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3rd May 2018

Helen Dixon
Data Protection Commissioner
Office of the Data Protection Commissioner
21 Fitzwilliam Square
Dublin 2

Dear Ms Dixon,

Please find attached a submission on the topic of the General Data Protection Regulation in relation to Biobanking and note appendix 1 which contains a comprehensive list of individuals who endorse this submission.

I would appreciate an opportunity to meet with the commission to discuss this submission in due course.

Yours sincerely,

Dr Pat O'Mahony
Chief Executive

CC Mr Cathal Ryan

Submission to the Data Protection Commission on the topic of the General Data Protection Regulation in relation to Biobanking

We are writing to you as representatives of Irish Research Institutions involved in biobanking and conducting scientific research on biological samples and data.

Recent technological advances have significantly increased the information that can be gained from the analysis of even very small amounts of biological material. Thousands of genes, proteins and metabolites can be measured in droplets of blood. Hence biobanking has the potential to provide important information and to answer important questions about a multitude of diseases, providing new diagnostics and new therapies, with huge societal and economic gain.

Within our institutions, we have numerous collections of clinical samples and data which have been, and continue to be, used to conduct significant scientific research in Ireland. These may be known as biobanks, biobank resource centres or collections of patient samples and data etc, all of which can be ascribed to biobanking activity.

Biobanking is defined by ISO/FDIS 20387 as the process of acquisitioning and storing, as well as some or all of the following activities: collection, preparation, preservation, testing, analyzing and distributing defined biological material as well as related information and data.

While biological material is defined as any substance derived or part obtained from an organic entity such as a human, animal, plant, microorganism(s) or multicellular organism(s) that is(are) neither animal nor plant (e.g. brown seaweed, fungi). The data involved in biobanking activity would be classified as special category of personal data under GDPR.

All patients who contributed their samples and data to any biobanking activity would have given their informed consent, and ethical approval for the research would have been granted by the relevant institution's Research Ethics Committee. In many cases, the patients were given the option to also consent to future unspecified research studies (also known as "broad consent") using their samples and data.

We are writing to seek clarification regarding the concept of "broad consent":

Q1. If data processing is to occur on the basis of the provisions of GDPR 9.2. (a), how should "specific" or "specified purpose" be interpreted?

Recital 33 states, "It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose."

Further, according to the draft Guidelines on Consent issued by the Article 29 Data Protection Working Party, *"When research purposes cannot be fully specified, a controller must seek other ways to ensure the essence of the consent requirements are served best, for example, to allow data subjects to consent for a research purpose in more general terms, and for specific stages of a research project that are already known to take place at the outset. As the research advances, consent for subsequent steps in the project can be obtained before that next stage begins. Yet, such a consent should still be in line with the applicable ethical standards for scientific research."*

Q2. Thus, how specific do the "research purposes" need to be?

For example, if a patient has consented to processing of their data for a named cancer research study *and for other future unnamed research studies in the same area of cancer research*, is this allowed? We consider this meets the requirements.

Or for example, if a patient has consented to processing of their data for a named study which is involved in the validation stage of a biomarker and *for future research studies*, *can their data be used for other research studies involved in the validation stage of different biomarkers?* We consider this meets the requirement.

Further, the draft Guidelines on Consent issued by the Article 29 Data Protection Working Party state *"Transparency is an additional safeguard when the circumstances of the research do not allow for a specific consent. A lack of purpose specification may be offset by information on the development of the purpose being provided regularly by controllers as the research project progresses so that, over time, the consent will be as specific as possible. When doing so, the data subject has at least a basic understanding of the state of play, allowing him/her to assess whether or not to use, for example, the right to withdraw consent pursuant to Article 7(3)."*

Q3. Applying this provision, if for example a patient has given broad consent to take part in a study and is informed that any further uses of their data will be publicised on a named website before the intended use begins, can this be judged sufficient?

We understand that the new Health Information Legislation provides for the formation of a Committee which can grant waivers to consent upon application. Does this process give effect to GDPR Article 9.2 (j) where *"processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law*"?

Q4. What is the interplay, if any, between Article 6.1.f and Article 9.2.j and further, what are the relevant factors to be taken into account if a legitimate interest is being invoked and is it applicable in relation to scientific research purposes?

In regard to the establishment of this Committee and process, we seek clarification on the following:

- Q5. If after May 25 2018, a model of broad consent, as appears to be provided for by Article 9.2 (a) together with Recital 33, is <u>not</u> generally applied, can studies consent patients to their primary purpose (named research study) and then in the future apply for a waiver to consent in order to process data for a secondary purpose? In such a case, would each new study count as a separate secondary purpose and require a separate waiver from the Committee?
- Q6. Will this also mean that studies that were set up (and patients consented to future use of data) prior to May 25 2018 be required to apply to this committee for a waiver to use the data for future studies?
- Q7. After May 25 2018, can a study that doesn't require patient participation, for example, a registry study, apply for a waiver to consent for their primary purpose?
- Q8. At present, many Research Ethics Committees are deciding on these scenarios in the context where a broad consent model is used. After May 25 2018, will Research Ethics Committees continue to be permitted to make these decisions? Should changes be foreseen, will the Department define a clear

interim/transition process that can operate effectively before the planned committee and its process are established?

- Q9. At present many hospital diagnostic laboratories store samples and data and may not in all cases be able to provide direct evidence of consent for data processing. Will they be required to apply to the planned Committee for a waiver to consent or can present arrangements apply pending any future guidance on this issue?
- Q10. There are many historical collections of samples and data (such as museums) used to support teaching. Will they be required to apply to the planned Committee for a waiver to consent or can present arrangements apply pending any future guidance on this issue?

The Article 29 Data Protection Working Party states as follows:

"*If a controller finds that the consent previously obtained under the old legislation will not meet the standard of GDPR consent, then controllers must undertake action to comply with these standards, for example by refreshing consent in a GDPR-compliant way. Under the GDPR, it is not possible to swap between one lawful basis and another. If a controller is unable to renew consent in a compliant way and is also unable – as a one off situation- to make the transition to GDPR compliance by basing data processing on a different lawful basis while ensuring that continued processing is fair and accounted for, the processing activities must be stopped. In any event the controller needs to observe the principles of lawful, fair and transparent processing*"

Q11. What types of situations are envisaged where a "different lawful basis" could be applied or when a swap between one lawful basis and another can be made?

Finally, we wish to highlight the BBMRI-ERIC (Biobanking and BioMolecular resources Research Infrastructure- European Research Infrastructure Consortium) joint comments to the Article 29 Working Party Guidelines on Consent under Regulation 2016/679 (wp259) and Transparency under Regulation 2016/679 (wp260) which we have attached to this letter. Although Ireland is not yet signed up to BBMRI-ERIC, we understand that the Department of Health are actively considering the case for membership, and that the Health Research Board shortly plans to launch a call to establish a national biobanking node, which is a pre-requisite for membership of the BBMRI-ERIC. As we are not a current member, we were not able to contribute to these joint comments although the sentiments and concerns expressed by the other countries would be similar to ours. It should be noted; however, that there is currently no Irish law governing biobanks.

Appendix 1: List of Representatives of Irish Research Institutions

Name	Position & Institution
Dr David Barton	Chief Scientist Molecular Genetics, OLCH Crumlin
Dr Suzanne Bracken	Translational Research Manager, CRDI
Dr Aileen Butler	Principal Clinical Scientist Molecular Genetics, OLCH Crumlin
Prof Dolores Cahill	Professor of Translational Science, School of Medicine, UCD
Mr Jason Carr	Chief executive of SuprTecbox
Ms Niamh Clarke	Coordinator of SJH-TCD Biobank Working Group, SJH
Dr John Cronin	Consultant in Emergency Medicine, St Vincent's University Hospital
Ms Anne Cullen	Chief Technical Officer at UCD Conway Institute
Dr Peter Doran	Scientific Director, Clinical Research Centre, UCD
Prof Joe Eustace	Director of the HRB Clinical Research Facility at UCC
Prof Maria Fitzgibbon	Vice-president of Association of Clinical Biochemists in Ireland
Dr Richard Flavin	Consultant Histopathologist, St. James's Hospital
Dr Emma Gabriel	St. James's Histopathology Cancer Biobank
Prof Andrew Green	Director of the Department of Clinical Genetics, OLCH Crumlin
Prof Martina Hennessy	Clinical Research Facility Director, Trinity College Dublin/SJH
Dr Rosanna Inzitari	Conway Institute, UCD
Prof Janusz Jankowski	Director (Corp.) Chief R&I Officer and Deputy Vice Chancellor, RCSI
Prof Dermot Kenny	Director RCSI Clinical Research Centre
Dr Sarah McGarrigle	Biobank Manager, Dept of Surgery, Trinity College Dublin
Dr Blanaid Mee	Biobank Manager, Biobank Ireland
Dr Brona Murphy	Lecturer in the Department of Physiology & Medical Physics, RCSI
Dr Daniel Murphy	National Rare Diseases Office, Mater University Hospital
Prof Alistair Nichol	Professor of Critical Care Medicine, St Vincent's University Hospital
Prof Colm O'Brien	Clinical Research Centre Director, UCD/Mater Hospital
Prof Martin O'Donnell	Associate Director of the HRB Clinical Research Facility Galway
Dr Sharon O'Toole	Senior Research Fellow, Histopathology, Trinity College Dublin
Ms Emma Snapes	Biobank Manager, INFANT Centre, University College Cork
Prof William Watson	Professor of Cancer Biology, School of Medicine, UCD