The Ethics Café
Europe Biobank Week
7th September 2018

The Ethics Café presented an opportunity for stakeholders to come together on the final day of Europe Biobank Week and voice their thoughts on the role that ethics frameworks play in the context of biomedical innovation.

Professor Isabelle Huys of KU Leuven, and Tristan Fuller, Policy Officer at the Ethics and Research Integrity Sector at the European Commission DG RTD, kicked off the discussion by offering differing viewpoints. Casting a gaze to the past, Professor Huys asked whether medical innovations would have been possible under current ethical standards and questioned how effective ethical policies really are when it comes to finding a practical and ethically sound solution. Tristan Fuller highlighted the individual and personal nature of research projects involving human participants, with the need for an according level of empathy and respect by the researcher for such participation. He stressed that without proper supervision and addressing of ethics and legal issues arising within research projects, there is potential for harm to individuals and society, as well the project itself. It is therefore crucial to consider and to address ethics issues from the very beginning of research projects and to firmly embed ethics into the research protocols. In both cases, it was agreed that ethical and legal frameworks have substantial role in biomedical research and in the protection of research participants and society at large. The question, however, was how beneficial existing norms are.

One by one, stakeholders came to the microphone and shared their thoughts on the matter. The following points were raised and discussed, and it was agreed to record these as a basis for policy development and further Ethics Café discussions:

<u>Red Tape</u>

A number of researchers expressed that ethical and legal norms have become unduly burdensome and bureaucratic for researchers, who do not have the necessary expertise to handle and address such issues. Furthermore, the different approaches taken across Europe mean that in certain countries, researchers have a greater administrative burden than their other European counterparts. It was however pointed out that if researchers embed the dealing of ethics early on within the research project, it can become less of a burden. It was also pointed out that whilst ethical checking mechanisms are perceived as red tape, they are necessary to ensure that projects are legally and ethically compliant. Ethical norms are in place to ensure safety and wellbeing of all stakeholders. As a result, researchers are encouraged to provide comprehensive explanations demonstrating that they are aware of and have addressed ethical and legal issues at proposal stage. Doing so, helps to reduce administrative work concerning ethics and avoids backtracking at a later stage.

<u>Patient Views and Patient Involvement</u>

The importance of involving patients and patient advocates from the beginning of research projects was stressed, as it allows patients to understand the nature of the research and allows for fruitful collaboration. It was questioned whether the current ethical framework is able to adapt quick enough to respond to patients' views, which includes a drive to increase the speed of innovation, and their desire for early involvement. Whilst there are requirements to provide information to patients, the

framework should also require that patients provide information to researchers, as well as to accommodate their requests, which includes both health care and innovation.

Benefit Sharing

The need for benefit sharing was also raised. Although ethical frameworks seek to protect research participants during research, participants do not always reap benefits from the project itself. An example was given concerning the development of vaccines following efficacy trials in low-income countries, where participants were not able to afford treatment when they came available on the market given the high costs. Ethical principles should therefore be integrated into market access and a model ought to be developed that would allow participants to benefit at an earlier stage rather than having to wait until market prices become affordable.

The Role of Ethics Committees

It was highlighted that Ethics Committees ought to take adopt a faciliatory rather an inhibitory approach. This means that they ought to take into account the wishes of patients and patient advocates, who wish to be participants of the research project, as well the wishes of researchers and clinicians who support the project. There is a perceived lack of responsibility on the part of Ethics Committees when they put a halt to research projects. The risks of not doing something as well as the risks of doing something are an important consideration in ethics frameworks. As it stands however, there is the perception that ethicists tend to focus on 'monster science' rather than focusing on the potential public good of research. Ethics should be perceived as a profession that says 'yes', whilst ensuring the application of the appropriate safeguards and advice Furthermore, the lack of or no patients in Ethics Committees was highlighted and deemed unacceptable, given that patients and their advocates are able to enrich discussion and views.

The Role of Biobanks

It was raised that researchers still continue to collect and store samples and data, without making them available to the wider scientific community. The crucial role of biobanks was therefore highlighted in assisting researchers to be more ethical so that samples and data can be stored and curated more openly.

The Role of the European Commission

There was concern as to how the European Commission develops and applies ethics standards. The EC was called upon to ensure that they enable experts to have the appropriate ethical debate and input before EC norms are finalised.

Training & Guidance

More often than not, researchers lack knowledge regarding legislative and ethical requirements. Therefore, rather than labelling them as unethical, which dismantles trust, there is an important role for educational institutes and the ethics community to train young researchers in a practical way. The European Commission's Guidance Notes were referred to and are a helpful starting point for researchers, with further guidance to be issued on ethics and data protection, informed consent and research involving social sciences.

Trust

It was agreed that trust is essential. Whilst it was felt that there is a lack of trust within the community, with researchers voicing that there is an assumption that scientists cannot be trusted from the outset, the purpose of ethics frameworks and reviewing mechanisms within the European Commission was clarified, namely that such evaluations/checks are far from not a vote of no-confidence. Rather these procedures have a statutory basis and constitute due process to ensure adherence to the Horizon 2020 legislation and to high ethics standards, but also to support adherence to ethics standards by researchers and research projects rather than to hinder. In order to gain trust, stakeholders must work together and enter into a dialogue. Awareness of the issues and clear communication become integral components of trust in order to allow and reinforce understanding between respective stakeholders.

In concluding the Ethics Café, a call was made for action, moving from an ethics debate to an ethics movement. Following the lead of patient experts, who have been active in making substantial changes, all stakeholders were encouraged to identify and take the next steps to contribute to change.