NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

Guidance on use of biological samples and associated data

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Regulated studies involving the storage and use of human biological materials and associated data

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1. Collection, use and storage of biological materials related to the clinical study protocol

The study documentation submitted to the National Research Ethics Committees (NRECs) for ethics assessment must clearly state:

- does this study involve the collection of biological material from participants,
- what kind of biological material is to be collected,
- how it is to be analysed,
- how privacy will be maintained, and
- where and for how long it is to be stored,
- how will consent be obtained.

The use of biological materials should correspond to the endpoints defined for the study being conducted. For this reason, any retention periods related to the use of biological materials must be clearly specified in the participant materials. Justification should be provided for the retention of biological samples and associated data beyond the duration of the trial.

In line with national[1] and EU legislation[2] the information set out in the participant information leaflets and consent and/or assent forms, must be clear and unambiguous to the NRECs and the participants what will happen to biological materials and associated data, once the retention period has come to an end.

Research participants who consent for their biological material and personal data to be stored for secondary research purposes must be informed of their right to withdraw their biological material and/or data, without any negative consequences. Where participants wish to withdraw their biological material and/or data, it should be clear and transparent what will happen to their biological material and/or data.

Regarding the use of biological materials and associated data, participants should also be made aware of the following:

- any commercial use and benefit sharing,
- any intellectual property considerations,
- the transfer of data and/or biological material to other third-party institutions or third countries,
- how incidental finding will be communicated, or otherwise managed[3].

2. Use of biological materials and associated personal data for optional future research

- *Lawful and ethical consent*

The future use of biological materials and associated personal data must always be underpinned by best ethical and safeguarding practices in accordance with national legislation, policy and international instruments.

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[1] The Health Research Regulations at Regulation 6(2)
[2] Article 4 of GDPR, 'Consent'
[3] The HSE National Policy for Consent in Health and Social Care Research, at Section 3.4

Blanket consent for secondary use of personal data for health research has never been lawful and is not lawful under GDPR or in accordance with national legislation, the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018 (HRRs)[4]. In Irish legislation, explicit consent (informed consent that is recorded), is a mandatory safeguard.

Furthermore, the Declaration of Taipei[5] sets out clear ethical principles for obtaining informed consent for the use of biological materials and associated data.

> *Section 11: The collection, storage and use of data and biological material from individuals capable of giving consent must be voluntary. If the data and biological material are collected for a given research project, the specific, free and informed consent of the participants must be obtained in accordance with the Declaration of Helsinki.*

While there is no legislation in Ireland regarding the use of human biological materials for health research purposes, the NRECs consider it essential to observe international instruments and national best practices and policy of informed consent for the use of biological materials, to the same standards that explicit consent for personal data for health research is required.

Therefore, in line with the requirement of explicit consent for the use of personal data for health research under the HRRs, consent sought for future use of biological materials should also be explicit.

Notwithstanding the requirement to seek explicit consent, the HRRs provide for broad explicit consent as long as it is informed within a disease/health/research area - (Reg 3(1)(e)):

> *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.*

If broad explicit consent is not possible to obtain, the Sponsor should consider obtaining consent to recontact participants in the future, for consent for specific use for health research, once defined. This should be captured in the participant materials.

Sponsors should also be aware that where consent for the use of personal data for health research cannot be obtained for legitimate reasons, a consent declaration may be necessary to apply for from the Health Research Consent Declaration Committee.[6]

Sponsors should ensure that consent for the use of biological materials for optional future research purposes is clearly distinct and unbundled from consent to study participation. This is to provide assurances to participants that by not consenting to optional future research, their participation in the clinical study will not be impacted in any way. Further information on

[4] DATA PROTECTION ACT 2018 (SECTION 36(2)) (HEALTH RESEARCH) REGULATIONS 2018
[5] Declaration Of Taipei on ethical considerations regarding health databases and biobanks
[6] Health Research Consent Declaration Committee, see Guidance

practice and policy regarding consent protocols can be found in the HSE National Policy for Consent in Health and Social Care Policy.[7]

- *Deferred consent*

In the event a legally designated representative consented on behalf of a participant lacking decision-making capacity, for the future use of biological samples and where the participant then regains capacity, every effort should be made to seek explicit consent directly from the participant, and provide accommodations where necessary to facilitate the consent process (*ie a deferred consent process*).

- *Scope of NREC ethics approval*

Ethics approval from the NRECs for study-specific applications is confined to the specific study described in the protocol and the application dossier. It is not acceptable to use the study-specific application to seek open-ended ethics approval for use of stored biological materials and associated data for future research programmes.

The use of these biological materials for future research purposes to address additional research questions objectives requires further ethics approval from a recognised ethics committee. This should be made clear to participants who consent for their biological materials to be used in optional future research.

[7] The HSE National Policy for Consent in Health and Social Care Research