



**LEARN. SHARE. ADVANCE.**

**Speaker:** Korbinian Bösl, University of Bergen

**Chair:** Nazeefa Fatima, University of Oslo



You are welcome to  
turn your video on  
while speaking



Use the 'hand up'  
function if you want  
to contribute directly



Mute yourself while  
not speaking



Or use the chat  
function





**Get your ducks in a row - steps for sharing of sensitive data  
including human genetic data**

*Open Access Week 2021*

**BioMedData**

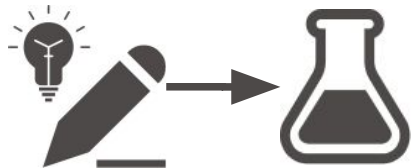


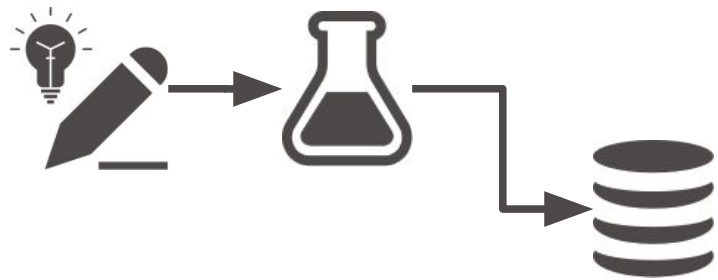
Korbinian Bösl  
Data management coordinator  
ELIXIR Norway/Digital Life Norway

## **Disclaimer:**

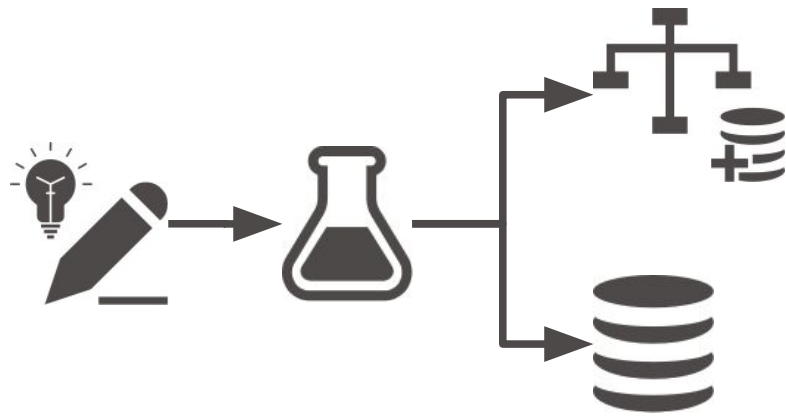
**This presentation is of informative character, does not claim to be complete and does not replace consulting legal advice from your institution.**

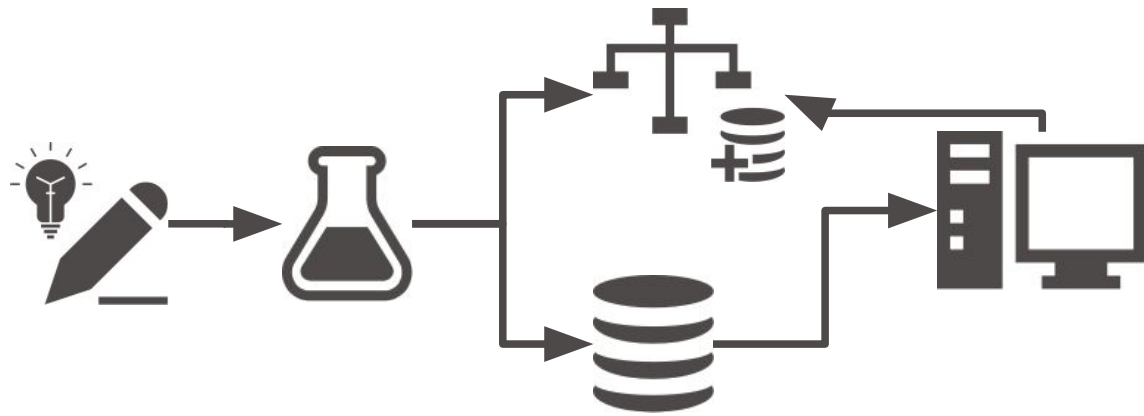


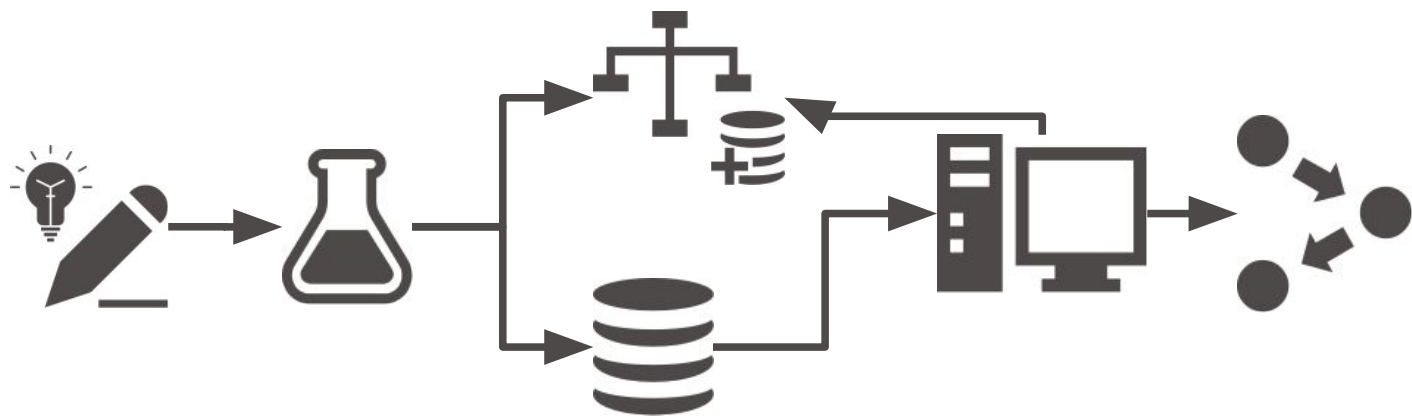


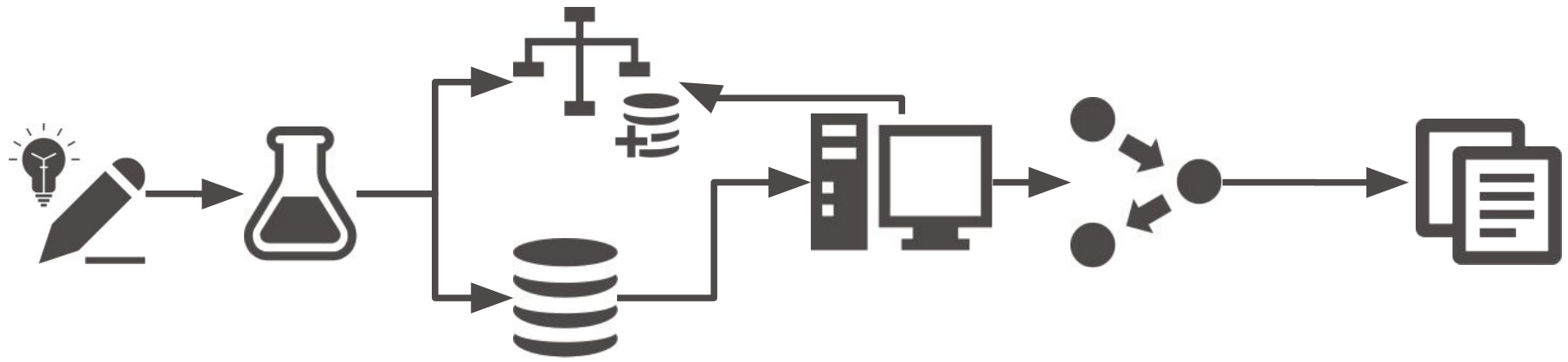


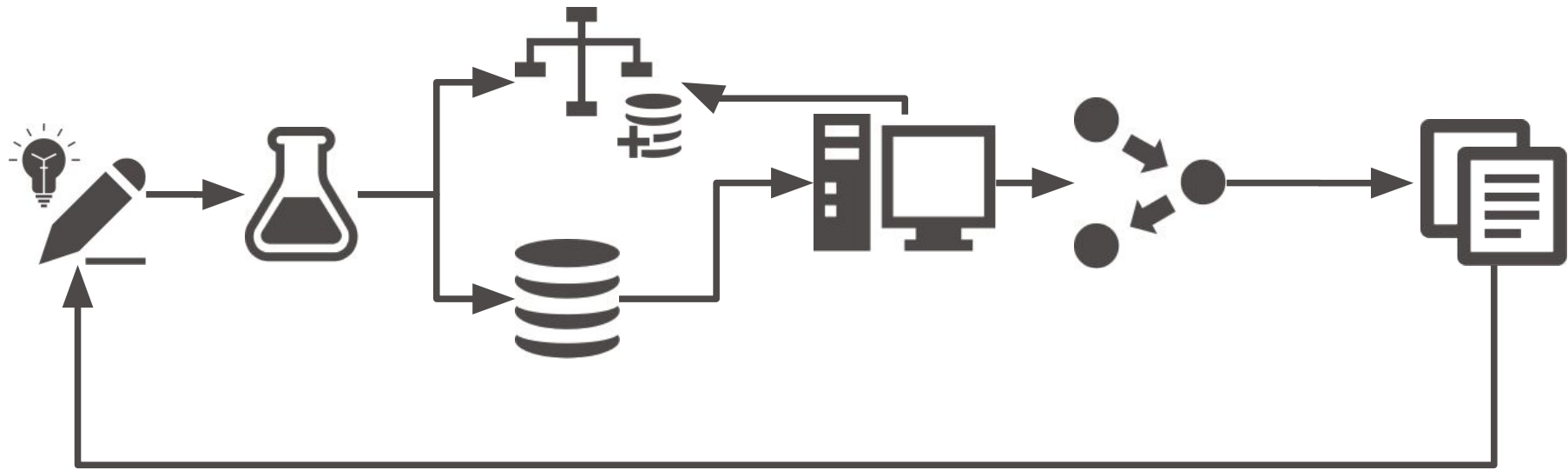


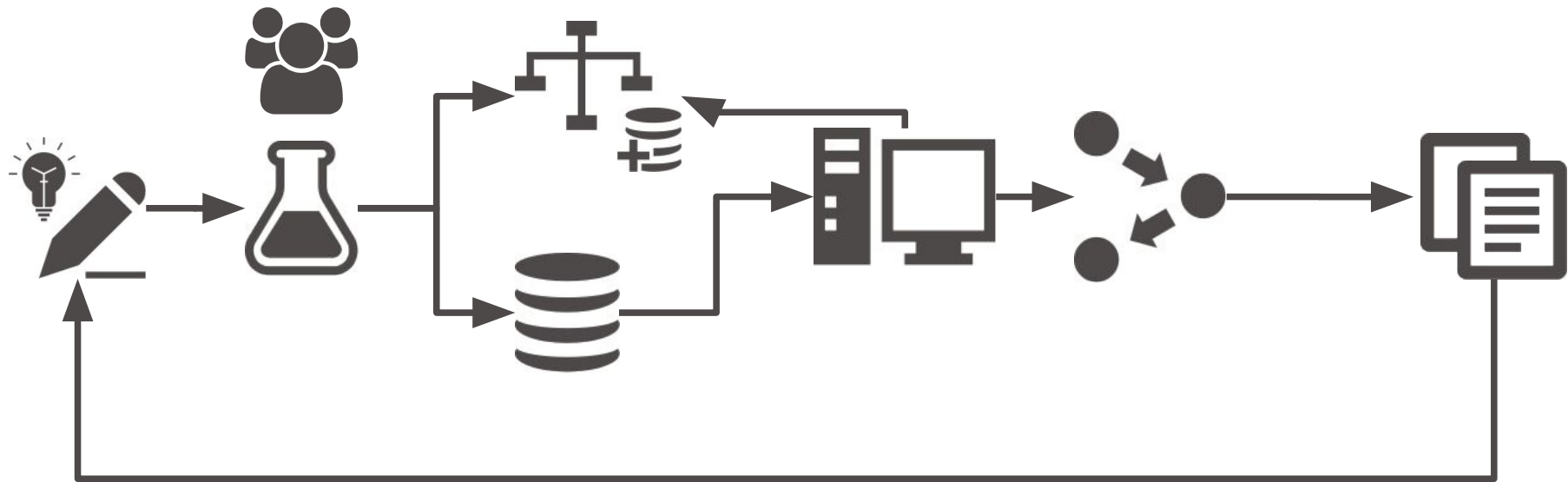












# What is personal data?



A name and surname



A home address



An email address such as name.surname@company.com;



Location data



An Internet Protocol (IP) address



A cookie



Data held by a hospital or doctor, which could be a symbol that uniquely identifies a person.

# What personal data is sensitive?

Personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs

Trade-union membership

Data concerning a person's sex life or sexual orientation.

 **Genetic data, biometric data processed solely to identify a human being;**

 **Health-related data**



# Genetic data

XXX GDPR art. 4(13): Genetic data: “personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person”

Always both: Personal identifier and sensitive information!

# Controlled access data sharing

Data Processor

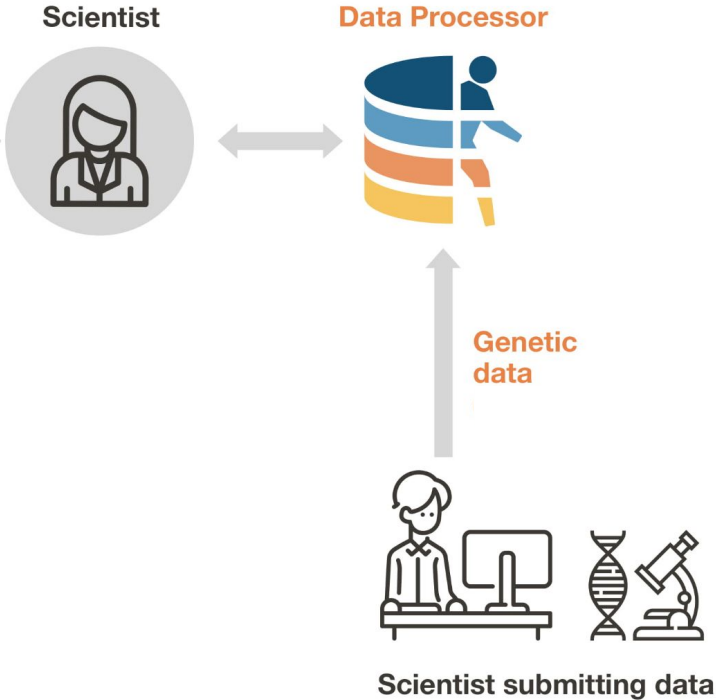


Genetic data

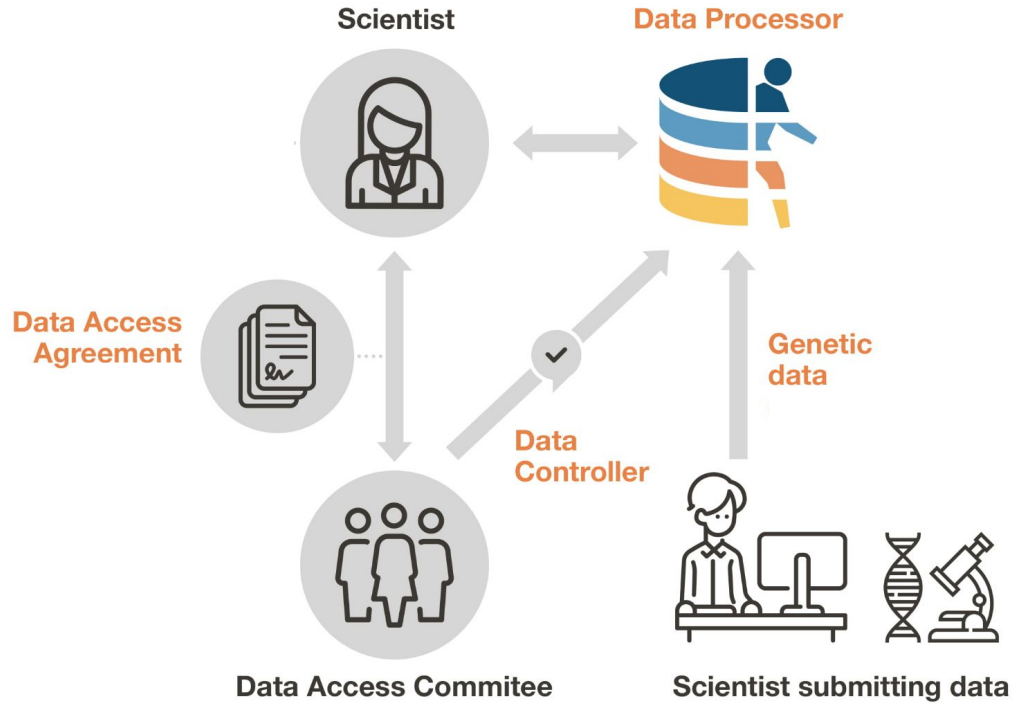


Scientist submitting data

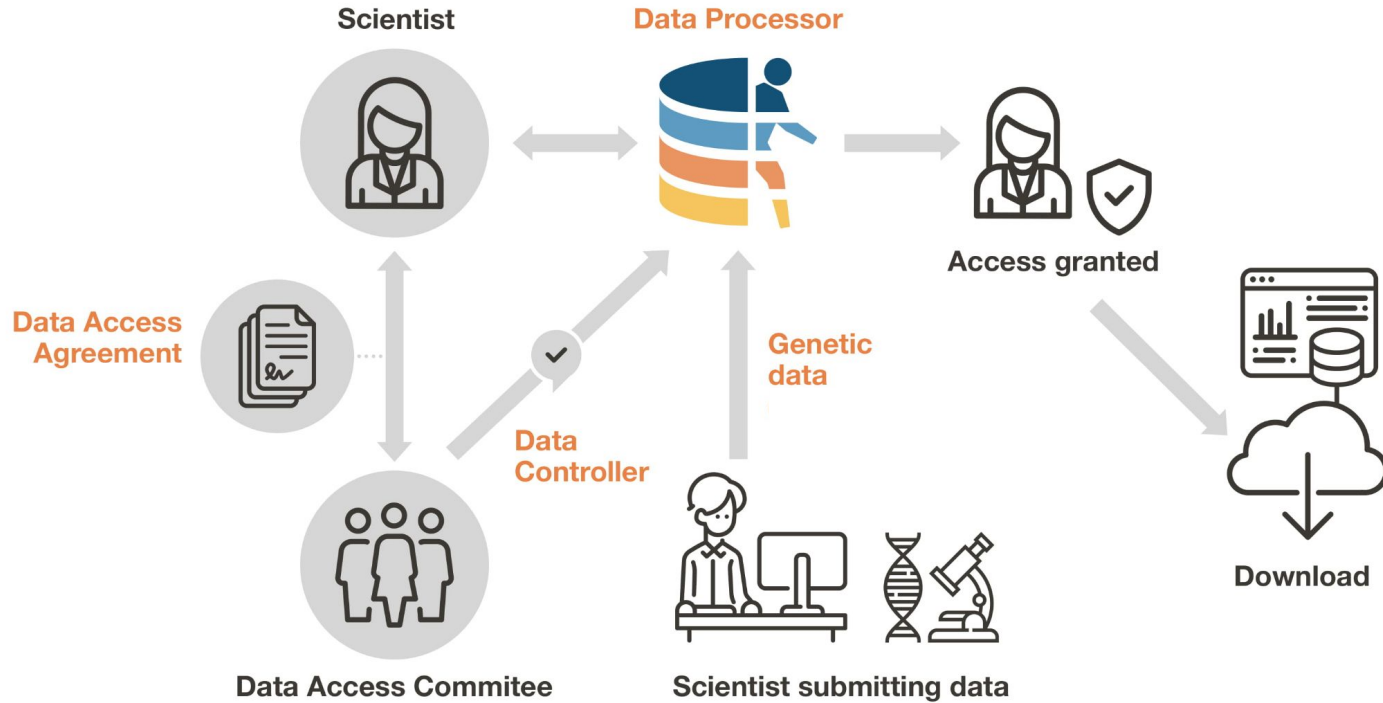
# Controlled access data sharing

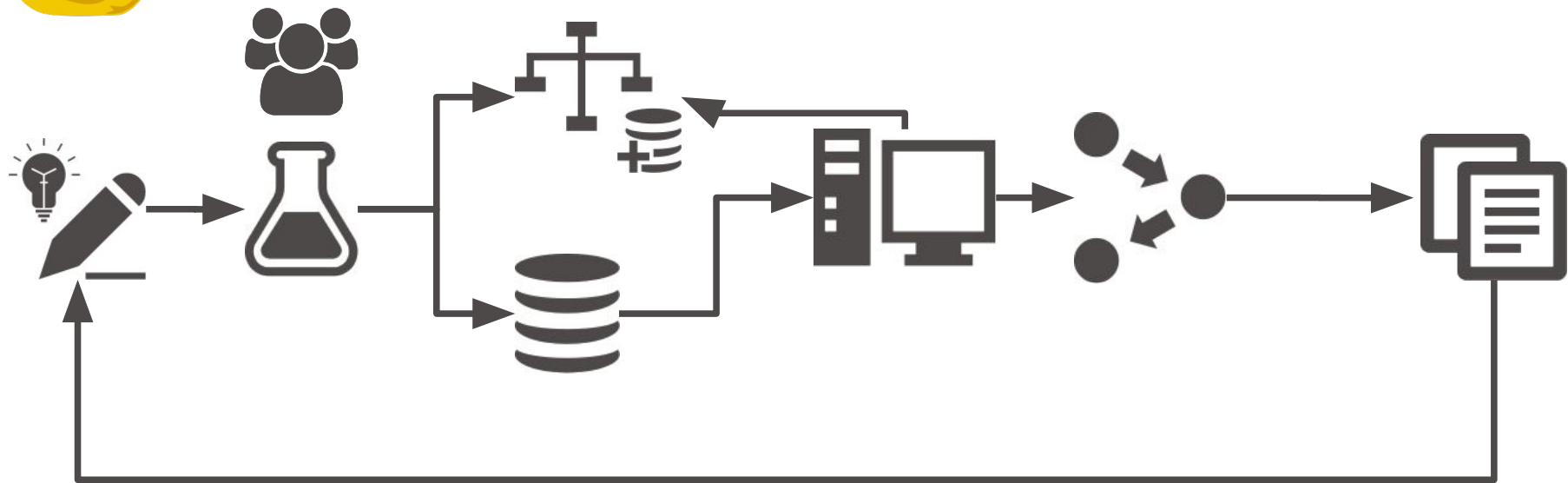


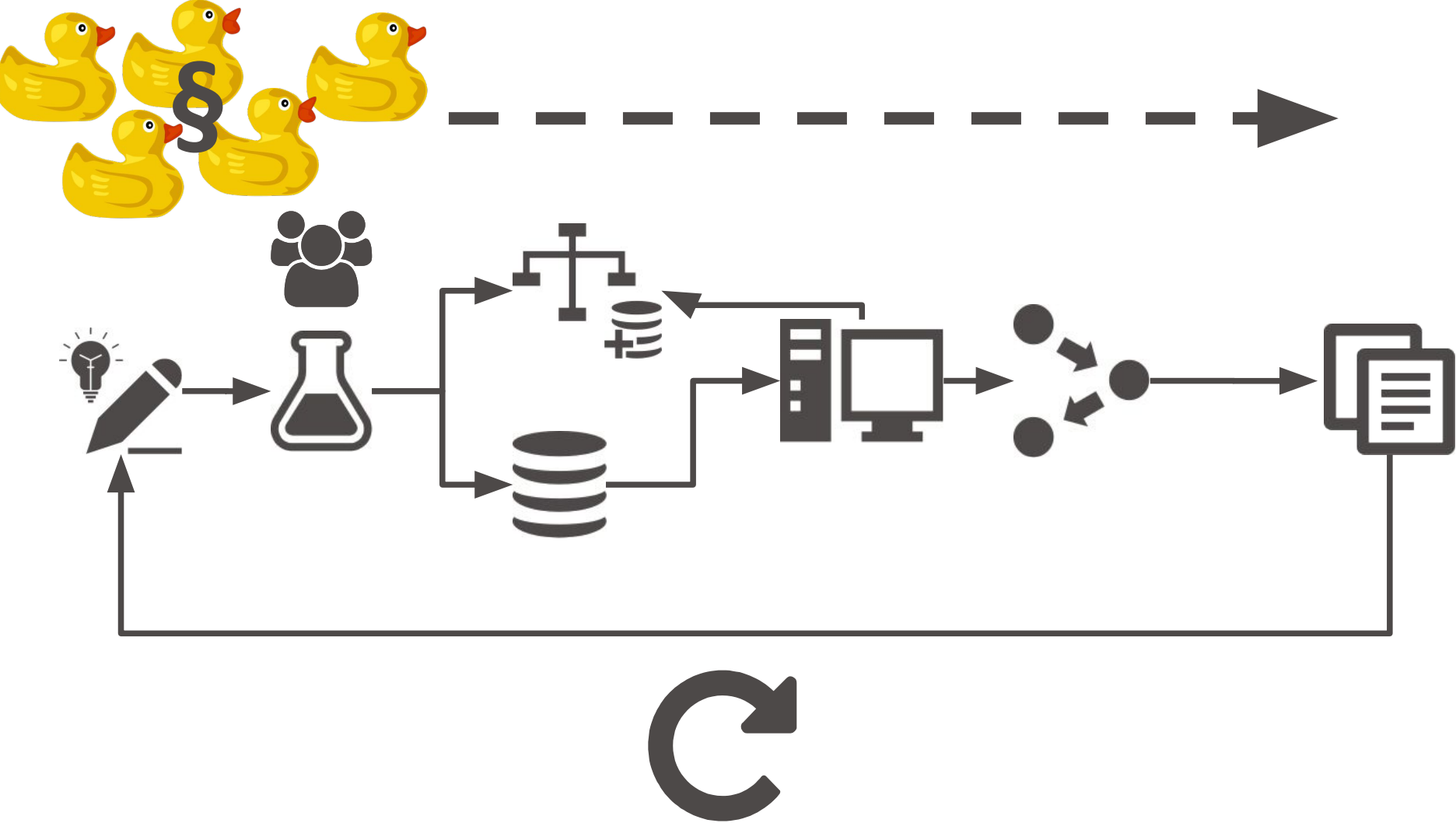
# Controlled access data sharing



# Controlled access data sharing

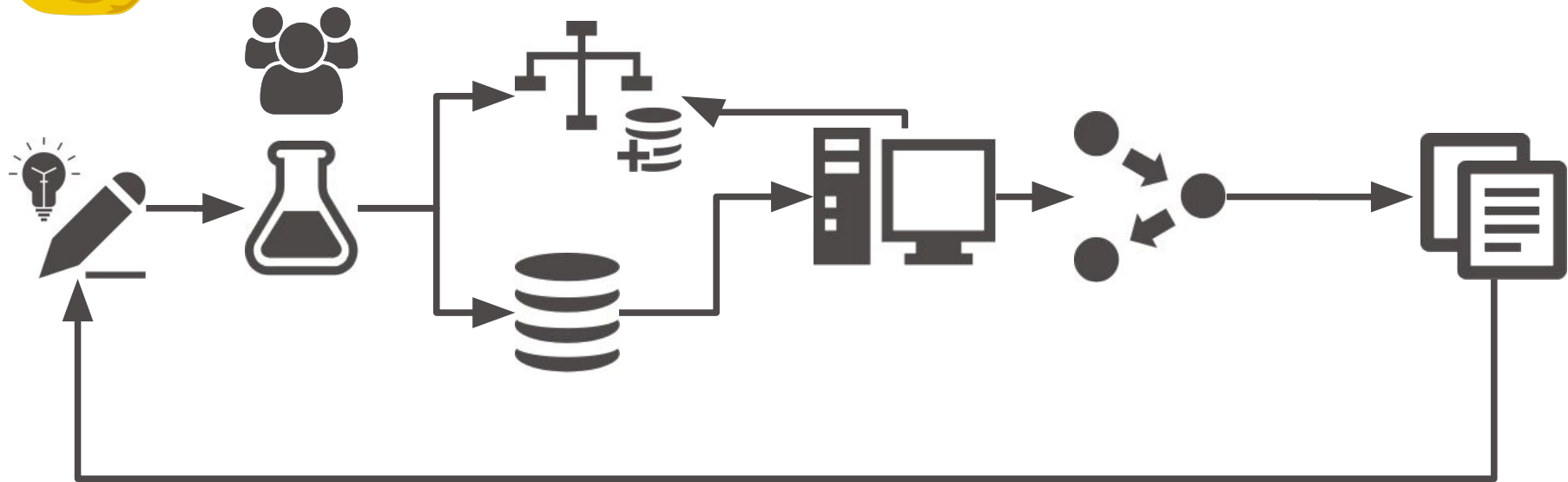




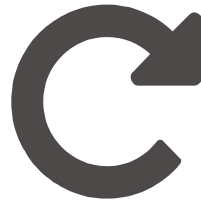
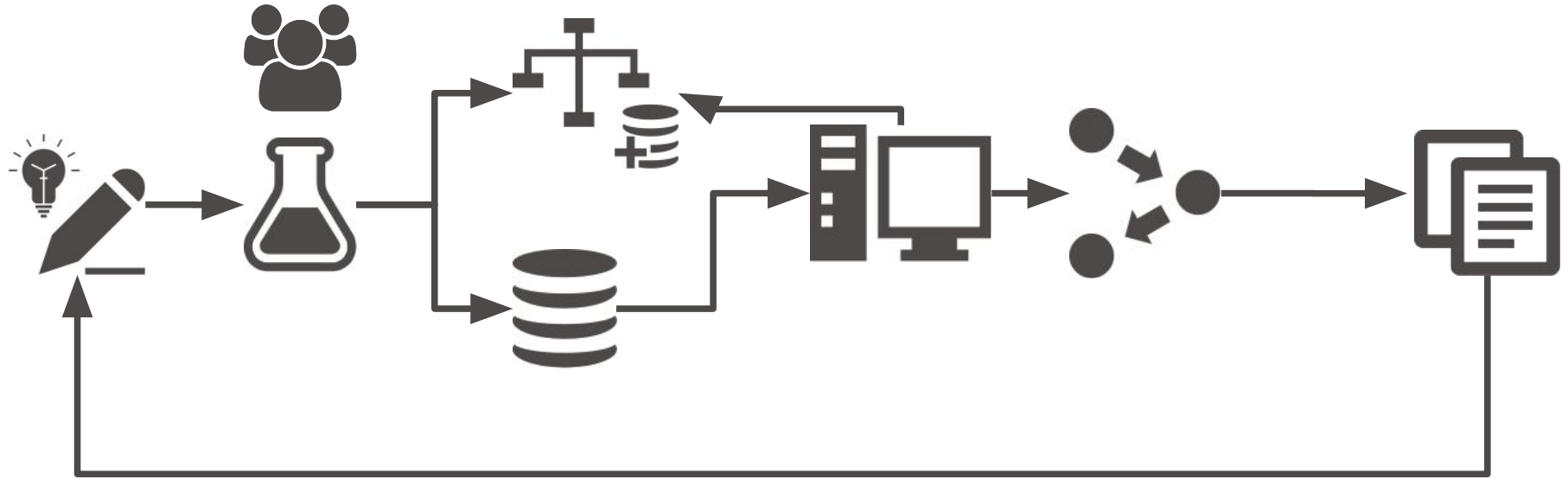




Most often this won't work







# Relevant laws

Research Ethics Act

Health Research Act

Health Registry Act

Biotechnology Act

Archive Act

Patents Act

Copyright Act

Personal Data Act

...

Regulations on the processing of personal data

General Data Protection Regulation



<https://lovdata.no/dokument/SF/forskrift/2018-06-15-876>

<https://lovdata.no/dokument/SF/forskrift/2018-06-15-877>

<https://lovdata.no/dokument/NL/lov/2014-06-20-43>

<https://lovdata.no/dokument/NL/lov/2003-12-05-100>

<https://lovdata.no/dokument/NL/lov/1992-12-04-126>

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<https://lovdata.no/dokument/NL/lov/2017-04-28-23>

<https://lovdata.no/dokument/LTI/lov/2008-06-20-44>

<https://lovdata.no/dokument/LTI/lov/2019-06-21-49>

<https://lovdata.no/dokument/NL/lov/2018-06-15-40>

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2016:119:FULL>

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...

[https://tess.elixir-europe.org/events?node=Norway&scientific\\_topics=Data+management](https://tess.elixir-europe.org/events?node=Norway&scientific_topics=Data+management)

Regulations on the processing of personal data

General Data Protection Regulation



<https://lovdata.no/dokument/SF/forskrift/2018-06-15-876>  
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<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2016:119:FULL>



# Informed Consent



The content form is **part of the research ethics application**

It should include the **general principles** you will apply on

Scientific Aims/Purpose

Data collection

Data processing/analysis

Data archival

Restrictions for Data Access - e.g. research subjects, geographical (adequacy!)

Controlled Access & Data Access Committees

It should be possible to give **granular consent**

Also describe already how you will deal with **withdrawal of consent** or if this is not possible (e.g. due to anonymization)



# Standard consent clauses



**Global Alliance**  
for Genomics & Health  
Collaborate. Innovate. Accelerate.



**Regulatory & Ethics  
Toolkit**



**BBMRI-ERIC<sup>®</sup>**

ELSI TOOLKIT



# Modelling consents - Data Use Ontology (DUO)

- data use modifier
  - clinical care use
  - collaboration required
  - ethics approval required
  - genetic studies only
  - geographical restriction
  - institution specific restriction
  - no general methods research
  - + not for profit, non commercial use only
    - population origins or ancestry research prohibited
  - project specific restriction
  - publication moratorium
  - publication required
  - research specific restrictions
  - return to database or resource
  - time limit on use
  - user specific restriction
- + data use permission
- + investigation



**Global Alliance**  
for Genomics & Health  
*Collaborate. Innovate. Accelerate.*

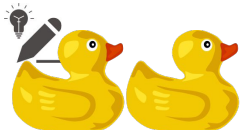
DUO:0000021 ethics approval required  
DUO:0000022 geographical restriction



# Research Ethics Approval - for Health Research

Should outline:

- Data collection
- Data processing/analysis
- Data archival
- Length of Data storage
- Data sharing
- Sharing restrictions
- Data Access Committee



# In parallel: legal basis according to GDPR

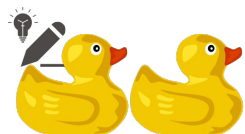
At least one of:

Explicit consent of the individuals

The data is processed for **archiving, scientific or historical research** purposes or statistical purposes on the basis of EU or national law.

Tasks carried out in the public interest

GDPR, Recital 33: “it is not always possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection”





# Data Protection Impact Assessment - DPIA

“Where a type of processing ... is likely to result in a **high risk** to the rights and freedoms of natural persons”

Based on new technologies, the nature, scope, context and purposes of the processing

Your research work is based on:

“Processing of **genetic data** in conjunction with **at least one other criterion**” and

“Processing of **personal data using innovative technology** in conjunction with at least one other criterion”

Identify risks and take measures to reduce the risk; DPIA helps ensure privacy of your data subject(s)



# Approvals from DPO/NSD/Datatilsynet/others

Additional approvals - depending on your institution & research



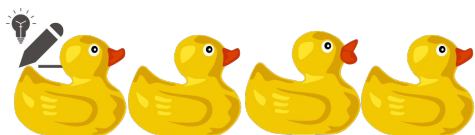
from your Data Protection Officer (DPO)

from NSD on behalf of your DPO

NSD NORSK SENTER FOR FORSKNINGSDATA

Datatilsynet

other authorities



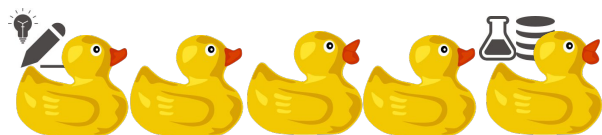
# Secure data processing environment

Personal data must be processed in a manner that ensures:

- appropriate security of the personal data,
- protect personal data against unauthorised access,
- unlawful processing,
- accidental loss, distribution, amendment, or damage



Your institution might have own guidelines+platforms



# DPA with Infrastructure

If the data is

Created

Stored

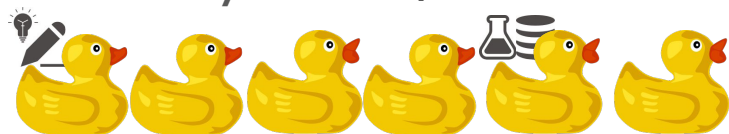
Computed on/Analyzed

...

Externally (outside of your institution) -> **Data Processing Agreement**

If possible: framework agreement with amendments

**Contact your DPO/institution!**



# DCA with collaborators

External Collaborators analyzing data

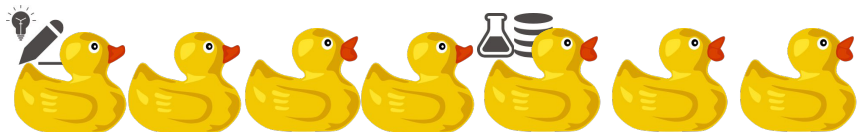


## Data co-controller agreement

“Determines the purposes and means of the processing of personal data”

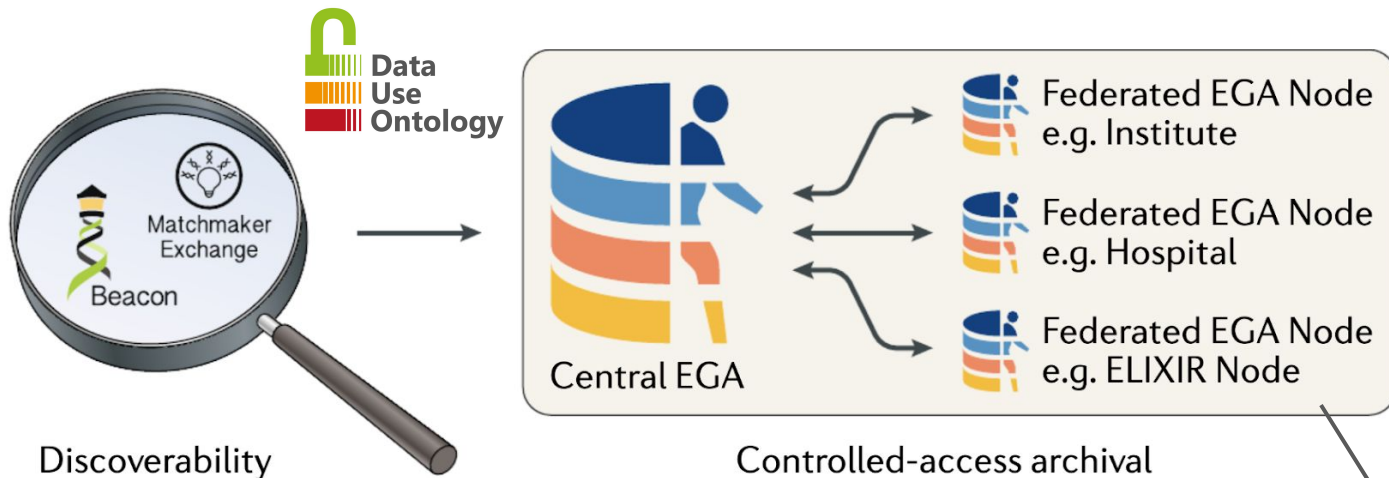
If possible: framework agreement with amendments

**Contact your DPO/institution!**



# Controlled access repository

Specialized repositories allowing controlled access (within country/EU/adequate countries)

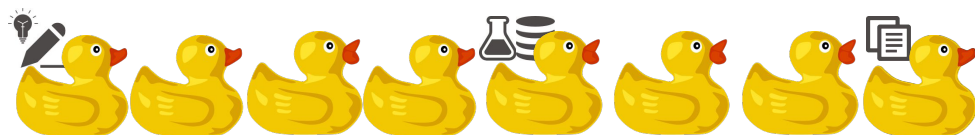


Discoverability

Controlled-access archival

ELIXIR-NO

FEGA soon in production



# Requirements for deposition

Depositing = Data processing

-> **Data Processing Agreement**

Compatible consent clauses

**Data Access Committee**



# Data access committee

Decision on access applications based on consent terms

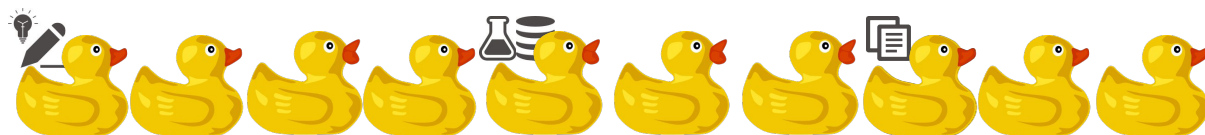
In case of European Genome-phenome Archive: max 2 weeks response time



Institutional  
committees



Project specific  
committee





# Data access agreement - DAA

Contract between Data access committee and the Data (Re-)User's institution

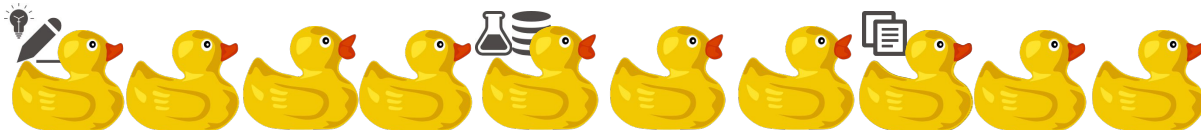
Details on:

data use (restrictions)

publication embargoes

storage

**Standardized, adaptable templates available**

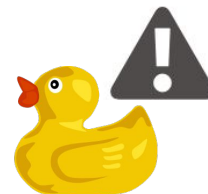
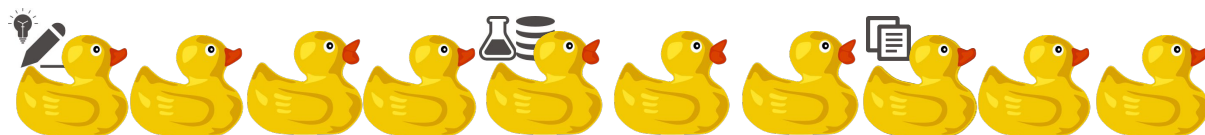


# Accountability & Documentation

“The controller shall be responsible for, and be able to demonstrate compliance with the principles”

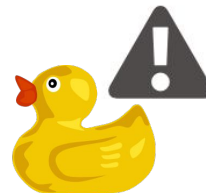
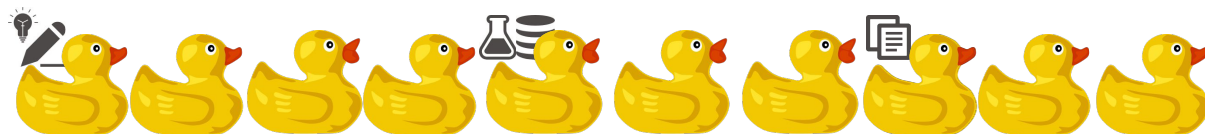
-> Obligation to **document the processing of personal (sensitive) data**

Dedicated tool:



# Checklist for controlled access sharing

- Documentation
- Compatible Consent
- REK approval
- GDPR legal basis
- DPO/NSD/Datatilsynet/... approvals
- DPIA
- DPA with external infrastructure(s)
- DCA with external collaborators
- DPA with repository
- Data Access Committee - DAC
- DAA between DAC and Data (Re-)User





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## Chapters

- I. Administrative information 1
- II. Re-using data 3
- III. Creating and collecting data 6
- IV. Data sensitivity 16**
- V. Processing data 3
- VI. Interpreting data 3
- VII. Preserving data 5
- VIII. Giving access to data 3

# IV. Data sensitivity

Ethical and legal issues




**1.a.1.a.1** For each data set/cohort


NeLS storage request

Sigma2

Desirable: *Before Submitting the Proposal*

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