

Sharing sensitive personal data resulting from life science research

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Many Swedish research projects generate sensitive personal data that cannot be shared openly. Which are the options for sharing this type of data?

Presentation outline

- What is sensitive personal data?
- How to comply with the law when sharing sensitive personal data?
- Which are the options for sharing sensitive data?
- FEGA Sweden - an archive for sharing sensitive personal data under controlled access

GDPR: What is personal data?

Personal data is any information that relates to an **identified or identifiable living individual**. Different pieces of information, which collected together can lead to the identification of a particular person, also constitute personal data.

https://commission.europa.eu/law/law-topic/data-protection/reform/what-personal-data_en

GDPR: Special category data (Art. 9)

- Racial or ethnic origin,
- Political opinions,
- Religious or philosophical beliefs,
- Trade union membership,
- **Genetic data**,
- Biometric data for the purpose of uniquely identifying a natural person,
- Data concerning **health**
- Data concerning a natural person's sex life or sexual orientation

“Sensitive data”

Processing is prohibited!

... except for certain cases, e.g. research

Playing by the rules: GDPR

General Data Protection Regulation (GDPR), in Swedish **Dataskyddsförordningen**

From Article 1

”This Regulation protects fundamental rights and freedoms of natural persons and in particular their right to the protection of personal data.”

Important concepts

- Personal data
- Special category data (“sensitive data”)
- GDPR Principles and lawful grounds
- Data controller, Data processor and Data Processing Agreement (DPA)
- Pseudonymization



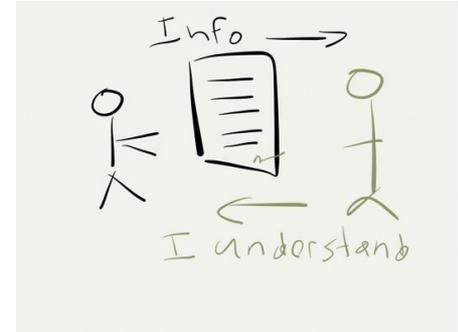
Playing by the rules: Ethical review

Act concerning the **Ethical Review of Research Involving Humans** (*Lag om etikprövning av forskning som avser människor*)

- If your research projects processes special category data under GDPR, you must have an **ethical approval** from the [Swedish Ethical Review Authority](#).
- The project must be approved **before it starts**.
- Depending on the type of research you are doing, you may be required to collect **consent agreements** (*samtycke*) from research subjects.

Ethical review: Informed consent

- The subject must be informed about the **purpose** of the research and the **consequences and risks** that the research might have.
- The subject must consent to participate.
- The subject has the right to **withdraw his or her consent** to participate at any point. Data that has been collected prior to the withdrawal can however **still be used** in the research.
- Consent under the ethical review act is different from *consent as the lawful ground for processing* under the GDPR!
 - In GDPR the research subjects consent to the processing of the data.
 - In the ethical review act the research subjects consent to participate in the research study.



Options for sharing sensitive data

Data regarded as special category data under GDPR may be possible to share under **controlled access**.

However, the number of controlled access repositories is limited. If you want to register a *public metadata record* describing your sensitive data, the following repositories can be considered:

- SciLifeLab is hosting an institutional repository, [SciLifeLab Data Repository](#). If you need any help connected to the SciLifeLab Data Repository, please contact [SciLifeLab](#).
- [BioStudies](#), hosted by the European Bioinformatics Institute (EMBL-EBI).

Options for sharing sensitive data

When you want to share both your public metadata and sensitive data, the following options are soon available:

- The [European Genome-phenome Archive \(EGA\)](#) is a repository for archiving and sharing sensitive personal data from biomedical research projects with a standardized application process involving a Data Access Committee.
- [FEGA Sweden](#) is the Swedish node of the Federated EGA where the public metadata is accessible via EGA but the sensitive data is stored in Sweden.



**EUROPEAN
GENOME-PHENOME
ARCHIVE**



**Federated
European
Genome-phenome
Archive
Sweden**

FEGA Sweden

- FEGA Sweden is an archive for storing and sharing all kinds of data resulting from biomedical research projects
- [FEGA Sweden](#) is expected to become operational after the ongoing discussions between the legal entities
- We are currently working with two pilots: Swedish Childhood Tumor Biobank and Human Developmental Cell Atlas
- Any data submitted to the archive is subject to controlled access
- FEGA Sweden is hosted by the [National Bioinformatics Infrastructure Sweden \(NBIS\)](#)



<https://fega.nbis.se>

Before FEGA Sweden becomes operational, it is possible to create a public metadata record in e.g. [SciLifeLab Data Repository](#) and deposit your sensitive data and public metadata in FEGA Sweden at a later stage.

What are the services of FEAGA Sweden?

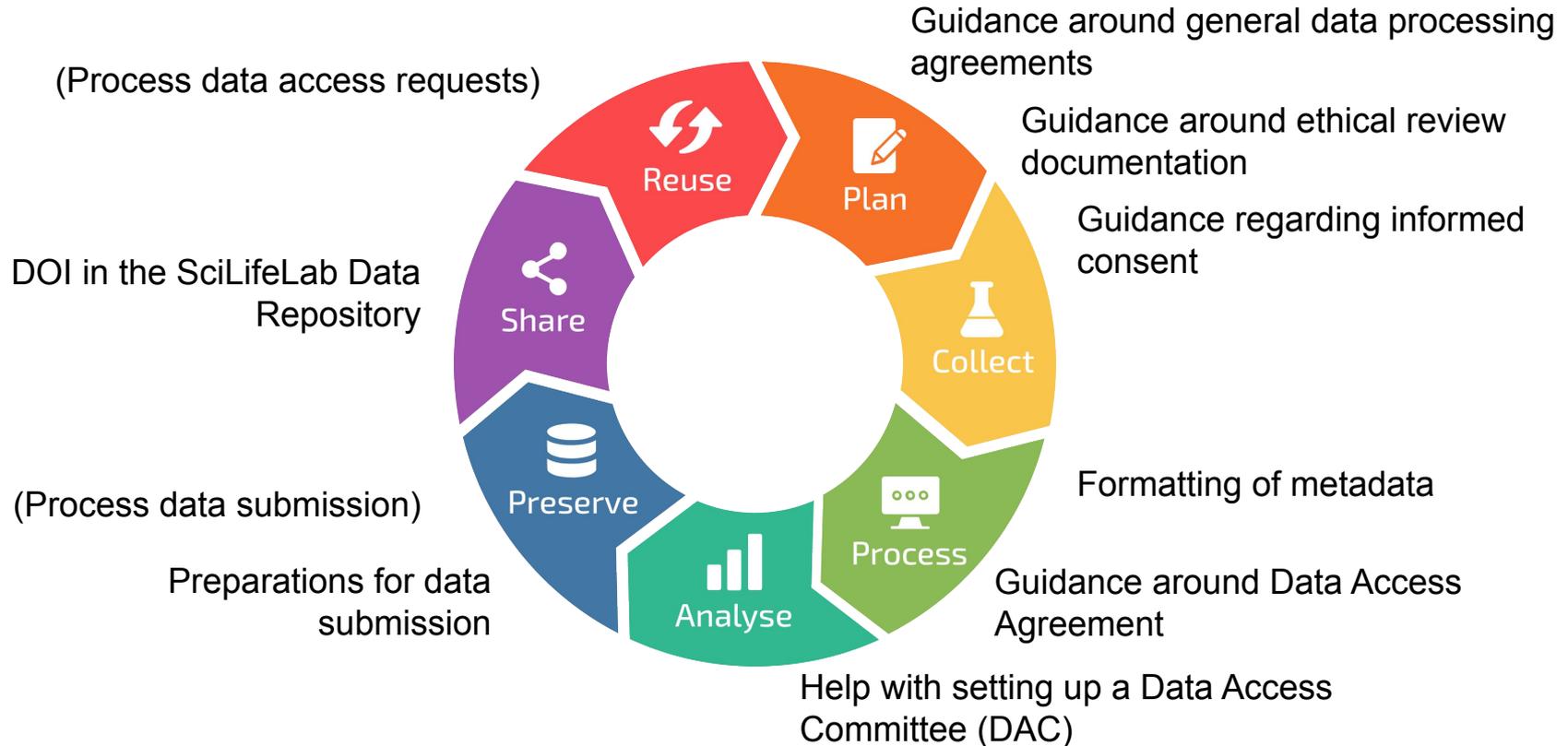


Image credit: <http://rdmkit.elixir-europe.org> (CC BY 4.0)

How should data be described in FEAGA Sweden?

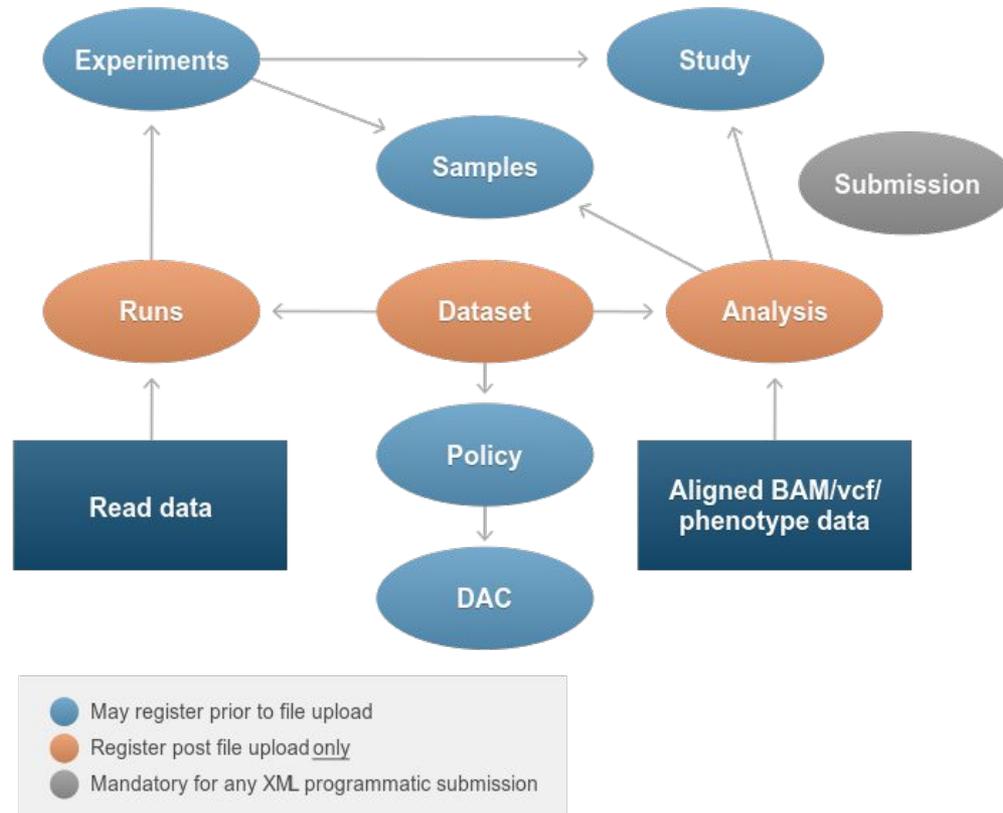


Figure from: <https://ega-archive.org/submission/tools/submitter-portal>

Contact FEGA Sweden

FEGA Sweden website: <https://fega.nbis.se>

Register a submission request:
<https://nbis.se/infrastructure/sensitive-data-archive.html>

Email FEGA Sweden helpdesk: ega-se@nbis.se

Learning more

Guidelines

- [ELIXIR RDMkit](#)
- [SciLifeLab RDM Guidelines](#)

Websites with useful information

- [The Swedish Authority for Privacy Protection \(IMY\)](#)
- [The Swedish Ethical Review Authority](#)
- [Swedish National Data Service \(SND\)](#)