An Roinn Sláinte
Department of Health

Guidance on Information Principles for informed consent for the processing of personal data for health research

INTRODUCTION

A person proposing to process personal data for health research purposes requires the explicit consent of any individual (data subject) whose data he or she is proposing to process and in order that such consent should be valid and lawful it must be (a) informed and (b) appropriately recorded (thereby making it explicit).

The Department of Health is not permitted to provide advice on the information to be provided to a data subject in any project specific health research study. However, the Department has prepared this note in response to requests from health researchers for guidance on what information needs to be provided researchers in order that consent is informed.

The note sets out:

-an explanation of informed consent;

-general considerations that apply to the information to be provided;

-information principles under relevant headings;

-application of the information principles to broad consent for future uses and biobanking

INFORMED CONSENT

Consent is defined in Article 4 of the General Data Protection Regulation (GDPR)-

'consent' of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.

Informed consent means just that: namely that the individual concerned has enough information provided to him to her to allow them to make an informed decision. It is also important that they are allowed sufficient time to digest and assess that information before being expected to make a decision. Most importantly, they must be assured:

(a) that consent is freely given and voluntary (and even if initially given can be subsequently withdrawn),

(b) that only the minimum amount of personal data necessary for the study is being sought, and

(c) that a decision not to consent will not impact on any care or treatment they receive.

GENERAL CONSIDERATIONS

While the actual information and the related level of detail to be provided in any case will depend on the nature and circumstances of the research study, the most important factor is always good faith on the part of the health researcher not just in the information they provide to the data subject but also in relation to the individual's personal data they then seek from healthcare providers or other data controllers after the data subject has given consent.

The information principles (set out in 1 to 6 below) are ones that every health researcher should address when it comes to obtaining informed consent –none of them are onerous or new but are in line with existing best practice- and the researcher should be able (if asked by the data subject or the Data Protection Commission) to justify why such information was not made available if it was not made available. Further, the list below is not intended to be comprehensive. Other information in relation to a particular study might be relevant as per the good faith approach.

Bear in mind, the onus is on the health researcher to (a) justify what information is or is not provided and (b) ensure that the data subject is not surprised by any use or disclosure of his or her personal health data by the researcher. Moreover, the researcher must always ensure 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 essential that the individual is advised that in the event that he or she decides not to give consent that no attempt will be made to access his or her data and that no application will be made for a consent exemption to the Health Research Consent Declaration Committee. That is the situation in relation to (a) new research and (b) research that was ongoing on 8 August and where no consent has been obtained but must be obtained before 30 April 2019.

The re-consenting scenario is different and as follows. Before 1 April 2019, the researcher (whose existing consent does not meet the standards of GDPR) must make reasonable efforts to contact everyone whose personal data he or she holds in order to obtain fresh consent and advise the data subject that where he or she declines to give that fresh consent that that decision will be respected and that the data will (a) no longer be used for research purposes or (b) deleted if there is no other lawful justification for holding it. In this situation, it cannot be anonymised unless the data subject consents to the anonymisation. Where the researcher decides to make an application to the Consent Declaration Committee it can only be in respect of personal data belonging to data subjects that it was not possible to contact for re-consent despite the reasonable efforts.

INFORMATION PRINCIPLES

(PLEASE NOTE THAT THIS IS GUIDANCE, NOT AN EXHAUSTIVE LIST)

1. GENERAL

- Title and Purpose of the Research
- Description of the personal data to be collected and used
- Reason why identifiable rather than anonymised data is required
- Enumeration of potential benefits that may arise from the research
- Clarification on whether the individual providing the personal data will be advised of any outcome from the research that would impact directly or indirectly on his or her health
- Statement that consent must be freely given and voluntary, that a decision not to consent will have no adverse consequences and advice on how consent can be withdrawn (before anonymisation of the data or publication of results) and the effect of any such withdrawal
- How and to who the data subject can make a complaint in relation to the research

2. DETAILS ON WHO IS CONDUCTING THE RESEARCH

- Identification of the data controller or joint data controllers and contact details for the data controller or joint data controllers and the name and contact details of the data protection officer associated with the research
- Name, title and contact detail of Principal Investigator and relationship to the data controller if he or she is not the data controller
- If there is a data processor, the name and contact details of that data processor and why it is necessary to have a data processor
- Confirmation that the persons carrying out the research or otherwise having access to the personal data are bound by a professional code of secrecy (like doctors) or a contractual code of secrecy (that would means disciplinary action for employees who disclosed or facilitated unauthorised access to the personal data) or some other arrangement that emphasises confidentiality (this may be applicable in the case of medical students).
- Specification of any person who provides funding for, or otherwise supports, the project and any direct or indirect access that person will have to the personal data collected –this is particularly relevant to any commercial involvement with the research and/or the researcher
- Confirmation that training in data protection law and practice has been provided to to those individuals involved in carrying out the research

3. OBTAINING, USE, STORAGE AND DISCLOSURE OF THE PERSONAL DATA

- Identification of the healthcare providers or other persons the personal data will be sought from
- Confirmation that arrangements are in place so that personal data will be processed only as is necessary to achieve the objective of the health research and will not be processed in a way that damage or distress will be caused to the data subject
- Length of time the personal data will be kept (in an identifiable or pseudonymised format) and why it is necessary to keep it for that period.
- Arrangements to be made for the personal data to be archived or destroyed
- Specification of any person to whom it is intended to disclose the personal data collected (whether in an identifiable, pseudonymised or anonymised form)
- Will the results of the research be used or disclosed for commercial purposes
- Description of the data security arrangements in place

- Confirmation that an assessment of the data protection implications of the health research and /or a data protection impact assessment was carried out and an indication of the level of risk identified by either or both
- Statement as to whether the personal data collected will leave the State and if so what countries it will go to and why it is going to those countries

4. RESEARCH ETHICS COMMITTEE

- The name and contact details –does not need to be a named individual- of the Research Ethic Committee that gave ethical approval to the research and whether any of the persons carrying out the research have a link to the Committee or the institution behind the committee.
- The date ethical approval was given by the Committee
- Reporting arrangements agreed with the Research Ethics Committee
- Any conditions attached to the research by the Committee

5. LAWFUL BASIS FOR THE RESEARCH

- Identification of lawful basis for the health research by reference to Article 6 and Article 9 of the GDPR

6. FOLLOW-UP CONTACT

- Any intended follow up contact with the data subject as part of the current or future research

APPLICATION OF THE INFORMATION PRINCIPLES TO BROAD CONSENT FOR FUTURE USES AND BIOBANKS

The Health Research Regulation address the matter of broad consent in line with Recital 33 and the Article 29 Working Party Guidance on Consent (April 2018). The Regulations state 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."

Where broad consent is being sought, the information principles relevant to informed consent (set out in this guidance note) apply. It is for the researcher to provide such information as is necessary and appropriate so that the individual knows what he or she is consenting to in term of the research that his or her information may be used for and by whom. That is particularly so when broad consent is being sought from the individual.

Blanket consent (use of a high level statement seeking consent for future unspecified purposes) is not an option and should not be sought.

As regards biobanks, the General Data Protection Regulation does not apply to biological samples, per se, but it applies fully to the personal data associated with those samples. In relation to biobanks and broad consent, 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.

The following **additional** information principles should apply in relation to informed consent and biobanks where personal data is associated with the biomaterial:

- Nature and purpose of the biobank;
- Governance and funding of the biobank;
- The process for gaining access to the biobank;
- Any partnerships that the biobank is involved in
- Types of samples held and associated personal data (including whether consent to donate biomaterial to the biobank also means consent to access medical records);
- What the biomaterial/ associated data will be used for and what secondary research purposes are anticipated (in particular, any purposes likely to be controversial)
- When relevant, details of whether the research might include whole genome sequencing;
- Access by third parties (including by any person outside the State) to biobank material/ associated data;
- Any linkages projects that might see biomaterial shared with/given to other biobanks (including with or without the associated data being shared or disclosed);
- Any benefits or risks to the individual associated with his or her donation of biomaterial to the biobank;
- Clarification on rights/ownership of samples;
- Whether biomaterial/ associated data will be used by commercial/for-profit entities and whether participants will receive any benefits;
- Where relevant, policy on use/disclosure to third parties for non-research purposes
- Length of time the samples/data will be stored;
- Processes in place if participants change their mind
- Contact details of the biobank and the data controller associated with the biobank

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