

# 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/](http://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

## Third Party Data Controller

### Biobank

### (Internal) Research Project

### (External) Research Project

- 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.

- 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.

- 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.

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

# Biobanks - Consent

