An Roinn Sláinte
Department of Health

[redacted]

3 September 2018

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Ref: CRDI submitted topics for discussion regarding Health Research Regulations

Given the amount of questions being posed it is important to again make certain key general points.

A. The GDPR, the Data Protection Act 2018 and the Health Research Regulations are, in the context of health research, individually and collectively an evolution rather than a revolution. They represent, in fact, established best practice. That is particularly so with the Health Research Regulations which are simply a set of sound information principles designed to help health research and to safeguard personal data. The Regulations give effect to government policy to support health research and to help ensure the necessary public confidence for health research to flourish. The Regulations are, therefore, about enhancing the health research climate in Ireland where researchers and the public can go forward together to achieve worthwhile outcomes for the benefit of individual patients and the health system generally.

B. The Government is committed to the continued development of a research-active health system in Ireland. That commitment has already seen significant public investment in physical infrastructure, personnel, new skills and technology. At the same time, the Government is equally determined to ensure good research governance as well as appropriate and streamlined regulatory processes.

C. Even without the Health Research Regulations, health researchers, as data controllers (or joint data controllers depending on the circumstances of the research project) are responsible and accountable for compliance with GDPR.

The Regulations help them by indicating (a) the decisions that must be made, (b) the actions that should follow the decisions and (c) the information that needs to be provided to data subjects.

D. The Health Research Board website (www.hrb.ie) has a section on the Health Research Regulations including FAQs that health researchers will find very helpful. The FAQs dealt with are being updated regularly.

E. The Department and the HRB are not permitted to offer advice (which would essentially be construed as legal advice) to individuals or organisations relevant to meeting their legal obligations.

F. The Department and the Health Research Board are planning a joint seminar on the Health Research Regulations for 19 October (Dublin). Details will be available when the agenda, speakers and expert panel are finalised.

1. Broad consent

There is still much confusion regarding what level of broad consent is acceptable.

It is difficult to understand why there is confusion on broad consent. We have addressed the matter clearly in the Regulations where the matter of broad consent is in line with Recital 33 and the Article 29 Working Party Guidance on Consent (April 2018) and is wider than that envisaged by the EU Commission because it extends beyond the particular to the general into related areas (see below).

The Regulations state (without referring to broad consent by name) what it means as follows:

> - explicit consent has been obtained from the data subject, prior to the commencement of the health research, for the processing of his or her personal data for the purpose of specified health research, either in relation to a particular area *or more generally in that area or a related area of health research*, or part thereof. (Our italics)

It appears that a patient can be consented to future unknown research studies once the research is restricted to specific disease(s)/condition(s). Is this the case for biobanks as well as for named research studies that also ask a patient to consent for future unknown research?

See previous answer. The text refers to areas or related areas of research, not to diseases or conditions. The specific context of the research project/centre/network/consortium will typically determine what can reasonably be considered an area,or related area, of research. Furthermore, there is no distinction drawn in the Regulations between health research involving biobanks and health research not involving biobanks. The Regulations apply to the processing of personal data for health research purposes.

In our submission we asked about a broad consent scenario where 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 involved in the validation stage of different biomarkers. This example was drawing on the Article 29 Working Party Guidelines on consent which gave the example of data subjects consenting to specific stages of a research project. The validation stage of research for a biomarker follows from a discovery study where a particular biomarker has been identified as promising. Validation usually includes analytical validation (to prove the biomarker is accurate, precise, specific, robust, and stable over time) and clinical validation (to determine sensitivity for disease, specificity for disease, positive predictive value, negative predictive value, likelihood ratio, and ROC analysis). Validation in a population of samples different to that used initially (external validation) is essential, thus many International collaborations or networks try to share their population's samples if the patients consented to do so. This stage of research usually precedes commercialisation/incorporation into clinical practice. Can you comment if this form of broad consent, which would ask patients to consent to future unknown research for a particular type/stage of research (as opposed to specifically within a particular disease) is acceptable?

In your submission, you asked about a broad consent scenario where 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 involved in the validation stage of different biomarkers. We requested an example.

However, we can say (even without an example), as per the point above, that it is for the data controller to provide such information as is necessary and appropriate and to frame the consent request consistent with that information so that the breadth of what is being consented to in terms of the area or related areas covered is clear to the data subject whether it is in relation to, for example, a disease area or by reference to biomarkers. In that regard, and indeed in every regard, when seeking either consent for a particular project or broader consent it is important that the language used avoids jargon and is easy to comprehend. Accordingly, information provided should be written from the

perspective of the data subject and not the researcher. In that regard, a researcher could consult the WP29 guidance on transparency (which is available on HRB website.

It is also essential that a health researcher understands that blanket consent (use of a high level statement seeking consent for future unspecified purposes) is not an option under GDPR (and in truth, has not been considered best international practice for a long time now).

A paper jointly produced for the UK Health Research Authority and Human Tissue Authority on "Consent to use human tissue and linked health data in health research -A Public Dialogue" (July 2018) found that most common "red lines" for individuals in consent matters (especially broad consent) were no access for commercial companies like insurance companies or marketing companies using data to sell a product. Some participants in the dialogue did not want pharmaceutical companies to have access to their data, but after their role in research was explained participants felt less strongly about pharma having access to their data.

The importance of transparency in the context of broad consent was emphasised by yourselves. Can you give more guidance on what measures would be required for the participant information leaflet/consent form?

It is recognised that patient information leaflets and consent forms are important elements in obtaining explicit consent and ensuring the GDPR principles of transparency and accountability are met.

The Department is not permitted (for legal reasons) to offer advice (which would essentially be construed as legal advice) to individuals or organisations relevant to meeting their obligations under the GDPR. Even if that were not the case, there would be very significant resources required to engage separately with every organisation individually on their specific GDPR matters. For those reasons, we cannot review specific Patent Information Leaflets or Consent Forms. What we will do –in the same spirit of helpfulness that has characterised the approach of the Department and the Health Research Board- is prepare general guidance principles relevant to consent forms and information leaflets. This will be made available online (when finalised) on the HRB's GDPR Guidance for Researchers.

The responsibility for compliance with GDPR and the new Health Research Regulations lies with the data controller. Researchers are recommended to always seek project

specific advice in relation to data processing for health research purposes from their organisation's DPO.

The issue of transparency is referenced again under 2 below.

Are the following points sufficient: how the samples/data will be stored, who will have access, what the decision-making process is for future studies allowed to use the samples/data; where information pertaining to future studies using the samples/data will be publicised; where aggregate results and general updates from the study will be published?

As above

The HSE National Consent Policy recommends layered consent for future unknown research with options for requiring re-consent or not and for specifying the type of future research or not. Can you comment on these and what is acceptable under the new regulations?

The HSE National Consent Policy is a useful guidance document that covers many different aspects of consent and capacity to consent and, presumably, it will be updated to reflect the legal obligations introduced by GDPR, the Data Protection Acts and the Health Research Regulations.

While we agree with offering participants the opportunity to be re-contacted and re-consented for each future study, many participants would prefer not to be re-contacted and we believe should be allowed to choose not to require recontact but still consent to their samples/data be used in future studies. Consent fatigue is a genuine issue that could harm progress in all health research.

Given that we have enabled broad consent in the Regulations, consent fatigue should not occur where the persons carrying out the research take the time to think through future scenarios and address them at the first consent point.

2. Studies approved under previous data protection directive

Where a biobank with a specific named purpose/primary outcome that was approved by a research ethics committee and has received samples and data with explicit informed consent, can they continue to operate under the new legislation?

If the explicit consent obtained from the data subjects meets all of the requirements of GDPR and the new Health Research Regulations, then yes, the biobank may continue to operate under the new legislation with no further consent action required.

Where the explicit consent is in line with the previous 1995 Data Directive requirements but does not fully meet the new requirements under GDPR, there is a transition period (up until 30 April 2019) to allow data controllers obtain re-consent in line with the new Regulations.

This transition period should also be used by the data controller to ensure that the other relevant GDPR provisions and the suitable and specific measures outlined in the Health Research Regulations are put in place (if not already so).

Where, after serious efforts have been made, it is not possible to seek the re-consent of the data subjects and where the researcher believes that the public interest of the research significantly outweighs the public interest in protecting the rights of the data subject, the Regulations set out for the first time a legal mechanism to apply for a consent declaration that the consent of the data subject is not required. It will be for the independent Health Research Consent Declaration Committee to determine whether a consent declaration is justified.

Where a biobank was established and approved by a research ethics committee with a broad consent model that consents patients to future unknown research beyond the primary named purpose, will this require upgrading the consent in order to continue to operate under the new legislation?

That depends on the broad consent obtained. As with all data protection concerns, health researchers should engage with their relevant Data Protection Officers. Under the GDPR, DPOs are required to be designated on the basis of professional qualities and, in particular, expert knowledge of data protection law and practices.

More generally in relation to biobanks and broad consent it can be said that evolving best practice and recommendations in the field of biobanking research, even in advance

of the GDPR, is for researchers to try to the greatest extent possible to describe future uses and to provide information on governance and objectives of the biobank. Much guidance has emerged on the critical informed consent elements, and include the following:

- Purpose and aim of the biobank; Funding and conflicts of interest; Why participant is being invited; Statement that participation is voluntary; Who has approved the research; Benefits and risks of taking part
- Type of data (including details on whether medical or other health records is being accessed)
- What the biospecimen/data will be used for and what secondary research purposes are anticipated (in particular, the public are interested in knowing if there are any controversial areas of potential research uses such as creation of cell lines, genetic testing, mental health, stem cell research)
- Whether the biospecimen/data will be identifiable; Rights/ownership of samples; Privacy protections in place
- Oversight mechanisms, including governance and access
- Whether biospecimens/data will be shared (locally and/or across national borders) and the types of researchers or institutions that might be involved; Whether biospecimens/data will be used by commercial/for-profit entities and whether participants will receive any benefits; When appropriate, details of whether the research might include whole genome sequencing; Whether results or incidental findings will be returned to individuals; Where relevant, policy on use/disclosure to third parties for non-research purposes
- How long the samples/data will be stored; Dealing with data/specimens after people die or become incapacitated
- What if participant changes their mind (withdrawal mechanisms)
- Contact details of the biobank and data controller

Based on the above best practice in biobanks, aligned with the GDPR requirements, the issue of information provision and transparency at the time of consent (and afterwards) is critical to any discussion around the validity of broad consent. Institutions and Data Controllers must track the information provided and the permissible scope of collected identifiable information and biospecimens and ensure that any access to, and use of them, is consistent with the terms of the executed broad consent.

Will upgrading consent to GDPR standard require a Data Protection Impact Assessment?

That will be a judgement call for the researcher and depends on the level of sensitivity, risk etc associated with the research project.

Under the new Health Research Regulations 2018, all data processing for health research purposes requires that the data controller(s) has processes in place in order to assess the data protection implications of the proposed research and, for high risk situations, a formal data protection impact assessment (DPIA) must be carried out.

And will it require a new ethical approval or amendment?

In general, it is not expected that the re-consent of an ongoing health research studies will require fresh ethical approval.

However, fresh ethical approval might be required if, in the context of the re-consenting process, there is a change to the research methodology to the extent that the research protocol no longer reflects that which previously received ethical approval by the Research Ethics Committee.

If participants need to be re-contacted to upgrade their consent, should they be asked to explicitly re-consent (read an updated participant information leaflet and sign an updated consent form)?

Yes

Does the information also need to be provided via other means such as websites, posters and leaflets in clinics?

Anything that aids transparency is desirable.

Will there be recommended wording as per the UK HRA, e.g. https://www.hra.nhs.uk/planningand-improving-research/policies-standards-legislation/data-protection-andinformation-governance/gdpr-guidance/templates/transparency-wording-publicsector/

That is not intended. The information on the Health Research Authority website concerning transparency is certainly a useful starting point. However, as that material

makes clear "it is for data controllers to determine what other transparency information they should provide and the means of providing it".

If an upgraded consent is not possible, despite exhaustive measures, do we then proceed to the proposed DOH Committee for a consent declaration?

No one has to proceed to the independent Health Research Consent Declaration Committee. That is a choice to be made by the researcher after having considered all the options including anonymising the personal data. However, it is fair to conclude that going to the Committee will be very likely unsuccessful if there is no tangible evidence of a serious effort to obtain re-consent by the researcher.
The HRB has developed a very useful consent declaration decision tree to help researchers assess:

- whether they might be eligible to submit an application to the Health Research Consent Declaration Committee to obtain a consent declaration, and
- whether such an application should be made under the transitional arrangements or as a new research project.

This decision tree also outlines a number of important preliminary steps that must be completed by researchers prior to the submission of any application to the Committee.

3. Legal bases: general

From your response to the CRDI submissions, we note that "explicit consent" seems to be the preferred legal basis allowed except in the rare cases where a "consent declaration" has been received. Yet GDPR describes multiple different legal bases for processing of personal data. The UK HRA has taken the point of view that for health research, consent is not appropriate as a legal basis under GDPR as there is an imbalance of power in the relationship between the data controller and the patient. Thus, they stipulate that for Universities, public hospitals etc, processing of personal data for research should be a 'task in the public interest' while for commercial companies and charities, processing of personal data for research should be undertaken within 'legitimate interests'. Note, the requirement for consent still exists for ethical purposes and in accordance with the common law duty of confidentiality. Can you comment on whether this approach could also be explored further for possible application in Ireland?

It is not for the Department to comment on the approach adopted in another jurisdiction where there has been and continues to be different rules and structures (including research ethics structures) for health research. We would, however, point out one thing that you cite in the HRA advice: namely, that the requirement for consent still exists for ethical purposes and in accordance with the common law duty of confidentiality. That indicates that the HRA is saying you need consent for processing personal health data irrespective of the Article 6 ground and Article 9 condition.

We have sought to be clear in our own approach: namely, the requirement for explicit consent in the Health Research Regulations is a suitable and specific safeguard distinct from Article 6 grounds and Article 9 conditions and arises from the distinct requirement in the GDPR for appropriate suitable and specific safeguards whenever special categories of personal data are being processed.

What would be the legal basis for processing health data in order to anonymise it prior to sharing with a third party?

Anonymisation can only take place because a data controller already has the personal data and presumably obtained it transparently, fairly and lawfully. A data controller who obtains personal data from a data subject should where he expects to anonymise the data and then disclose it advise the data subject of such intention in line with the GDPR principles of transparency and fairness. Failure to do so could render the anonymization unfair. However, it is only where the Article 6 ground and Article 9 condition were consent and explicit consent respectively that there is a legal obligation to go back to the data subject for permission to anonymise (unless the data subject was informed of the anonymization or potential anonymization at the time the data was obtained from him or her).

4. Legal basis for patient chart review (also known as medical chart review/ retrospective chart review):

An essential element of some research studies is reviewing patient charts as a prescreening activity. The steps involved prior to approaching the patients would be outlined in the protocol which is reviewed during study approval/ethical approval process. Once patients are approached, they can be asked for their explicit consent but obviously cannot consent before being approached. Thus, what legal basis should cover the pre-screening activity? Would GDPR Article 6(1)(e) public interests and Article 6(1)(f) legitimate interests be appropriate for public

institutions and private 3 institutions respectively, in combination with section 54(b) of Irish Data Protection Act 2018?

It is for a researcher to determine the applicable legal basis in Article 6. If the research is "public interest" research then Article 6(1)(e) may well be appropriate. If the research is being carried out by a private sector entity, legitimate interests may be appropriate. However, everything depends on the particular circumstances: for example, a private sector research project could argue that its research is in the public interest. Legitimate interest as a ground should be just that –legitimate interest- rather a catch all when everything else has failed. Further the use of legitimate interest (given its vagueness) is likely to be subject to higher scrutiny and more rigorous safeguards than other grounds. Moreover, if the research involves a public/private partnership (and creates a Joint Data Controller scenario) the parties involved will have to fully think through the legal basis question. As regards Section 54 of the Data Protection Act, it is an elaboration of Article 9(2)(j) of the GDPR and is the substantive condition applicable to research involving sensitive personal data, which includes personal health data.

However, regardless of which Article 6 legal basis or Article 9(2) condition that are relied on by the researcher, where the data processing is for the purpose of health research then suitable and specific measures outlined in the Health Research Regulations apply.

The definition of health research in the Health Research Regulations 2018 includes the line "may include actions taken to establish whether an individual may be suitable for inclusion in the research". The use of the word "may" in the Regulations aims to distinguish between:

> a) the actions of a health professional (who is providing care to the patient) searching through his or her records, and
> b) the actions of another person (unconnected with the care and treatment of the patient) going through the records.

In the first case, the search will not require explicit consent. In the second case, it will require explicit consent because of the involvement of the third party.

In a specific example of pre-screening/candidate selection: There are currently 2 places available on a trial. The potential candidates are no longer patients in the hospital and have not given explicit consent to have their data used for possible

selection for trial purposes. However, this trial will potentially be of great benefit to these candidates. How is it possible to contact these people without accessing their data?

The hospital that has treated those patients will have their medical records which are held for the purpose of the care and treatment of the patients. There is no difficulty with the health professionals who were involved in their care and treatment going through those records and identifying them for possible inclusion in the trial. However, contact details cannot be passed on to a third party without the health professional getting the explicit consent of the individuals concerned.

Can a Data Controller give e-mail contact details for recruitment to a health researcher without notifying people about this?

No

Should we consider implementing a policy whereby patients, either at admission or at discharge are asked if their data can be reviewed in the future for potential recruitment into research?

That is certainly an option –and one worth pursuing- but bear in mind that they must be suitably informed so as to make a decision and allowed time to make that decision.

It must also be made clear to the patient that their decision will have no bearing on the standard of care they will receive now or in the future.

Research involving medical chart review within the hospitals, often performed by medical students and a very important part of undergraduate training, generally does not consent the patients. Previously these studies sought REC approval for a waiver to consent. How should these studies proceed now?

As explained previously, consent waivers by RECs never had any legal validity so the problem has not been created by GDPR, the Data Protection Act or the Health Research Regulations. It is simply that the problematic practice is now revealed and must be addressed by the research sector. For its part, the Department is willing to look at possible options that might help if suitable options can be identified consistent with the parameters of GDPR and protecting the rights of data subjects.

5. Return of research results to patients

Under GDPR and the health research regulations, will patients be allowed to ask for their individual results of research (Article 15: Right of Access)?

Under the GDPR, the right of access conferred by Article 15 can be restricted and that was done in the case of research in section 61(2) and (4) of the Data Protection Act (which should be consulted by health researchers). Any intended limitation on the right of access must be fully explained to the data subject when explicit consent is being obtained as it may influence his or her decision to allow their personal data to be processed.

What if we are unclear of the clinical significance of a result or we identify the significance in 5 years' time. Is it our duty to then attempt to go back and inform these patients?

If there is a duty to do so, it does not arise under the GDPR but, most likely in terms of a moral and ethical duty that if a health professional or a researcher has information of direct clinical relevance to an identifiable individual the individual should be advised as soon as possible.

Currently there is huge variation between research studies in terms of returning results to patients with many studies not returning individual results. However, the HSE National Consent Policy QPSD-D-026-1.2 recommends that incidental findings should be returned to a patient (once the patient was given the option at consent stage, and a plan for disclosing findings is approved by the REC). Can you comment on what is required and what is preferable under the new health regulations?

The Health Research Regulations do not impact directly on this matter except to the extent that when obtaining explicit consent from an individual to process his or her personal health data for research purposes the matter of disclosing findings to the individuals should be addressed. As a general moral and ethical principle, where anyone has clinical information relating to an identifiable individual it should be disclosed to that individual unless the individual has explicitly indicated that he or she does not want to know.

6. Deceased persons

How are persons deceased whose information is held by an institution to be treated regarding the lawful basis of processing, given that re-consent would be impossible?

The GDPR, Data Protection Act and Health Research Regulations do not apply to the personal information of deceased persons. Notwithstanding that, any information held that identifies deceased individuals should be subject to the same data security arrangements and general respect as would apply to information about living individuals.

7. Research with minors and those lacking capacity:

Will there be provision in the new regulation for research with minors and those lacking capacity?

The Regulations cannot and do not change the law in relation to minors and those lacking capacity.

Will the Assisted Decision-Making (Capacity) Act 2015 be applicable and if so we note it is not expected to be commenced for at least another 18 months?

The Assisted Decision-Making (Capacity) Act 2015 only applies to persons over 18. Parents or guardians remain as decisions makers for children unless they are a Ward of Court. To answer the question, that Act applies in the circumstances set out in its provisions and health researchers should familiarise themselves with its provisions so that they can address them as necessary.

Are there to be interim provisions?

It is our understanding (subject to confirmation with the relevant Unit in the Department) that there won't be interim provisions.

Which category of decision-maker in the 2015 Act will be able to consent to participation in research?

Assisted Decision-Making is when a person whose capacity to make a decision is in question can appoint a person to assist, co-decide or has somebody appointed to

represent them for the purpose of making a decision. A health researcher will have to establish at the time consent is being sought whether the person from whom consent is being sought is availing of the provisions of the 2015 Act and in what way. It is important to note that the provisions of the new Act are not limited to people with a disability or impairment but applies to any person whose decision-making capacity is in 'question'.

8. Use of mobile devices for handling patient data:

In many heath research studies, the participant information leaflet provides a mobile phone number for participants to contact the researcher. We suggest guidelines are required for researchers that stipulates a) a specific mobile phone is to be purchased and allocated for this role and this role only, and b) the phone should not have commercial social Apps such as Facebook, Messenger, WhatsApp, Instagram etc installed or pre-installed (such as is the case with e.g. the Samsung galaxy note) that could access contact lists or contents of digital communications.

If guidance is required it should be provided by the REC giving ethical approval as these matters are essentially ethical ones.

We also suggest guidance stipulating that commercial Apps such as Facebook, Messenger, WhatsApp, Instagram etc. should not be used to contact or discuss patients (whether research participants or as part of clinical service) see https://www.digitalhealth.net/2018/02/whatsapp-doc-legal-and-practicalperspectives-of-using-mobile-messaging/

As above and it has to be said that using commercial Apps such as Facebook, Messenger, WhatsApp, Instagram etc. to contact identifiable patients or discuss identifiable patients is wholly unacceptable practice.

9. Committee to be established under the Health Research Regulations:

Who will appoint this committee and how will members be selected? There is a strong view that adequate representation from active clinician researchers is essential to its success. We will be pleased to assist in identifying potential members for consideration if deemed helpful.

The Minister appoints the broadly based Committee. The Regulations provide that the Committee shall consist of persons who in the opinion of the Minister, having regard to the functions of the Committee, are suitably qualified, including: (a) persons with knowledge of data protection law, research ethics, statistics or other relevant knowledge; (b) persons with experience in healthcare or health research; (c) persons who are representative of data subjects.

10. Research Ethics Committees:

While we are aware that Research Ethics Committees (RECs) are going to be re-structured as part of separate legislation, there is a concern that the RECs are currently taking differing approaches/interpretations of GDPR. • In the interim, could multi-centre research seek approval from one REC with Chairman's approval from RECs in other centres?

As it stands, there is little legislative regulation of RECs (outside of RECs dealing with clinical trials of medicinal products). It is for RECs to determine their own procedures consistent with the applicable law on fair procedures. However, see answer to next point.

Some RECs are not receiving applications at present due to confusion about GDPR, others are introducing additional bureaucratic procedures that are delaying research. Can you provide advice, guidance and training to the RECs on how they should handle requests for approvals/amendments during this 9-month period of adjustment? We consider this matter is quite urgent.

The Department is working with the Health Research Board to provide information (including FAQs) on the HRB website on GDPR and the Health Research Regulations. We will work with the HRB, over the next few weeks, to include general information on the points raised under this heading but it is very unlikely that we will be able to provide training in the short term given the resources that would involve. We have engaged with some REC members already and we hope that they will contribute to and review the evolving FAQs on the HRB website and that they will participate in our discussions at the upcoming event on 19 October.

11. Roles and Responsibilities

Who is the Data Controller?

That has not changed under GDPR. Essentially, it is the legal person (who can be an individual or organisation) who controls the controls the contents and use of the personal data involved. As always, It is determined by the individual circumstances of the research project which could see a funder become involved as a joint data controller in some circumstances.

Where the data controller is an organisation (for example, a hospital or a university) the responsibilities of the data controller extend to include departments, sections or units within the organisation (e.g. academic departments, research centres etc.) and employees (including academics, researchers, technicians, research students etc.) that do the actual processing as part of their employment duties. Consequently, there is both corporate and individual employee responsibility to comply with the regulations.

It is possible to have two or more data controllers (i.e. joint controllers). In such circumstances, GDPR requires the joint data controllers to identify their respective roles and responsibilities for compliance and to have a formal agreement of respective roles and responsibilities.

It is extremely important that the data controller or joint data controllers are correctly identified from the outset in any research project because compliance requirements and sanctions for breaches are centred on the data controller in the GDPR, Data Protection Act and the Health Research Regulations. (Data processors must also be properly identified as they too face compliance requirements and sanctions under GDPR.)

Is it the Principal Investigator or the Institution where the data is held?

See answer to above. Where the Principal Investigator is employed by an institution and acts as its employee in the research project then it –the institution- will most likely be the data controller. However, every case has to be determined by reference to the particular organisational facts associated with the research project.

Can a University/hospital be both data controller and data processor in respect to health research?

Yes –and the law in this area has remained unchanged under GDPR.

In a clinical trial, if the sponsor is the data controller, what position does the University/Hospital have - can they be joint data controller?

Yes.

12. Diagnostic samples

Regarding your question as to why samples and data are stored in diagnostic labs without explicit consent, to clarify, we did not mean these samples are used for research, just that they are stored in the diagnostic labs for some time. Many histopathology labs store diagnostic slides and paraffin blocks of tissue in what may be termed a "diagnostic archive". The slides and blocks that make up the "diagnostic archive" are a by-product of diagnosis, and form part of the patient record.

To that extent that they are related to and held for the purpose of patient care and treatment and not for research purposes the personal data associated with the samples do not come within the Regulations. Should that change, even in terms of intention, the matter would need to be revisited and documented.

13. General:

Who does a researcher go to when seeking advice – Data Protection Commissioner or the Department of Health?

The Department of Health and the Health Research Board are legally not permitted to give advice on individual research projects. However, the Department has been working with the Health Research Board to provide a wide range of FAQs. Health researchers should, therefore, always visit that website. Health researchers should also always engage with the DPO in their organisations if they have any data protection issues associated with a particular project. We cannot speak for the Data Protection Commission except to say that Article 36 of the GDPR requires consultation with the Commission in certain cases: namely, that the controller shall consult the supervisory authority prior to processing where a data protection impact assessment under Article 35 indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk.

I hope the above is helpful and we look forward to our continuing engagement with you and your constituent members.

Yours sincerely,