Human Brain Project

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Responsible Data Governance for Neuroscience: The role of ethics and the law

Eke Okaibedi Damian

Neurohackademy, 2023

DE MONTFORT UNIVERSITY LEICESTER

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What to expect

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At the end of this, you should be able to:

1. Understand the meaning, nature, scope and rationale of data governance in neuroscience
2. Identify the role ethics and the law play in effective data governance in neuroscience
3. Be prepared to identify and address some of the DG issues in your data pipelines

What do I mean by Neuroscience data?

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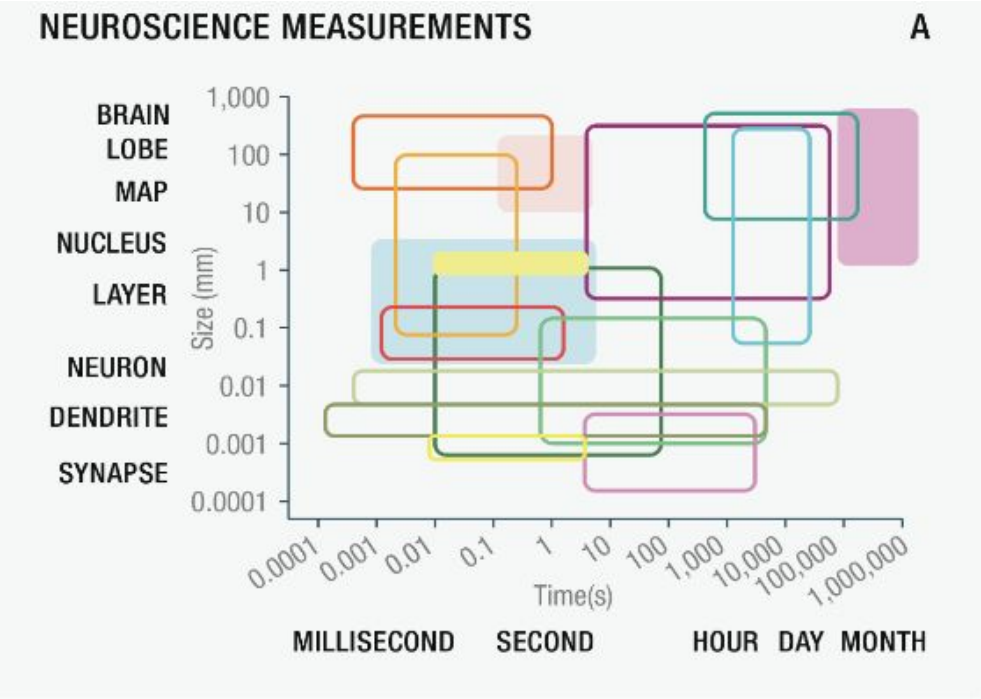

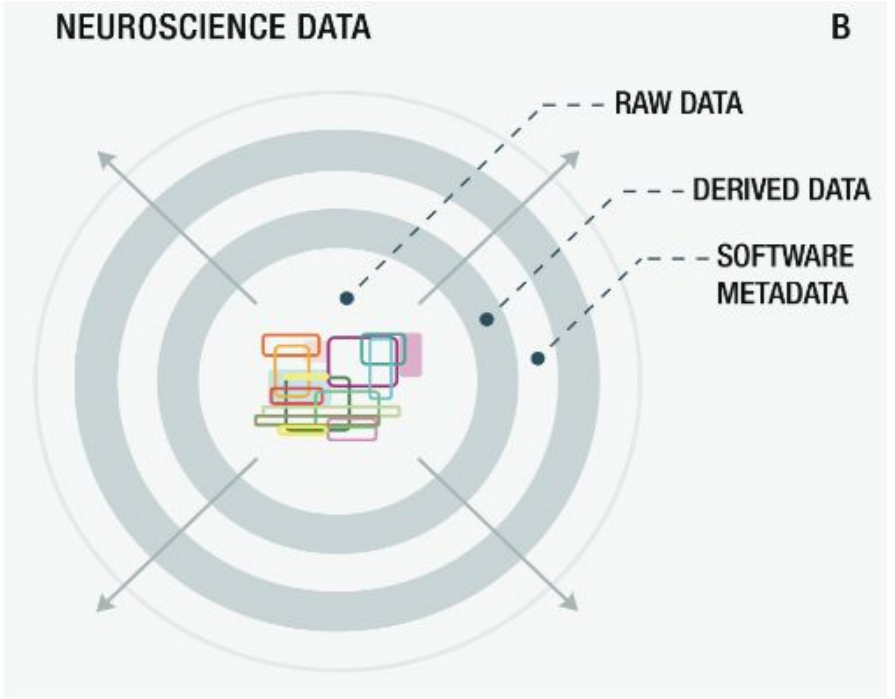

EEG and MEG · VSD Imaging · TMS · 2-DG Imaging · PET Imaging · fMRI Imaging · Brain Lesions · Optogenetics

Field Potentials · Optogenetics · Light Microscopy · Single Units · Patch Clamp · Calcium Imaging · Electron Microscopy · Microstimulation

Eke et al., 2021

There is an increasing need to share these datasets

- Funder's requirement
- Cost reduction
- For Reproducibility
- Increase your citation
- Or simply because it is the right thing to do

…however there are a number of barriers

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- Legal requirements
- Ethical Concerns
- Organisational barriers
- Technical requirements
- Wider socio-cultural concerns

…this is where data governance comes in

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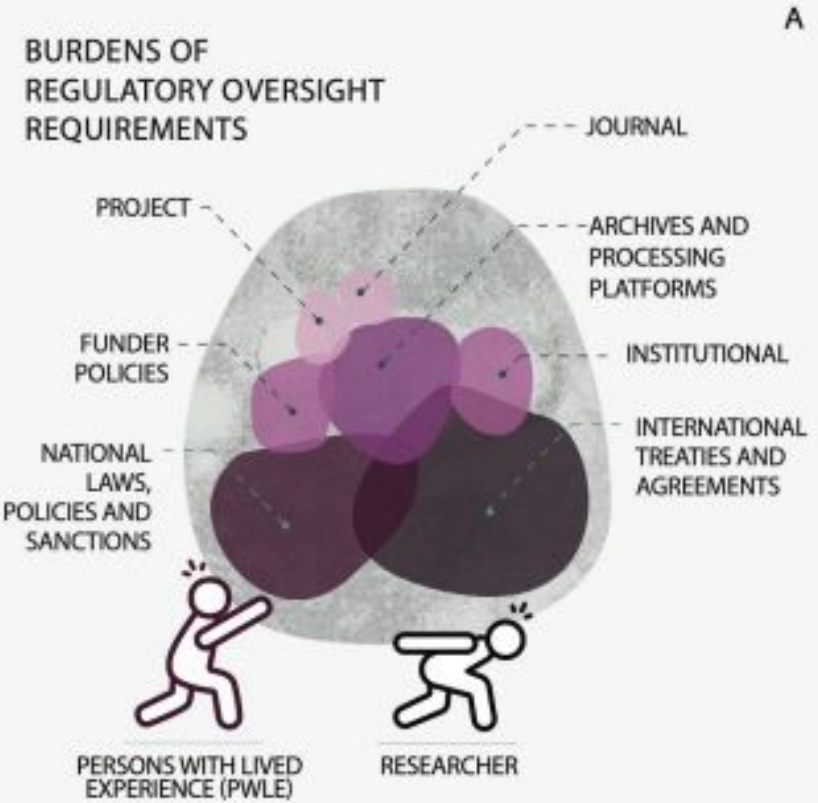

Eke et al., 2021

What is Data Governance?

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"the overall management of the **availability, usability, integrity, quality, and security** of data in order to ensure that the potential of the data is maximised whilst regulatory and ethical compliance is achieved within a specific organisational context"

...Fothergill et al., 2019

DG…Contd

"the principles, procedures, frameworks, and policies that ensure acceptable and responsible processing of data at each stage of the data life cycle, from collection, storage, processing, curation, sharing, and use to deletion"

…Eke et al., 2022

CellPress
OPEN ACCESS

Neuron

Review

International data governance for neuroscience

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SUMMARY

As neuroscience projects increase in scale and cross international borders, different ethical principles, national and international laws, regulations, and policies for data sharing must be considered. These concerns are part of what is collectively called data governance. Whereas neuroscience data transcend borders, data governance is typically constrained within geopolitical boundaries. An international data governance framework and accompanying infrastructure can assist investigators, institutions, data repositories, and funders with navigating disparate policies. Here, we propose principles and operational considerations for how data governance in neuroscience can be navigated at an international scale and highlight gaps, challenges, and opportunities in a global brain data ecosystem. We consider how to approach data governance in a way that balances data protection requirements and the need for open science, so as to promote international

Fundamentally...

Data governance is about the **people, processes/procedures** and **technologies** used to provide an effective and functional data processing ecosystem that not only benefits the organisation but that is compliant with regulatory and ethical principles.

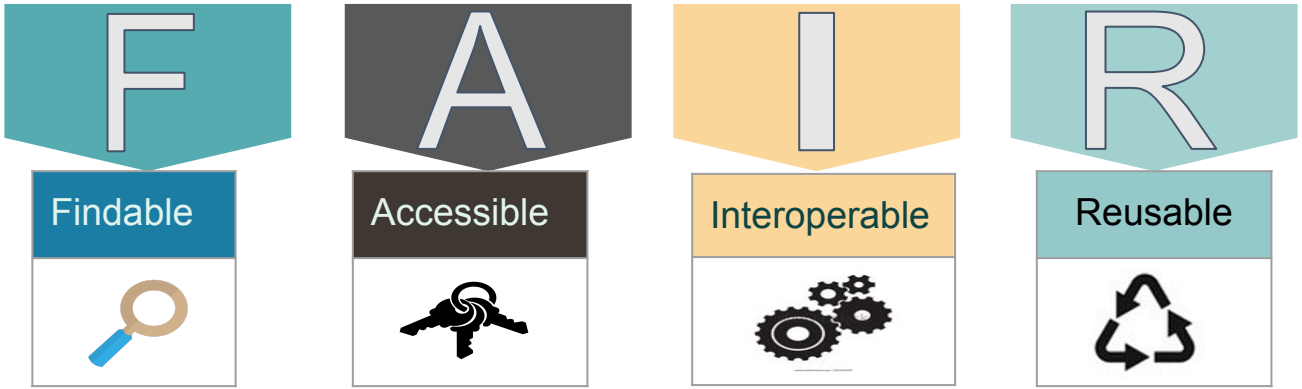
It is not just …

Data Protection →

Data Management →

And Certainly not a ‘Gotya’ process →

DG facilitates …



With data DG it becomes FAIR-C

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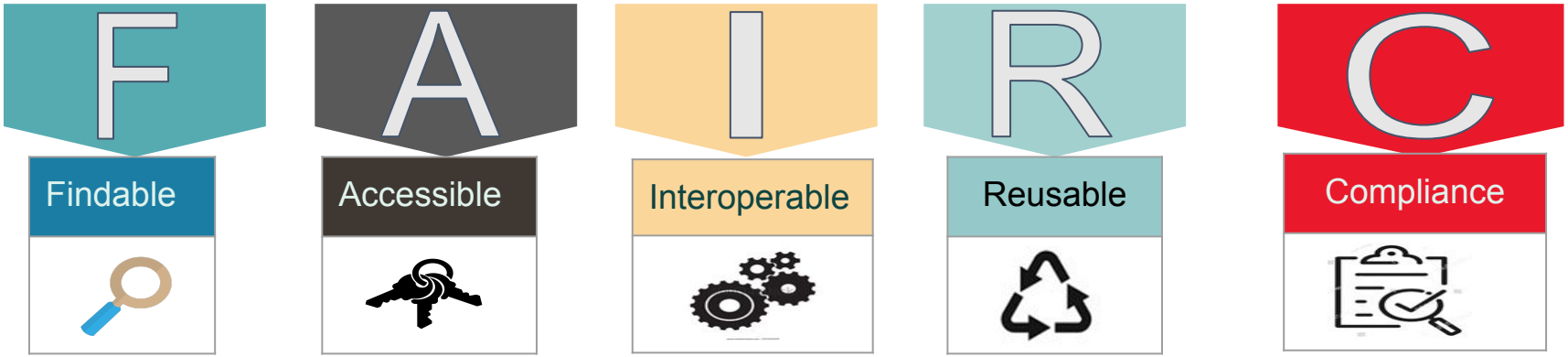

Compliance with …

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- Ethical Principles
- Technical Requirements
- Legal provisions
- Societal Expectations

Technical Requirement

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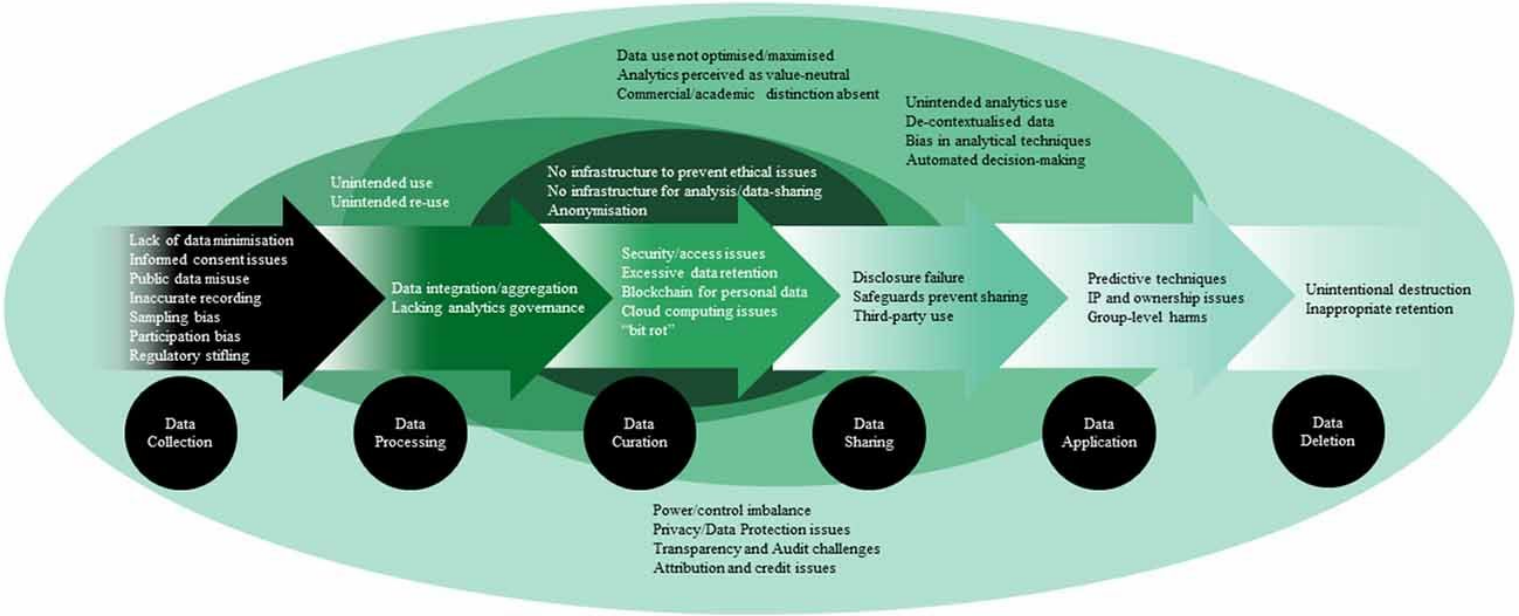
- Metadata standards
- Storage Infrastructure
- Cybersecurity

Ethical concerns



Ethical issues and the overlapping stages at which they may arise in the data lifecycle. - Fothergill et al., 2019

Animal Welfare
Differences (e.g NHPs)

JOURNAL ARTICLE

Transgenic rhesus monkeys carrying the human *MCPH1* gene copies show human-like neoteny of brain development

Lei Shi, Xin Luo, Jin Jiang, Yongchang Chen, Cirong Liu, Ting Hu, Min Li, Qiang Lin, Yanjiao Li, Jun Huang ... Show more
Author Notes

National Science Review, Volume 6, Issue 3, May 2019, Pages 480–493,
https://doi.org/10.1093/nsr/nwz043
Published: 27 March 2019 **Article history** ▾

Ethics

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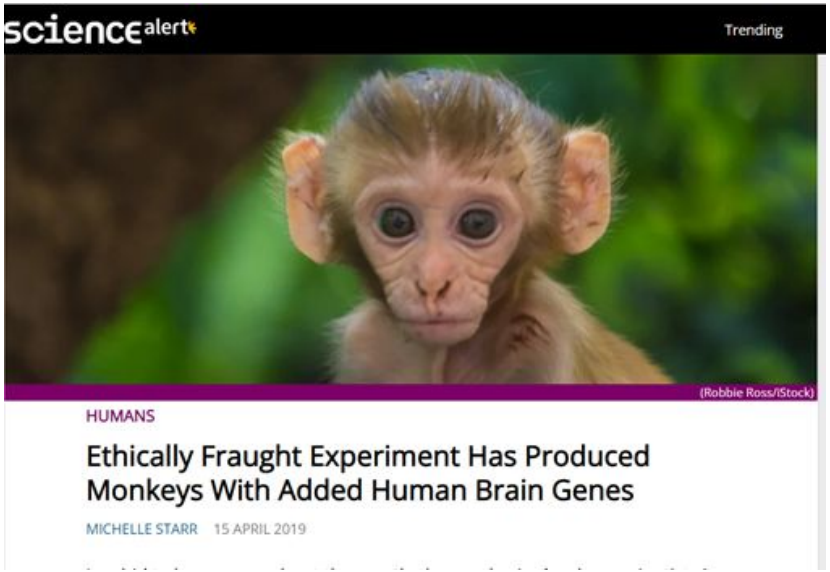

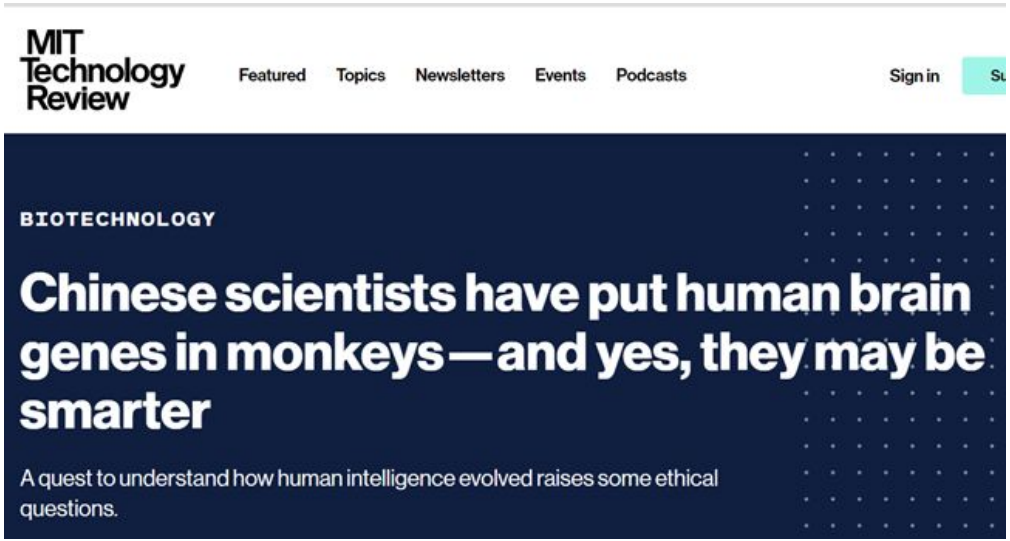

Scientists Breed Monkeys With Human Genes in 'Ethical Nightmare' Experiment

The Chinese experiment has drawn harsh criticism from the global

"There are a bunch of aspects of this study that you could not do in the US," - Martin Styner

Legal concerns

Legal Concerns

- Privacy and Data Protection
- Informed consent
- Data Ownership
- Data Control
- International Transfers
- Regulatory Differences

Legal Considerations & Compliance - GDPR

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- Legal basis for processing

- Technical and Organisational Measures
  - Data Protection Impact Assessment (DPIA)
  - Anonymisation/Pseudonymisation
  - Encryption

- Relevant Agreements
  - Data use agreements
  - Data Transfer Agreements
  - Data processing agreement
  - Joint Data controllership agreement

EU General Data Protection Regulation (GDPR)

GDPR applies to the **processing** of **personal data**

Data processing - "any operation or set of operations which are performed on personal data"

Personal Data is any information relating to an identified or identifiable person

Recital 26 – Identifiable – If anyone can identify a natural person using all means reasonably likely to be used, then the information is personal data.

GDPR

‘General Personal Data’: Names, telephone numbers, email addresses, identification numbers, account related data such as Human Resources data, location data, IP addresses.

‘Special category Personal Data’:

A. personal data revealing racial or ethnic origin,
B. political opinions,
C. religious or philosophical beliefs,
D. trade union membership,
E. genetic data,
F. biometric data for the purpose of uniquely identifying a natural person,
G. data concerning health
H. data concerning a natural person's sex life or sexual orientation.

Personal data

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Includes:

- Pseudonymised/De-identified Data

Excludes:

- Anonymised Data
- Post-mortem data
- Animal data

Identify Lawful Basis art. 6

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Consent- Clear Consent for a clear purpose

Contract – necessary for a contract with the individual

Legal Obligation – Necessary to comply with the law

Vital Interests – Necessary to protect someone's life

Public Task – necessary to perform a task in the public interest, or an official function, and is necessary in law

Legitimate interest – necessary for our legitimate interest, unless there's a good reason to protect someone's personal data

Lawful Basis (art. 9)

- Explicit Consent
- Made public by the data subject
- Public interest in the area of public health
- Substantial public interest on the basis of union or state law
- Employment
- Carried out by a not for profit organisation (e.g religious organisation or trade union)
- Preventive or occupational medicine, inc. to assess the working capacity of the employee
- Vital Interests
- Legal Claims
- Archiving purposes in public interest, scientific or historical research purposes or statistical purposes

One lawful basis is always required under Article 6 (General processing)

For special category data, in addition to a lawful basis under Article 6, a lawful basis is required under Article 9

Criminal offence data requires a lawful basis under Article 6 AND the processor must have an official authority to process the data (GDPR Article 10 and the DPA 2018) and have a policy

Also consider GDPR principles (including information security)

Need to comply with

Privacy & Electronic Communications Regulations (PECR)

Need to consider

Common law duty of confidence

Human Rights Act (Article 8)

Data Subject Rights

The right to be informed – always applies

The right of access – always applies

The right to rectification – always applies

The right to erasure

The right to restrict processing

The right to data portability

The right to object

Rights in relation to automated decision making and profiling.

Lawful Basis and data subject rights

Think about whether you can comply with these rights when determining the legal basis. Consider resource implications.

Select only one lawful basis under Article 6. Think about whether you can comply with these rights when determining the legal basis. You must consider the resource implications.	RIGHT TO ERASURE	RIGHT TO PORTABILITY	RIGHT TO OBJECT
CONSENT	☑	☑	Right to withdraw consent
CONTRACT	☑	☑	☒
LEGAL OBLIGATION	☒	☒	☒
VITAL INTERESTS	☑	☒	☒
PUBLIC TASK	☒	☒	☑
LEGITIMATE INTERESTS	☑	☒	☑

Create Organisational Safeguards

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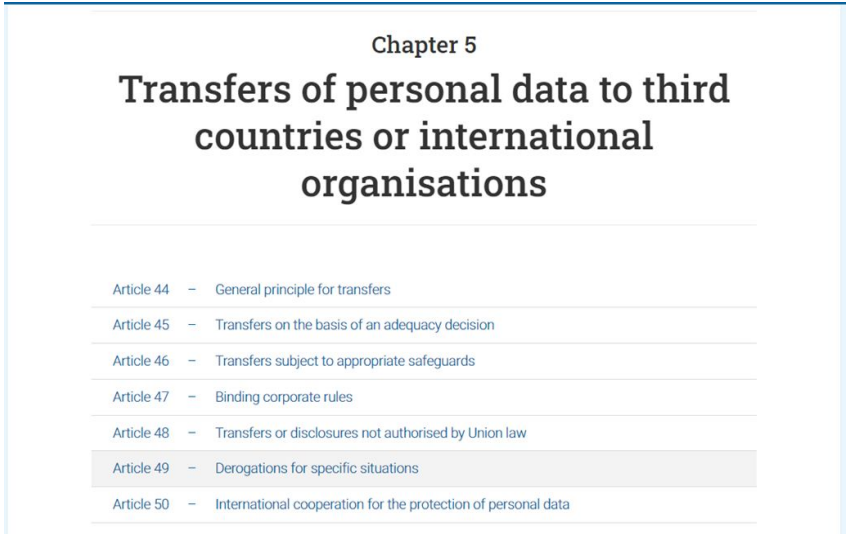
Relevant Agreements

- Data use agreements
- Data Transfer Agreements
- Data processing agreement
- Joint Data controllership agreement



Chapter 5

Transfers of personal data to third countries or international organisations

Article 44	–	General principle for transfers
Article 45	–	Transfers on the basis of an adequacy decision
Article 46	–	Transfers subject to appropriate safeguards
Article 47	–	Binding corporate rules
Article 48	–	Transfers or disclosures not authorised by Union law
Article 49	–	Derogations for specific situations
Article 50	–	International cooperation for the protection of personal data

Establish Technical Measures

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- Anonymisation/Pseudonymisation
- Encryption

Key Points to Note…

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- GDPR is not an excuse not to share your data
- Consent for the research protocol is different from consent as a lawful basis
- Consent is not the only lawful basis and is not usually the only lawful basis
- Always remember your duties to the data subjects

Summary

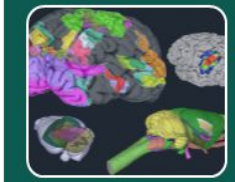
- Identify lawful basis
- Create organisational safeguards
- Establish technical measures

Research Infrastructures/Repositories have a role to play here

HBP/EBRAINS

Data and Knowledge

- Online solutions to facilitate sharing of and access to research data, computational models and software



Atlases

- Navigate, characterise and analyse information on the basis of anatomical location

Simulation

- Solutions for brain researchers to conduct sustainable simulation studies and share their results

Brain-Inspired Technologies

- Understand and leverage the computational capabilities of spiking neural networks

Medical Data Analytics

- The Medical Data Analytics service provides two unique EBRAINS platforms, covering key areas in clinical neuroscience research

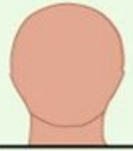
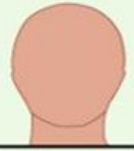
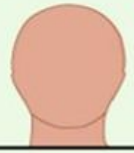
What you get…

- Infrastructure that balances FAIR requirements with compliance to ethical and legal principles and provisions
- Curation process that supports you with technical requirements as well as with organisational safeguards
- Consent and agreement templates

EBRAINS SSD / Service for Sensitive Data (2023)

EBRAINS HDG (2021)

EBRAINS Data and Knowledge

	Raw	Pseudonymous			Anonymous	
	Personal	Key coded	Pseudonymous	De-identified	Anonymous	Aggregated anonymous
Direct identifiers	Intact 	Eliminated or transformed 	Eliminated or transformed 	Eliminated or transformed 	Eliminated or transformed 	Eliminated or transformed 
Indirect identifiers	Intact 	Intact or partially intact 	Intact or partially intact 	Partially intact 	Eliminated or transformed 	Eliminated or transformed 
Re-indentifi-cation	High probability 	Medium probability 	Medium probability 	Low probability 	Not Possible 	Not Possible 

A Case Study

A global consortium is planning to study the effects of genetic variation on cytochrome P450 (CYP)-mediated drug metabolism. This project involves partners working in Europe, USA, China and Africa and who are working with:

- ***laboratory animals** having genetic variants of CYPs;*
- *neuroimaging data from transgenic **non-human primates (NHP) from China***
- *neuroimaging data from **living human beings**.*
- *and groups that use neuroimaging methods to assay the effect of genetic variants naturally occurring in the population on brain function.*

They plan to build a repository located in the US and the EU where all generated datasets will be curated and stored. All partners will be expected to have access to these datasets for the purposes of the research.

What are the technical, ethical and legal requirements these researchers need to consider?

Questions?