MINUTES OF APPEAL HEARING AGAINST DECISION 19-006-AF3 OF THE HEALTH RESEARCH CONSENT DECLARATION COMMITTEE IN RELATION TO APPLICATION "Contribution of Whole Genome Sequencing to Brain Tumour Biology".

Date: 3 September 2019
Time: 09:30 – 12:00
Location: The Alex Hotel, 41-47 Fenian St, Dublin 2

Attendance

Panel
Professor Gerry Whyte - Chairperson
Professor Seth Love
Dr. Francesca Lundström
Helen Tierney (note taker)

Appellant Group
Dr. Michael Farrell, Beaumont Hospital
Felix McEnroy SC
Patrick Buckley, Laboratory Director, GMI
David Kavanagh, Director Clinical Partnerships & Programmes, GMI
Hilary Lemass, Data Protection Officer, GMI
Karen Holmes, VP & Head of Legal, GMI
Emma Kearney, Director of Privacy, GMI

Meeting Notes:

The Chairperson opened the meeting by welcoming all, introduced the panel and stated their roles. The Chairperson called on the appellants to make their presentation. Mr. McEnroy provided a verbal presentation and supporting documents to the panel. On agreement of the Chairperson, other members of the appellant group spoke at different intervals throughout the presentation and responded to the questions from the panel.

Mr. McEnroy provided the panel with the following documents:

> Extract from William Lowrance 'Privacy, Confidentiality and Health Research' (CUP, 2012)
>
> Handbook of European data protection law (2018 edition).

He referred to the number of people in the room who had significant expertise in medical research and data protection and noted that there was no *legitimus*

contradictor with whom the appellants could work on a collaborative basis to get to an understanding of the Regulations. He also referred to EU law underpinning the Regulations and to the policies of the European Patients' Forum and Wellcome Foundation UK.

Mr. McEnroy also referred to Dr. Farrell's expertise in this jurisdiction and noted that there is only one centre of excellence in Ireland, namely, Beaumont Hospital. He said there is no current policy guidance or legal instruments that will assist decision-making in this country. Such policy guidance exists in the UK and other countries that can be looked at to see how academic analysis has informed their decisions.

Dr. Farrell detailed his background and his work on diagnosing brain tumours. He said that there have been changes in the way in which pathologists assess brain tumours, with increasing reliance on the analysis of DNA within a tumour. Brain tumours can now be identified by their genetic signatures that provide information of the types of tumour and predict their behaviour. He referrd to major scientific advances that had been made by groups in Germany in the use of information derived from the analysis of tumour DNA to help predict outcomes and responsiveness to treatments, and mentioned the work of Dr. Eric Holland in Seattle in this area too. Dr. Farrell referred to the tissue samples that are routinely taken for diagnosis and noted that any surplus tissue that remained after diagnosis was retained, usually in paraffin blocks, under the custodianship of the pathologists He said that this retention was important as the retained tissue may be needed if a second or third treatment opinion is later sought, or if a new test is introduced that may influence clinical management, or for medico-legal reasons. Dr. Farrell said it is possible to isolate and fully sequence DNA from the block of tumour tissue. He compared the amount of genetic detail that can now be obtained by DNA analysis of the tumours to elucidating subtle nuances in the information provided by the language in a book, including not only a spell check for example, but also a deep understanding of the meaning of the language, allowing the reader to distinguish between identical sentences read with different patterns of emphasis. He said that all of this information is within the genome and that recent advances in technology provided an opportunity to use anonymised data from archival tumour tissue collections to improve the diagnosis and treatment of current and future patients' tumours while taking account of GDPR and Health regulations.

The panel questioned in 2015 the mention of children to which Dr. Farrell responded that this reference was dropped as brain tumours in children behave differently from those in adults. The panel referred to the original application, the commercial partners and meniton of data downloads, in relation to achieving a balance between the desirability for explicit consent versus the public good that would derive from the research. The question was asked as to whether the raw data derived from the research (i.e., the genetic, demographic, treatment and clinical outcome data) would, within a reasonable time, be lodged in a public repository for other research groups

to use (e.g. to develop predictive algorithms and tools for patient management that might complement or be better than the analysis software that GMI would produce.) It was not clear from the application that this would be the case. Dr. Farrell responded by saying his objective is to predict in a better way the behaviour of brain tumours and this work is only done in Beaumont, not by GMI; the focus of GMI was drug development and their aim was to use the data to see if there are common pathways for future therapies. A GMI representative talked through the journey and evolution though collaboration on the project and confirmed that the genetic data files would be returned to the Beaumont collaborators and thereby made accessible for other research.

The panel asked about the attitude of the appellant to publicising the proposed study and offering patients or their relatives an opportunity to say if they were unhappy for the tissue to be used in the study, even if the expectation was that the great majority of people would support the research. Dr. Farrell confirmed that he had spent time with Brain Tumour Ireland (BTI) and the Board, where he offered support to attend information campaigns about the research running in October. He talked about producing a public notice and a helpline with a brain tumour nurse. He thought it important to distinguish between the tumour DNA that would be analysed and the heritable (germ line) DNA that would not. The panel asked if there was information on this or templates/leaflets for distribution by Brain Tumour Ireland. Dr. Farrell said that there was a body of work to be completed on this. Mr. McEnroy offered to try to formulate an approach to this to tailor conditions attached to the declaration.

GMI referred to their CEO being on record stating that responsible management required multi stakeholder engagement and that anonymised data is managed in a thoughtful and responsible way. Mr. McEnroy referred to the mechanics by which the material is analysed. The Data Protection Officer confirmed that all data is pseudo-anonymised under GDPR, that there are three rounds of coding and that each time between links the codes are broken so that it would not be possible to track back to Beaumont and individuals in the brain tumour samples.

The panel asked how the study would work going forward. Presumably consent would be obtained from new participants and in time there would be a link back to other health resources. Dr. Farrell confirmed that, consent forms having been already modified, this work going forward would be the subject of a separate application to the ethics committee. He confirmed that there are two databases, Beaumont's old archive of data and an emerging data set from current patients who will be asked to provide their consent for the research. He confirmed that the archival dataset in question is complete. The panel asked about the designed consent form for new patients to which Dr. Farrell confirmed two new colleagues have started work on this.

In his legal submissions, Mr. McEnroy cited Arts.6(a), 16, 168(1) and Title XIX of the Treaty on the Functioning of the European Union. He noted, in particular, that Art.179(2) committed the EU to supporting the involvement of private companies in research and he argued that the public/private collaboration between Beaumont and GMI was a legitimate choice for addressing the public interest. He also cited Arts. 3, 8, 13 and 35 of the Charter of Fundamental Rights of the European Union. He noted that the 2018 Regulations contained the procedures laid down by law for respecting the consent of data subjects, as required by Art.3 and that they also provided a legitimate basis for the use of personal data for the purpose of Art.8(2). He contended that Art.13 implicitly recognised the value of medical research in promoting the public interest and noted that, having regard to Art.35, EU law regarded a high level of human health protection as an aspect of the public interest. Mr. McEnroy drew the panel's attention to the criteria used in Australia, Canada, the UK and the US for using personally identifiable data without the consent of the data subject, as described in the extract from Lowrance, *Privacy, Confidentiality and Health Research*. These included difficulties in contacting members of the study population because of the passage of time, the risk of causing stress or resentment by attempting to recontact the data subjects and where the logistical effort and/or cost required for attempting to obtain consent would be forbiddingly high. Mr. McEnroy additionally argued that the panel should adopt a purposive interpretation of the Regulations and he referred to EU law authorising limitations on the exercise of fundamental rights which requires that such limitations be in accordance with the law, respect the essence of the right, be necessary (subject to the principle of proportionality) and pursue an objective of general interest recognised by the EU or protect the rights of others. He drew the panel's attention to pp.339-342 of the *Handbook on European Data Protection Law* dealing with data processing for research and statistical purposes. He argued that if the researchers did not have access to the entire dataset held by Beaumont, this could distort the benefit derived from the research.

The panel referenced data being given to GMI and asked what would happen if nothing constructive came from the analysis of the data by GMI. The panel suggested that it should then be made available to others within a reasonable timeframe. It would be useful to show what the format of the shared data would look like. This would provide assurance that the research was likely to make a contribution to the greater good.

Mr. McEnroy suggested that he draft a set of conditions to meet the concerns of the panel and he would submit this within two days. He was open to discussion and happy to return. The panel stated that they would be reserving their decision and that they were happy to receive supplementary information after the hearing.

The panel then invited Mr. McEnroy to address the regulations and the four points of appeal against the decision by the committee.

Speaking to the written grounds of appeal submitted by the applicants, Mr. McEnroy argued that in determining when it is appropriate to dispense with consent from living patients, the panel should have regard to international practice. He also contended that while it was normally important to get the consent of living patients, the balancing exceptions to that requirement also served the public interest and should receive equal consideration. He submitted that the fact that GMI was a for-profit entity was an irrelevant consideration that should not have been taken into account by the Committee. With regard to the Committee's concern that there had not been more effective engagement with the patients and general public, Mr. McEnroy argued that in a small jurisdiction such as ours, where there was limited interest on the part of the general public in this research, engagement with BTI should be sufficient.

Dr. Farrell noted that the declaration cannot cover the unknown use of future products and that there is a need to go back each time to the HRCDC for a new declaration, including for data sharing. The panel indicated that there should be some assurance that the data would not be restricted to GMI and some indication given as to how the data might be made available to other researchers.

The Chairperson asked if there were anything else to add. Mr. McEnroy confirmed if the panel required more information, the appellants will supply this. Dr. Farrell stated that the appellants will provide information relating to the proposed opt-out clause.

The hearing then concluded. The panel will receive draft conditions from the appellants within two days following which the panel will confer in order to reach an agreed decision.