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GUIDANCE NOTES TO SUPPORT AN APPLICATION TO PROCESS OR FURTHER PROCESS PERSONAL DATA FOR THE PURPOSES OF HEALTH RESEARCH COMMENCING BEFORE 8 AUGUST 2018

(RE-CONSENTING)

BACKGROUND

Introduction

Health research delivers enhanced care for patients, promotes the recruitment and retention of outstanding clinicians, ensures better returns on healthcare expenditure and supports broader Government goals of employment and economic gain.

Equally, good information governance is essential to ensure the support of individuals and the public generally for health research. That support is most likely where there is transparency and engagement and where patients feel empowered in relation to their health information which they rightly regard as highly personal and in some cases extremely sensitive.

The Legal Framework

The collecting, use, storage, sharing and disclosure ("processing") of personal data for health research purposes operate within a legal framework. The elements of that framework are

-the General Data Protection Regulation (GDPR) and legislation giving effect to it in Ireland including the Data Protection Act 2018 and the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (otherwise known as and referred to in this Guidance as the Health Research Regulations);

-the Irish Constitution and its right to privacy;

-the common law duty of confidentiality which is at the heart of the health professional-patient relationship; and

-the rights of individuals in relation to their health information under the European Convention on Human Rights and the related case law of the European Court.

Consent and confidentiality in relation to personal health data are very much to the fore in each of the above.

General Data Protection Regulation (GDPR)

The GDPR came into effect in Member States of the EU on 25 May 2018. It permits the processing of personal data for health research purposes where there is a lawful basis under Article 6 (grounds for processing) **and** a condition in Article 9 (conditions attached to the processing of sensitive personal data) is met. In addition, the GDPR also expressly requires suitable and specific safeguards for any processing of sensitive personal data (which includes personal health data).

Those safeguards referenced in the GDPR are listed in section 36 of the Data Protection Act 2018 and explicit consent is one of them.

Health Research Regulations 2018

The Health Research Regulations were made by the Minister for Health under section 36(2) of the Data Protection Act 2018. They contain a definition of health research and set out the specific suitable and specific safeguards required, as per the GDPR, for the processing of personal data for health research purposes.

The Health Research Regulations maintain the existing situation in law where explicit consent is the default position for all processing and further processing of personal data for health research purposes (unless the personal data is wholly anonymised or there is specific legal provision authorising the processing without consent in a particular case).

The Regulations cover new research and research that was ongoing at the time the Regulations were made on 8 August. They provide for a 9 month period of transition (up until 30 April 2019) to allow for current health research projects that commenced on or before 7 August 2018 to reach the consent standard laid down by the GDPR.

The Regulations address the situation where the obtaining of the required explicit consent by a data controller for the processing of personal data is not practicable. The consent declaration process in the Regulations sets out for the first time in Irish law a formal mechanism to allow for a consent declaration in health research in certain limited and specified situations. The Regulations provide that decisions will be made by an independent and broadly based committee appointed by the Minister for Health. The name of that Committee is the **Health Research Consent Declaration Committee.**

Applications for a consent declaration to the Consent Declaration Committee must be made by the **data controller** and it is essential that there is engagement with their Data Protection Officer to ensure that the application and the related research meets all applicable data protection requirements. In the case of an application to the Committee by joint data controllers, the DPO of each data controller must be equally involved.

THE HEALTH RESEARCH CONSENT DECLARATION COMMITTEE

Role and Remit

The role of the Health Research Consent Declaration Committee is to strengthen public confidence in the way that patient information is used for health research. The Committee will work to achieve that goal through transparency in everything it

does. Openness is the best basis for securing and maintaining the trust of the public, individuals and health researchers in the Committee.

The Committee is appointed by and reports to the Minister for Health. The Committee is broadly based in terms of representation so that various perspectives can be brought to bear on applications made to it. Specifically, the Committee will consist of persons:

(a) with knowledge of data protection law, research ethics, statistics or other relevant knowledge such as individuals with an IT security or governance background;

(b) with experience in healthcare or health research;

(c) who are representative of data subjects; for example, patients.

The Committee is not designed to take over the functions of Research Ethics Committees (RECs). RECs play a separate, distinct and important role in the health research process. Applications to the Committee for a consent declaration must be supported by evidence of provisional or final REC approval for the research.

Applications for a consent declaration will be assessed by a minimum of seven members of the committee at least one of whom will be the chairperson or deputy chairperson. There is provision for an appeal from the decision of the Committee to an Independent Appeal Panel appointed by the Minister.

Decision-making by the Committee

The Committee will meet most months and an application should be made to it in good time for consideration.

The Committee may, by notice in writing, request such further information from the applicant as it requires to consider the application including any evidence that it may reasonably require to verify any particulars or information furnished as part of the application.

Where an applicant does not comply with a request for further information within 15 working days of the request being made the Committee must refuse the application.

The Committee may also consult with any person who it believes can assist it in the consideration of an application. For example, an expert in a particular area related to the research in the application.

Conflicts of Interests

Where a member of the Committee has a material interest in any application being considered by the Committee he or she must-

(a) disclose to the Committee the nature of the interest in advance of any consideration of the application,

(b) not seek to influence the decision on the application,

(c) withdraw from any discussion by the Committee on that application, and

(d) take no part in any deliberation or decision relating to the application.

Decisions of the Committee

The Committee may:

- Make a decision that the application does not fall to be considered by them – for example, the research is not health research as defined in the Regulations.
- Make a consent declaration
- Make a consent declaration subject to conditions to protect the interests of an individual likely to be affected by the consent declaration
- Not make a consent declaration
- Revoke a consent declaration
- Review the operation of declarations made by it or by the appeal panel.

Notification of Decision

The Committee will notify the applicant in writing of its decision and the reasons for making the decision.

The applicant may appeal the decision of the Committee where it refuses to make a declaration or where the Committee attaches conditions to a declaration. A decision by the Committee to revoke a declaration can also be appealed (following the making and consideration of representations). Appeals are made to the Minister who will establish an Independent Appeals Panel to hear the appeal.

An applicant who has been notified by the Committee that a declaration has been made in respect of his or her application under the Regulations must confirm in writing to the Committee his or her acceptance of the declaration within 30 working days of the date of the notification of the decision or it will lapse.

The Committee's Secretariat

The Committee has its own dedicated Secretariat. Its role is to administratively support the Committee in all aspects of its work. All correspondence,

communications and enquiries to the Committee should come through the Secretariat.

Making an application to the Committee

Applications must be made on the appropriate Application Form.

The Application Form with attachments should be scanned into one PDF document and emailed to the Secretariat at **secretariat@hrcdc.ie**

There is a checklist at the end of this Guidance that should be consulted before sending the application to the Secretariat.

Applications will be acknowledged by the Secretariat. Where all the questions have not been answered (with accompanying attachments) the application will be returned by the Secretariat.

GUIDANCE

1. These Guidance Notes have been prepared to assist you –the data controller- with making an application to the Health Research Consent Declaration Committee for a consent declaration. The application can only be considered by the Committee where it can be shown by the applicant that consent was obtained in line with the EU Data Protection Directive and the Data Protection Acts 1988 & 2003.

2. The best advice that can be given is to be as open and informative as possible in the answers provided to the questions in the Application Form so that the Committee will have the information it needs to fully consider your application. If the Committee has to come back looking for further information that will delay consideration of your application.

3. Applications for a consent declaration can only be made by a data controller (or where there are joint data controllers by the joint data controllers) and must be signed off by the data controller(s).

4. The Data Controller must engage with their Data Protection Officer in making the application and his or her advice is required to be attached to the application form together with any action taken by the data controller in relation to that advice. In the case of an application to the Committee by joint data controllers, the DPO of each data controller must be equally involved and the advice of each DPO (and action taken) must be attached to the application.

5. You should consult the Decision Tree –Can I apply for a consent declaration- prepared by the Health Research Board and available on this website.

6. The consent declaration process is not there as an alternative to seeking re-consent. The Committee will need to know why re-consent is not practicable.

7. The scope of a consent declaration, if made, will be typically for a defined part of the research project rather than the entirety of the project and the application should be prepared accordingly.

8. A consent declaration, if made, will relate only to personal data that you currently hold.

9. The Committee will also require evidence of consideration of an exit strategy from the declaration if one is made. For example, anonymization at some specified point in the future.

10. The application to the Committee must be in line with the Heath Research Regulations and relate to 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.

11. Please complete the application form in Tahoma font size 12.

PART A: APPLICANT DETAILS

Part A of the Application Form requires information in relation to the applicant. The following points must be addressed.

1. The application must be made by the data controller involved. If the Committee determines that the application is not made by the data controller they cannot consider it.

This may be the person carrying out the actual research (Principal Investigator) or it may be the institution that employs him or her. The question of who is the data controller is always one that is determined by the application of the definition (Article 4 of the GDPR) as it applies to the facts/circumstances of the particular situation. The definition of "data controller" is set out immediately below so that those considering making an application to the Committee can better determine roles and responsibilities in relation to the application consistent with GDPR.

The GDPR defines the data controller as-

"the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data".

By way of example, the HSE is a data controller (legal person), as is a voluntary hospital (legal person), a single handed GP (natural person).

The data controller is fully responsible for all personal data processed on its behalf. Employees of data controllers are not data controllers in relation to personal data that they process in their capacity as employees of the data controller. Nor are they data processors.

If the Principal Investigator is the data controller/applicant, he or she should familiarise himself or herself with the range of obligations that will apply separately and in addition to the Health Research Regulations under the General Data Protection Regulation and the Data Protection Act.

Data processors are third parties who carry out data processing operations on behalf of a data controller. A data processor follows the instructions of the data controller and has no control over the content and use of the data.

See also 3, 4 and 5 below.

2. The lead contact person to receive correspondence/communications in relation to this application must be specified and a telephone number and email address provided.

3. The principal business of the data controller(s) must be given - for example, the data controller may be a hospital or a university and in a collaboration they may be joint data controllers.

4. If there are joint controllers (see Article 26 of the GDPR), they must be identified, the division of responsibilities between them specified and they must sign the application form. Joint data controllers are most likely to arise in a collaborative project between institutions.

5. Care should be taken to distinguish between another data controller involved in the research and a data processor whose sole role is to process personal data on behalf of the data controller. Information on data processors is also required as is a copy of the contract entered into with them –see Article 28 of the GDPR.

6. Any research site/s involved in processing activity must be identified and specified.

7. The name of and contact details for the Principal Investigator must also be provided. If the Principal Investigator is regarded as the data controller, this should be made clear and information provided to support that view.

8. Name and contact details for co-investigator(s) must be provided.

9. Name and contact details for collaborator(s) must be provided and their role(s) in the research set out.

10. If it is proposed to process any personal data outside of the State, you must specify the countries in which this will take place. If any of those countries are outside of the European Economic Area, you must specify the legal basis for the transfer of the personal data to those countries for processing –see Article 45 of the GDPR

11. You are required to specify any person, organisation or group from whom funding or other material support has been sought or is intended to be sought and indicate whether such funding or support has been provided or committed at the time of this application. Material supports would include making resources available or providing assistance with travel expenses etc.

12. You must also specify any sponsor for the research activity (where appropriate). This would be relevant, for example, in clinical trials of medicinal products under the Clinical Trials Directive (and the new Clinical Trials Regulations). Outside of pharma-led trials, in the world of academic-led trials, networks may take on the insurance in order to act as sponsor for trials they approve and are involved in.

13. You are required to specify any person (other than a joint data controller or data processor with whom it is intended to disclose any of the personal data obtained (including where it has been pseudonymised or anonymised) and the purpose of such disclosure. Please note, in answering this question, that disclosure

of personal data (which includes pseudonymised data) obtained under a consent declaration can only be with the consent of the data subject or if it is required by law.

14. It is a legal requirement, under the Health Research Regulations, that research ethics approval is obtained before personal data can be processed for health research purposes. Therefore, in making an application to the Committee, you must provide evidence of REC approval. You are required in this application to list all Research Ethics Committees involved in approval of this research and attach a copy of the outcome letter from each of those RECs. Please also note that in the case of a successful application, the Committee must always be advised of any material change to the ethical approval granted.

PART B: NATURE OF HEALTH RESEARCH AND PERSONAL DATA INVOLVED

Part B of the Application Form requires information in relation to the research you are carrying out. The following points must be addressed.

1. You are required to provide a lay summary of what the research is about and why the application is being made (Max 500 words). As has already been outlined, the Consent Declaration Committee is broadly based with members from different backgrounds and the purpose of the lay summary is to explain the research to a general audience in a way that they will understand.

2. You should be as expansive as possible when describing the nature and objective of the research and the parts of the research for which the consent declaration is sought.

3. You must indicate the start date and expected duration (in months) of the research.

4. You are required to specify the study endpoints and expected deliverables from the research.

5. You must provide an overview of the design and methodology (3 pages max to be attached to the application).

6. You should clearly describe the personal data which you hold and use and explain why the health research requires the personal data described. Particular attention should be paid here to the types of personal data in Article 9 of the GDPR, especially where genetic data is being processed.

7. You must also explain why personal data rather than anonymised data is required for the research.

8. You must confirm and show that the personal data held is not being processed and will not be processed in such a way that damage or distress is, or is likely to be, caused to the data subject.

9. You must further confirm that the personal data collected and used in the research will go no further than is necessary for the attainment of the research objective (data minimisation principle).

10. Data often have a longer lifespan than the research project that creates them. You are required to describe the envisaged data processing activities (reflecting the data lifecycle and not just the research lifecycle) focusing on access, storage, analysis, sharing, transfers, archiving and destruction. A short and helpful video on this subject is available at **data life cycle**

11. You must also confirm that there will be no disclosure of the personal data unless that disclosure is required by law or the data subject has given his or her explicit consent to the disclosure. The purpose of the consent declaration process is to allow the data controller concerned to obtain and use personal data for the research specified in the application. It is not about allowing such information to be disclosed further unless such information is anoynmised and even there the application (see Part A above) must address such a disclosure.

12. The Committee must be informed of the sources from which the personal data has been obtained.

13. If the research involves data linkage between different sources of information, you must describe what is involved and its purpose. In that regard, you should note that the required Data Protection Impact Assessment (see Part D) must include the identification of any data linkages associated with the research and the data protection risk associated with those linkages.

14. You are required to elaborate on the extent to which you have involved patient and user organisations/representatives in the development/oversight of the research to date.

15. The Committee will be interested to know your envisaged exit strategy from a reliance on a consent declaration, should one be made, with timelines to address the issues that led to this application, such that the research described will no longer require support under the consent declaration process. If you will continue to require the support of a declaration over a number of years, you must set out the reasons why that is the case.

16. The scope of a consent declaration, if made, will be typically for a defined part of the research project rather than the entirety of the project and the application should be prepared accordingly to identify the particular part(s) of the research for which the consent declaration is sought.

17. You must set out the reasons why re-consenting is not practicable. This will tie in with your answers to Part D.

PART C: LEGAL BASIS FOR THE PROCESSING OF PERSONAL DATA

Part C of the Application Form requires information in relation to the legal basis of the research.

Under the GDPR, the processing of personal data requires that:

(i) the data protection principles in Article 5 are met

(ii) a lawful ground for the processing of personal data in Article 6 can be identified, and

(iii) that in the case of processing Article 9 type data (which includes health and genetic data) that a condition in Article 9 can be found.

These grounds and conditions are separate from the safeguards including explicit consent in the Health Research Regulations. Public authorities, in particular, should, be aware that the Recitals to the GDPR states that they should not rely on consent as an Article 6 ground given the disparity of power that exist between a public authority and a data subject. Further, the text of Article 6 prohibits public authorities from relying on "legitimate interests" as a lawful ground for processing.

1. You must identify the lawful ground you are using in Article 6 and the relevant condition you are relying on in Article 9 of the GDPR for the proposed processing of the personal data for the research.

PART D: EVIDENCE THAT CONSENT WAS OBTAINED AND EFFORTS MADE TO RE-CONSENT

Part D is concerned with efforts to re-consent.

Your application can only be considered where you can show evidence that consent was obtained in line with the EU Data Protection Directive and the Data Protection Acts 1988 & 2003. If you cannot demonstrate that to be the case, the Committee cannot consider the application in terms of re-consenting. Any relevant documentation that supports the case that such consent was obtained should, therefore, be provided to the Committee.

The Committee will need to be persuaded that reasonable efforts have been made to re-consent the data subjects involved so you should fully outline the efforts you have made. The Committee will consider those efforts to determine their reasonableness having regard to all the factors that are relevant in any case. Accordingly, vague statements like "it would be costly" or "data subjects would be annoyed if we go back to them" are unacceptable and must be fully elaborated. If your claim is based on cost, then you must fully set out the estimates of the cost elements involved. If you are claiming that data subjects would be upset then you should consider providing evidence from a focus group. If the reason for not making any effort is that no contact details exist, the Committee will need to be persuaded that such is actually the case and the reasons for that situation. In every case, the onus is on the applicant to make the case that re-consenting is not practicable.

A consent declaration to which this declaration applies, if made, can relate only to personal data that you currently hold and cannot be blanket consent even if that is what you state to have been obtained previously.

1. You must provide evidence that consent was obtained in line with the EU Data Protection Directive and the Data Protection Acts 1988 & 2003.

2. You must fully outline the efforts have been made to re-consent the data subjects involved.

PART E: INFORMATION REQUIREMENTS, DATA SECURITY ARRANGEMENTS AND TRAINING

Part E of the Application Form requires information in relation to the transparency, and security of the data being collected and used in the research as well as training provided.

Transparency is a new core data protection principle. It can be summarised as requiring the data controller to take such steps, as necessary, to ensure that the data subject will be not be surprised as regards what may happen to his or her personal data held by the data controller. The Health Research Authority has updated it transparency guidance information and you may wish to visit it at

HRA transparency

Technical and organisational controls –which are referenced in Article 89 of the GDPR- to safeguard the personal data you hold or propose to hold are very important to protect against unauthorised access to and use of that data.

1. You must outline the transparency arrangements (highly visible posters, information leaflets etc) put in place to ensure that the data subject would not be surprised that the data controller might wish to use his or her personal data for research and might make an application for a consent declaration in certain instances.

2. The Committee will need to informed about the controls you have put in place to

> (i) limit access to the personal data undergoing processing in order to prevent unauthorised consultation, alteration, disclosure or erasure of personal data;
>
> (v) log persons who access personal data;
>
> (vi) technical, organisational and physical measures to protect the security of the personal data concerned;
>
> (vii) arrangements to anonymise, archive or destroy personal data once the health research has been completed;
>
> (viii) any other technical and organisational measures designed to ensure that processing is carried out in accordance with the GDPR, together with processes for testing and evaluating the effectiveness of such measures.

3. You must attach to the application form a copy of the data protection impact assessment that has been carried out and the DPIA must include the identification of any data linkages associated with the research and the data protection risk associated with those linkages and details of any consultations undertaken with data subjects. On the application form itself you are required to:

(a) set out a summary (max 750 words) of the findings of the Data Protection Impact Assessment that has been carried out and ensure that you have attached a copy of the full Assessment.

(b) indicate the steps you have taken to address any risks identified in data protection impact assessment.

(c) attach the advice of the Data Protection Officer (or each DPO where the application is from joint data controllers) on the research and any actions taken in relation to that advice.

Technical, organisational and other safeguards will not be effective if those involved in the research are not aware of the data protection obligations placed on them. For that reason, it is important that they receive training in data protection law and practice. You must provide that training or arrange for it to be provided and your application must set out the training provided or to be provided with explicit reference to the proposed health research.

4. You must provide information on the training in data protection law and practice that has been provided to those individuals involved in carrying out the health research.

PART F: SIGNATURES -DATA CONTROLLER (OR PERSON DUTY AUTHORISED TO SIGN ON BEHALF OF DATA CONTROLLER)

Part F of the Application Form deals with the formal sign-off by or on behalf of the data controller or joint data controllers.

1. The application has to be signed by the data controller if he or she is an individual (natural person) or where the data controller is an institution (legal person) such as the HSE, university or voluntary hospital by someone duly authorised to sign on behalf of the data controller. His or her position in the data controller's organisation should also be given. Where there are joint data controllers, they must sign individually.

It is important that the application be signed on behalf of the data controller by someone at the appropriate corporate/management level in the organisation. A formal arrangement within the organisation should be in place to ensure that is the case.

2. The application must also be dated.

CHECK LIST

Before you submit your applications…….please

Make sure you are using the correct Application Form

Make sure you have read the Guidance fully and filled in your Application Form in accordance with it.

Make sure all questions are answered and any attachments are attached.

Make sure your Application Form has the correct required names and signatures and is dated. This is particularly important where joint data controllers are involved.

Make sure you have provided contact details.

Make sure you have used Tahoma 12 font.

Make sure you keep a copy of your Application Form.

Make sure that you have emailed it to the correct email address - s**ecretariat@hrcdc.ie**