Guidance Notes - Biobanks

- Due to a number of queries on this topic, these general guidance notes have been drafted to assist Researchers.

- Context and details are essential when applying these guidelines.

- The term ‘biobank’ has not been defined and therefore the term ‘biosamples’ is a general term being used for ease of guidance.
  - E.g. blood, tissue blocks

- A Declaration can only be granted to a Data Controller who is determining the means of data processing.

- A Declaration does not cover the ‘transfer’ of data for other/future projects.

- Third party Data Controllers maybe interchangeable with ‘recipients’ or ‘joint/collaborators’

- The processing of personal data within Ireland falls under the Health Research Regulations.

- Anonymised data does not fall under the Health Research Regulations.

- Please always consult with the Data Controller’s DPO to ensure compliance with data protection legislation.

- Please consult www.hrcdc.ie/guidance / - See Important Clarification: ‘Ensuring explicit consent: Re-consenting/Re-contacting/Transparency’ when considering whether to re-consent
Biobanks - No Consent

Primary Data Controller

- Biobank
  - A Declaration maybe required for the continuation of processing activities associated with the establishment and maintenance of the biobank – i.e. collecting, storing, data alteration (pseudonymisation etc) ‘processing’ activities
  - A Declaration can not cover use for unknown future projects.
  - In this scenario, the Data Controller of the biobank would be the applicant seeking a declaration.

Third Party Data Controller

- Research Project
  - (Internal)
  - A Declaration would be required for the use of biobank samples for a particular project where the processing activity is defined (i.e. scope of project)
  - In this scenario, the Data Controller of the project would be the applicant seeking a declaration.
  - The lead Principle Investigator should liaise with the biobank manager or equivalent to discuss further.

- Research Project
  - (External)
  - A Declaration would be required for the use of biobank samples for a particular project where the processing activity is defined (i.e. scope of project).
  - In this scenario, the third party Data Controller would be the applicant seeking a declaration.
Biobanks - Consent

Primary Data Controller

Biobank

- A Declaration **maybe** required for the continuation of processing activities that currently fall outside the scope of the consent obtained.
- A Declaration can not cover use for future projects.
- A Declaration will not cover the ‘transfer’ of biosamples to third parties.
- In this scenario, the Data Controller of the biobank would be the applicant seeking a declaration.

(Internal) Research Project

- A Declaration may be required for the use of biobank samples for a particular project where the processing activity is defined (i.e. scope of project), but falls outside the scope of the original consent.
- In this scenario, the Data Controller of the project would be the applicant seeking a declaration.
- The lead Principle Investigator should liaise with the biobank manager or equivalent to discuss the consent documentation.

Third Party Data Controller

(External) Research Project

- A Declaration maybe required for the use of biobank samples for a particular project where the processing activity is defined (i.e. scope of project) but falls outside the scope of the original consent.
- In this scenario, the third party Data Controller would be the applicant seeking a declaration.

NOTE: For ease of guidance, it has been assumed that re-consenting is not possible.