

This document outlines some things to consider if you are working with data subject to the GDPR and have plans to make the data available as FAIR and/or Open Data. It is written on the basis that you have already outlined the legal and ethical basis for collecting or accessing personal data and now wish to consider how you can share those data post-project. This should be considered in parallel or as part of the ethical approval process.

**If you are working with research data which falls under the GDPR here are some things that you should consider;**

### **GDPR**

- The [General Data Protection Regulation](#) governs the collection, use and storage of personal data from living individuals whether it relates to their public or private life.
- This can include anything from a name, photo, email address, bank details, posts on social media, medical information, even a computer IP address.

### **The FAIR Principles**

- [The FAIR Principles](#) were developed to facilitate the discovery and reuse of research data. FAIR stands for Findable, Accessible, Interoperable and Reusable
- FAIR data does not equate to Open Data, the principles contain the clause 'as Open as possible but as closed as necessary.' This allows for the reality that not all research data can be shared as Open Data.

#### **1. Informed Consent for future use and reuse of the data by others**

- Data sharing should be addressed at the informed consent stage, including informing potential participants of how their data are expected to be used and shared.
- Sharing of anonymised data does not require explicit consent as anonymised data is not considered personal data under the GDPR. However, consent for sharing of anonymised data is part of the ethical research process.
- It is important to tell participants about the benefits of archiving their contribution for future discovery and reuse.
- In the case of qualitative data allowing your interviewee or participant to review their redacted transcript gives them control and allows for informed decision making about data sharing.
- Things to consider and inform your participants of;
  - Where will the data be archived?
  - Are there access conditions will the repository be Open or Closed?
  - What data will be archived (raw data, de-identified, anonymised, transcripts, audio files)?

- If the data will be processed before archiving give details of that for example the anonymisation protocol
- Terms of use of the shared data and any access conditions which will be associated with the data.

## **2. The right to withdraw**

- Under the GPDR participants have the indefinite right to withdraw and request deletion of their data. You should consider how you will facilitate this during active research.
- Once data is anonymised the right to withdraw no longer applies and this should be explained clearly during the process to obtain consent.
- Best practice suggests that you should give a timeframe within which participants can withdraw their data.
- If you are sharing data which has not been anonymised you must consider how the right to withdraw is protected and make participants aware of how they can withdraw their data at any time. In this scenario you also need to consider how participants' data will be kept up to date and how this can be ensured.

## **3. Anonymisation vs Pseudonymisation**

- Data which is pseudonymised is still subject to the GDPR as the assumption is that there is key or a link between an identifiable individual and the data. Data which is anonymised is no longer subject to the GDPR. It is important to make the distinction between them.
- Indicate how the data will be anonymised, give an outline of the process or an example.
- Avoid terms like strictly confidential or fully anonymised as these are hard to define.
- Once anonymised and before sharing the data there should be a review process to consider if any indirect identifiers in the data could be used to re-identify participants.

## **4. Reasons not to share research data**

- Participants do not give their consent. While data which has been anonymised is not subject to the GDPR the question of whether to share the data now becomes an ethical one and guidance on the ethical practice of research suggest that if you plan on sharing data as FAIR and Open Data you should have consent from participants to do so. When developing your methodology you need to consider how this will be incorporated into your workflow.
- There is a continued risk of re-identification or there is a risk of re-identification due to data linkage. In this case it may be possible to share as a FAIR but Closed dataset if a suitable repository is available.
- Ethical considerations; there may be ethical reasons why it is not appropriate to share your research data or other outputs. This is beyond the scope of this document and should be explored when you are applying for ethical approval within your own institution.

## **Resource and references**

<https://ukdataservice.ac.uk/learning-hub/research-data-management/#ethical-issues>

<https://www.hrb.ie/funding/gdpr-guidance-for-researchers/general-gdpr-faq/>

<https://www.dataprotection.ie/en/dpc-guidance>

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