

# Data sharing & biobanks

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# GDPR: Challenges for biobanks

- Data minimisation
- Transfer of data abroad

# Data minimisation

- 1. Personal data shall be:
- (c) adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation')
- Recital 156: The processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be subject to appropriate safeguards for the rights and freedoms of the data subject pursuant to this Regulation. Those safeguards should ensure that technical and organisational measures are in place in order to ensure, in particular, the principle of data minimisation.



# Territorial scope

- Article 3:
- This Regulation applies to the processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union, regardless of whether the processing takes place in the Union or not.
- This Regulation applies to the processing of personal data of data subjects who are in the Union by a controller or processor not established in the Union, where the processing activities are related to:
  - (a) the offering of goods or services, irrespective of whether a payment of the data subject is required, to such data subjects in the Union; or
  - (b) the monitoring of their behaviour as far as their behaviour takes place within the Union.

# GDPR: Broad consent

## Article 5 (b) (1):

Personal data shall be collected for **specified, explicit and legitimate** purposes and not further processed in a manner that **is incompatible with those purposes**; further processing for archiving purposes in the **public interest, scientific or historical research purposes or statistical purposes** shall, in accordance with Article 89(1), **not be considered to be incompatible** with the initial purposes ('purpose limitation');

Recital 33: It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.



# POPI: Challenges for biobanks

- Data minimisation
- Transfer abroad
- Consent
- Responsible person

# Data minimisation

- S.10: Personal information may only be processed if, given the purpose for which it is processed, it is adequate, relevant and not excessive.

# Transfer abroad

- S.72: Can only send data abroad if:
  - Consent
  - Subject to laws or binding agreement that offers substantially similar provisions
  - Contractual agreement between the two parties
- If no consent, can transfer data if for the benefit of the data subject
  - Not reasonably practicable to obtain consent
  - If was reasonably practicable to obtain consent, data subject would likely have consented



# Consent

- S.11(a) Personal information may only be processed if the data subject or a competent person where the data subject is a child consents to the processing;
- S.1: **consent** means any voluntary, specific and informed expression of will in terms of which permission is given for the processing of personal information

# Consent: sharing

- S.12: 12. (1) Personal information must be collected directly from the data subject, except as otherwise provided for in subsection (2).
  - (2) It is not necessary to comply with subsection (1) if—
    - (a) the information is contained in or derived from a public record or has deliberately been made public by the data subject;
    - (b) the data subject or a competent person where the data subject is a child has consented to the collection of the information from another source

# Secondary use of data

- S.13: (1) Personal information must be collected for a specific, explicitly defined and lawful purpose related to a function or activity of the responsible party.



# Secondary use of data

- S. 15: (1) Further processing of personal information must be in accordance or compatible with the purpose for which it was collected in terms of section 13.
- To assess whether further processing is compatible with the purpose of collection, the responsible party must take account of—
  - the relationship between the purpose of the intended further processing and the purpose for which the information has been collected;
  - the nature of the information concerned;
  - the consequences of the intended further processing for the data subject;
  - the manner in which the information has been collected; and
  - any contractual rights and obligations between the parties.

# Secondary use of data

- (a) The further processing of personal information is not incompatible with the purpose of collection if—
  - the data subject or a competent person where the data subject is a child has consented to the further processing of the information;
  - the information is available in or derived from a public record or has deliberately been made public by the data subject;
- (d) the further processing of the information is necessary to prevent or mitigate a serious and imminent threat to—
  - public health or public safety; or
  - the life or health of the data subject or another individual;
  - the information is used for historical, statistical or research purposes and the responsible party ensures that the further processing is carried out solely for such purposes and will not be published in an identifiable form; or
  - the further processing of the information is in accordance with an exemption granted under section 37



# Requirements for secondary use

- Participant must consent to secondary use
- Must fall under one of these conditions
  - Related study
  - Serious and imminent threat to public health
  - Life/health of data subject
  - Information is used for research purposes and not identifiable - commercial activities would not fall under this.
  - Section 37 exemption
- Responsible party must approve



# Waiver of consent?

- A responsible party may, subject to section 27, not process personal information concerning—
  - (a) the religious or philosophical beliefs, race or ethnic origin, trade union membership, political persuasion, health or sex life or biometric information of a data subject

# Waiver of consent?

- S.27(1) The prohibition on processing personal information, as referred to in section 26, does not apply if the—
- (a) processing is carried out with the consent of a data subject referred to in section 26
- (d) processing is for historical, statistical or research purposes to the extent that—
  - (i) the purpose serves a public interest and the processing is necessary for the purpose concerned; or
  - (ii) it appears to be impossible or would involve a disproportionate effort to ask for consent,
- and sufficient guarantees are provided for to ensure that the processing does not adversely affect the individual privacy of the data subject to a disproportionate extent

# Possible waiver of consent

- If original consent does not provide for processing of data, possible waiver of consent
  - Approved by responsible party
  - If for research purposes
  - Privacy protections in place for the individual
  - Public interest, or
  - Impossible/disproportionate to achieve consent
  - Must be unlinked data (prior authorisation required)



# Exemption: S.37

- Granted by the Regulator
- Regulator must be satisfied that
  - the public interest in the processing outweighs, to a substantial degree, any interference with the privacy of the data subject that could result from such processing; or
  - the processing involves a clear benefit to the data subject or a third party that outweighs, to a substantial degree, any interference with the privacy of the data subject or third party that could result from such processing.

# Prior authorisation

- Subject to S.57 prior authorisation required from Regulator if want to process any unique identifiers of data subject:
  - for a purpose other than the one for which the identifier was specifically intended at collection; and
  - with the aim of linking the information together with information processed by other responsible parties;

# Exemption: public interest

- The public interest referred to in subsection (1) includes—
  - the interests of national security;
  - the prevention, detection and prosecution of offences;
  - important economic and financial interests of a public body;
  - fostering compliance with legal provisions established in the interests referred to under paragraphs *(b)* and *(c)*;
  - historical, statistical or research activity; or
  - the special importance of the interest in freedom of expression



# Responsible party

- **Responsible party** means a public or private body or any other person which, alone or in conjunction with others, determines the purpose of and means for processing personal information
- Generally the person who will be fined
- Biobank: PI, REC, Data access committee
- DoH Guidelines must be compatible - likely to be REC

# Recommendations

- Review all consent forms
- Consider dynamic consent
- Review data management plans
- Review all MTAs/DTAs