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Biobank perspectives

current issues in biobank ethics and law



ELSI Helpdesk: What does it do?

The organisation of the ELSI Helpdesk is coordinated by the Swedish node. It gathers input from various sources and collaboration is ensured with other ELSI experts from the national nodes from the BBMRI-ERIC member states. LL.D. Moa Kindström Dahlin is the Chief Responsible Officer. Here, she offers her thoughts on the process of setting up a federated Helpdesk.

BBMRI-ERIC PROVIDES support on ethical, legal and societal issues related to biobanking activities through its Common Service ELSI. Among other things, the ELSI-group is offering practical interpretation on new legislation. It also monitors relevant ethical and legal frameworks in development and communicates publications, research results, surveys, and informs about relevant meetings. We are also setting up a federated Helpdesk. The vision and aim is to make the Helpdesk available, feasible, practical, usable, reliable, verifiable and sustainable.

THIS HELPDESK WILL provide general information on topics that are crucial for biobanking, regarding for example consent, ethics approval and data protection. It will also offer customized help. The practical tools to help provide this service are currently under development together with IT experts.

OFFERING THIS SERVICE is faced with some challenges. The field covers many questions intimately connected to fundamental legal rights, and involves ethical and societal issues that often are politically controversial. Different countries have



different regulations, professionals bring different perspectives and different expertise, and the knowledge of genetics and genomics is uncertain. Working with BBMRI-ERIC Common Service ELSI sometimes compares to the experience of Alice in Wonderland, looking down the rabbit hole: You cannot see where it leads but you can be sure that the hole is very deep indeed.

THE CHALLENGE SEEMS to be to decide when to stop digging, and to accept that the service can never replace local lawyering or professional advice of any sort. Researchers will always have to reflect on, and be responsible for, their practice themselves: both legally and ethically. But the BBMRI-ERIC Common Service ELSI will provide tools and expertise to navigate within this landscape of reflection.

Public-private research partnerships: Workshop

By Deborah Mascalzoni

In recent years, universities have done a lot of work to promote research partnerships with industry. Medical schools are encouraging their research faculties to pursue entrepreneurial strategies (start ups) to start companies and partnerships with industry. Together with RD-Connect and CHIPme, we invite you to discuss these issues in a two day workshop looking at current practices for public private collaborations and especially initiatives on rare diseases on November 7-8 this year.

PUBLIC PRIVATE PARTNERSHIPS in research have been debated for a long time. On one hand is the perceived need to involve more industry in the research-flow in order to maximize efforts in the search for results and therapies. On the other, there is fear and concern regarding the ethical challenges, conflicts of interest and exploiting of public resources.

PUBLICALLY FUNDED RESEARCH in the biomedical field collects great amounts of data and biological samples that could be extremely precious in the industrial context for translational purposes. Public-private partnerships are especially interesting in the rare disease field. But there are barriers and concerns. We still lack generalized common regulatory, technological and financially supportive frameworks. This places a burden on the potential positive impacts on the wellbeing of citizens. There is a need to explore different partnership models and discuss their relevance for genomic research and the particular challenges and opportunities for rare disease research.



Managing data protection in practice – Swedish perspectives

The legislative process regarding the General Data Protection Regulation (GDPR) is closed within the European Union as the Regulation was decided in April this year. The activity at the Government Offices of Sweden has, however, not ceased. Here, Anna-Sara Lind gives us her view on the consequences for Sweden.

PROCESSING OF PERSONAL data in research will, as we have seen earlier in this Newsletter, continue to be allowed. But to what extent and under what circumstances? What new limitations can arise?

THE SWEDISH GOVERNMENT is determined to investigate the boundaries of data protection and has appointed several commissions of inquiry. Until the end of 2017, at least five extensive inquiries have been asked to do thorough analysis, and their reports will have great impact on research and health care. The Data Protection Inquiry will suggest the general framework needed for Swedish law to comply with the GDPR. As this inquiry has a broad and general mission, there are also other inquiries appointed. One has been tasked with suggesting complementary rules on processing of personal data for research purposes. This mission is highly relevant as the GDPR to some extent leaves some leeway for national legislation. Research as a practice is also the center of attention in another inquiry that studies the rules relating to research, ethics and clinical research and health care. As the GDPR is broadly construed and has effects for research, also this inquiry needs to take it into account.

THE INSTRUCTIONS TO the inquiry regarding human tissues and biobank rules



highlight the need to investigate what the consequences will be when the GDPR enters into force. This must be taken into account when writing a new Biobank Act. In addition, there is another special inquiry analyzing how processing of personal data should be carried out, and how to adapt the rules relating to the field of the Ministry of Health and Social Affairs.

To conclude, the Chancellor of Justice has been given the task to suggest how the protection of personal integrity can be strengthened in Sweden. One question that she is investigating (at the time of writing) is how to best task a new agency with supervising some or all processing of personal data. The GDPR puts higher demands on such an authority and Sweden needs to be prepared in order to comply with the Regulation. The report will be presented when this Newsletter goes to print.

THE GOVERNMENT HAS clearly shown its commitment to solving several of the questions that are vaguely or poorly addressed in Swedish law today. We will of course continue to follow how the legal settings of health and biobank research evolve in the next phase.

Informed consent guidelines listed among IRDiRC Recognized Resources

We are pleased to announce that a set of guidelines for informed consent in international collaborative rare disease research developed within the RD-Connect framework has received the IRDiRC Recognized Resources" label.

The label is a quality indicator based on a specific set of criteria. It is open for platforms, tools, standards and guidelines of fundamental importance to the international rare diseases research and development community. The endorsement is valid for three years.

Read about the label on the IRDiRC website: <http://www.irdirc.org/activities/irdirc-recognized-resources/>



Want to discuss ethics?

Have a look, read and discuss with us on the Ethics Blog: www.ethicisblog.crb.uu.se

Or visit the Swedish language version at www.etikbloggen.crb.uu.se

Questions?

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Recent publications from CRB

Responsible implementation of expanded carrier screening, Henneman L et al., European Journal of Human Genetics, 2016;24.

Improving the informed consent process in international collaborative rare disease research: effective consent for effective research, Gainotti S et al, Eur J Hum Genet, 2016;24(9):1248-54.

Perceptions of risk and predictive testing held by the first-degree relatives of patients with rheumatoid arthritis in England, Austria and Germany: a qualitative study, Stack RJ et al., BMJ Open, 2016;6(6).

Ethical issues in consumer genome sequencing: Use of consumers' samples and data, Niemic E, Howard H, Applied and Translational Genomics, 2016;8:23-30.