<Responsible person>

