



Informed consent as a mean to protect and empower people

February 6th, 2017 the Danish Board of Technology hosted a stakeholder webinar to open a discussion on the ethical and legal principles on informed consent in the Human Brain Project.

“If you don’t know you are a research participant, if you don’t know your data are being used, you cannot exercise the right to withdraw from research” (Prof. Søren Holm)

Prof. Holm and three other guest speakers were invited for a two hour webinar to present their views on how to tackle the ethical and legal principles of informed consent in The Human Brain Project. Stakeholders and everyone else interested in the subject were encouraged to join the discussion.

Informed consent was originally developed in the context of clinical research to protect vulnerable people from potential harm. However, as Prof. Holm rose during the webinar:

“Informed consent works together with another right that we also think that people participating in research have, and that is the right to withdraw from research”.

Since the HBP involves large datasets, aggregated forms and has goals that reach far into the future, the right to know what your data is being used for and the right to withdraw from HBP research is not straight forward. Looking at different aspects of informed consent, the guest speakers gave their recommendations on how to ensure sufficiently informed consent while still being able to conduct good research.

Ethics goes beyond the law

Within the HBP the problem of informed consent is to some extent being addressed by anonymizing and depersonalizing all clinical data at the hospitals. Guest speaker Dr. Daniela Ovadia, Director of the Neuro Psychology Department at the Niguarda Hospital, explained the complexity of informed consent in relation to the Medical Informatics Platform, one of the six ICT platforms developed in the HBP and agrees that anonymization of the data would solve many legal problems, but she is not sure it would solve all ethical problems:

“Ethics sometimes goes beyond the law”, Dr. Ovadia stated.

However, Dr. Ovadia also stressed the importance of also considering two other basic principles related to informed consent, namely the use of data for the good of the individual versus data as a potential public good.

Dr. Dianne Gove, Director for Project in Alzheimer Europe was guest speaker presenting informed consent in relation to people with Alzheimer's disease. Dr. Gove stressed the need to develop an informed consent framework that offers not only sufficient protection from potential harm, but also provides the necessary support to empower the affected people as far as possible:

"Developing such framework would ensure that whom who have the capacity are able to exercise self-determination and those who don't are able to make their voices heard", Dr. Gove said.

Active involvement and targeted communication would, according to Dr. Gove help to support the empowerment of vulnerable people such as people with dementia. In addition, Dr. Gove pointed out that rather than focusing on how people could withdraw from research it is important to build a framework that strengthen the acceptance by involving people in the research and communicating with them in a language they understand.

The essence of all presentation is that informed consent does not solve all problems, but that the researchers themselves also bear a large responsibility:

"It requires that we within our project we keep track of all the data flows, so we actually know where all the data are and what they are being used for." Prof. Holm emphasized.

The webinar took place February 6th 2017 and was organized by the HBP Subproject 12 'Ethics and Society'. Guest speakers included Prof Søren Holm (University of Manchester), Dr. Daniela Ovadia (University of Pavia/Niguarda Hospital), and Dr. Dianne Gove (Alzheimer Europe) and Dr. Stephen Rainey (De Montfort University)

All presentations are available online:

1. [Prof. Søren Holm, Professor in Bioethics at University of Manchester](#)
2. [Dr. Daniela Ovadia, director of the neuro psychology department at the Niguarda Hospital](#)
3. [Dr. Stephen Rainey from HBP Ethics Management, De Montfort University](#)
4. [Dr. Dianne Gove, Director of Project, Alzheimer Europe](#)

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