Oslo universitetssykehus

Oslo University Hospital HF

Mail adress:
Section for Research Administration
Ulleval Hospital
P.O Box 4956 Nydalen
0420 Oslo
Norway

Switchboard:
02770

Org.nr:
NO 993 467 049 MVA

www.oslo-universitetssykehus.no

Principles and guidelines regarding regulations of rights and publishing in study agreements between OUS and Pharmaceutical Industry

General Principles

- The ownership to background IPR, Know how and materials brought into the Clinical Trial by a party shall rest with that party.

- The Hospital recognizes the Sponsors rights to ownership regarding data, material and results directly resulting from the Clinical Trial according to the Trial protocol.

- The parties shall declare obligations to publish the results of the Clinical Trial in accordance to the Norwegian Health Research Act and Helsinki declaration. Any regulations regarding publication in the Trial agreement shall be based on the Helsinki declaration, including ICMJE`s Ethical Considerations in the Conduct and Report of Research: Authorship and Contribution (Vancouver Convention).

Guidelines for Trial agreement

General

- A clear, defined point of departure where rights and duties commence

- A clear and defined point of termination of the study related to when the study (or the actual branch of the study) database is closed and all agreed data are received and accepted received by the sponsor. .

Intellectual Property Rights (IPR)

- The Hospital recognizes the Sponsors right to commercial utilization all IPR resulting from the Clinical Trial according to the protocol.

- If needed the Hospital and Investigator shall assist the Sponsor with necessary documentation or other necessary acts in order to secure proper protection of IPR resulting from the Clinical Trial. In such case the Hospital shall be duly compensated.

- If requested the Hospital will give the Sponsor right to negotiate to ownership to its own background IPR that reasonably is related to a Clinical Trial and the materials used herein, on commercial terms and based on separate agreements.

- Neither the study agreement nor the Sponsors ownership to resulting IPR shall hinder the Hospital from using know how gained during the performance of the Clinical Trial in the furtherance of its normal activities. Restrictions of such use are only acceptable to hinder disclosure or misuse of Confidential Information or the infringement of any resulting IPR related to the Clinical Trial.

Publication

- The Sponsor shall recognise that the Hospital and Investigator have a responsibility under the Norwegian Research Act to ensure that results of scientific interest arising from the Clinical Trial are appropriately published and disseminated.

- In multicenter studies the Hospital in general accepts that publication of own results shall not be made before the first multicenter publication.

- In other studies, the Hospital generally accepts the Sponsors right to have reasonable time for reviewing the trial data, and the Sponsor's right to direct publication accordingly.

- The Hospital recognizes the Sponsors right to review and comment on a publication before it`s being submitted to the journal. In such case the Sponsor will be given up to maximum 30 days to respond. Further delay of publishing can be agreed for reasons like the Sponsor's protection of IPR resulting from the Clinical Trial, or other matters related to confidentiality.

Survival of Clauses (issues related to rights and publication)

-All background received by one party from the other party, that specifically or reasonably fall under the confidentiality clauses of the agreement

- All agreed rights related to use of results arising from the trial according to the protocol.

- All matters agreed between the parties related to regulation of publishing

- All matters agreed between the parties related to rights to negotiate utilisation of results that are reasonable related to the study, but not resulting from the Clinical Trial according to the protocol

19.12.2014

Kristin Bjordal
Director, Research Support Services
Oslo University Hospital HF