Case Study: Consent to use human tissue and linked health data in health research

In March 2017, the Health Research Authority (HRA) and the Human Tissue Authority (HTA) partnered with the Department for Business, Energy & Industrial Strategy's (BEIS) Sciencewise programme to run a public dialogue. The aim of the dialogue was to explore public participants' views on consent procedures used by researchers to link patient data with human tissue samples in health research to inform new HRA and HTA guidance.

1. Background

Figure 1. Image from Unsplash: Louis Reed.

Biobanks store human biological or tissue samples for future use for research. Linking healthcare records to biobanks allows researchers to monitor health outcomes and connect them to biological, genetic or behavioural factors and treatments. Participants must provide consent to allow the linking of their biobank data with existing and future health records. This is usually given as part of 'broad consent' for donated tissue to be used in a range of unspecified future research projects and treatment. However, some tissue in tissue banks goes unused by researchers because it is not adequately linked to patient data or not linked to future health data because it is unclear what broad consent is required and how it should be obtained. Tissue without data is of limited value and is problematic for the ongoing viability of tissue banks.

The dialogue considered the information that should be included in broad consent and hybrid consent; what needs to be in place (e.g. accompanying information, assurances etc.) so that those donating tissue and sharing their data feel comfortable with that decision; and attitudes to electronic dynamic consent for linking patient data to tissue with the opportunity to update consent on an on-going basis.

At the start, an oversight group was convened to advise on the dialogue's scope and process, information provided to participants, and the project outputs. Two rounds of public dialogue were run in London, Sheffield and Birmingham. During the first round, the public participants heard from a range of experts on biomedical research, health data, data privacy, safeguards on the impact of linking patient data with tissue samples. Between rounds one and two, participants were involved in an online community where they could reflect on their initial views and take part in activities about the future of research and possible risks in tissue donation and data linkage. In round two participants were asked to clarify their views on different consent protocols.

2. Impact

It is too close to the conclusion of the dialogue to determine if and how the findings have informed the development of HRA and HTA guidelines on consent. However, the evaluation

report identified that the project had met three of its key indicators. First, the dialogue results reached those best placed to learn from, and act on them, such as senior decision makers. Second, those senior decision makers trusted both the process and products of the dialogue. Third, the results were disseminated more widely, to other interested parties. In post dialogue interviews representatives of the HRA and HTA stated their intention to share the report to their stakeholders via a wider range of channels.

Figure 2. Image from Unsplash: Markus Spiske.

As a result of participants' call for more transparency about the current system and the safeguards in place, it was concluded that there are six key tests that the HRA and HTA should use to identify what information should be made clear to the public such as who can access tissue data and how it will be used[1]. The HTA project lead said that the dialogue would help "*researchers in consent form design*" and that the report from the dialogue would inform a review of guidance for researchers. Additionally, the HRA hopes to invite dialogue participants to return for an event to inform them of the impact of the dialogue.

The dialogue was identified by Oversight Group members to be having dual impact and benefit, not just informing the HRA and HTA's new guidance on consent but also how the field communicates with the public in the future. They stated that findings would be used "*to inform how we educate the public about our work, as we now have a better handle on what public understand and don't understand*."[2]

The HRA and HTA concluded "*People's attitudes to how their personal data is used and shared are changing, and there is a clear challenge around how to future proof consent in an uncertain world. What is not uncertain is that the dialogue we had with participants in this research project has identified a need for clarity on the uses of tissue and data, and the requirement to provide a straightforward and accessible consent process. That work falls to us, as the relevant authorities, to address.*"[3]

3. Vital Statistics

Commissioning Body	Health Research Authority and Human Tissue Authority
Duration of Process	March 2017 to April 2018
Number of Participants	75 public and 11 specialist participants in Birmingham, London and Sheffield
Budget of Project	£120,000 (including £9,000 for evaluation)
Dialogue Contractor	Ipsos MORI
Evaluation Contractor	3KQ

[1] Castell, S. et al. 2018. Consent to use human tissue and linked health data in health research. Pg42. 1) Who can access the data? 2) Data de-identification 3) How will donated tissue and data be used? 4) Who can access the findings at an individual level? 5) How will the donor be protected? 6) Sharing the research findings.
[2] 3KQ. 2018. Evaluation of public dialogue on patient consent for sharing data linked to human tissue. For the Health Research Authority and the Human Tissue Authority. Pg54
[3] Ipsos MORI. 2018. Consent to use human tissue and linked health data in health research. Pg7.