



ETHICAL REVIEW FOR BIOBANK-BASED RESEARCH PROJECTS: TOWARDS A RISK-BASED ETHICAL REVIEW

FEBRUARY, 20, PLATEFORME MALADIES RARES, 96 RUE DIDOT, 75014 PARIS

RD-CONNECT, EURORDIS, BBMRI-ERIC, UPPSALA UNIVERSITY

The growing complexity in the use of existing data highlights some gaps in the Ethical Review model currently in use across Europe. Reports from scientists highlight that the typology of reviews and constraints applied throughout Europe are highly uneven.

Research using human data and samples should occur under ethical scrutiny. The general rule is applied unevenly across borders and even across institutions. While some Review Ethical Committees (REC) apply strict constraints for primary and secondary uses of data and samples by binding possible projects to strict and specific consent, others do not apply the same rules to primary and secondary studies. In certain instances, if data and samples are used for secondary studies, no ethical review is performed at all. There is a compelling need to push the conversation towards agreed standards and minimal requirements.

In light of the new GDPR and the upcoming new legislation in the US replacing the Common Rule, this consensus conference organized jointly by Uppsala University, BBMRI ERIC, EURORDIS-Rare Diseases Europe, and RD-Connect, building on existing work, aims at bringing together different stakeholders and experts in order to collect good practices and provide input to the Rare Diseases Research Community.

Lunch and coffee breaks will be provided.

Program

<i>09.45-10.00</i>	Welcome and introduction: (Mats Hansson)
<i>10.00-10.30</i>	Overview: Is ethical review required for secondary use of data and samples? (Deborah Mascalzoni)
<i>10.30-11.00</i>	Coffee Break
<i>11.00-11.45</i>	History of risk-based ethical review and the US model for risk-based review and ethical considerations (Berge Solberg)
<i>11.45-12.15</i>	Patient perspective on ethical review for secondary use (Virginie Bros Facer)
<i>12.15-12.45</i>	Panel discussion (all speakers with questions from the participants)
<i>12.45-13.45</i>	Lunch
<i>13.45-15.00</i>	Group discussion: towards minimal requirements for ethical review
<i>15.00-16.00</i>	Report to the bigger group and discussion
<i>16.00-16.30</i>	Wrap-up session

Obligatory to register! No fee

Registration page: <http://www.crb.uu.se/ethical-review>

