Ethics, legal aspects, and privacy in EEG research

Robert Oostenveld

Mikkel C. Vinding

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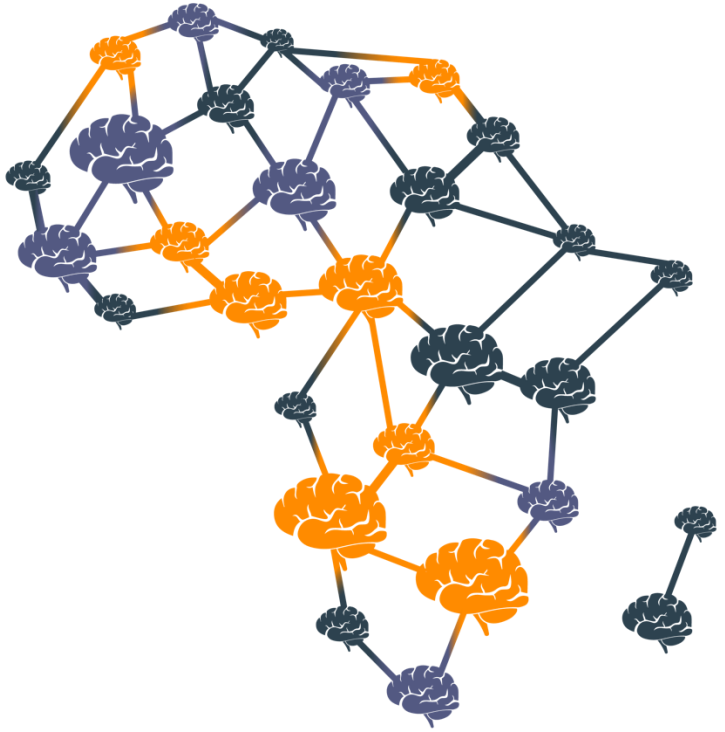


African Brain Data Network

Research versus clinical use of EEG

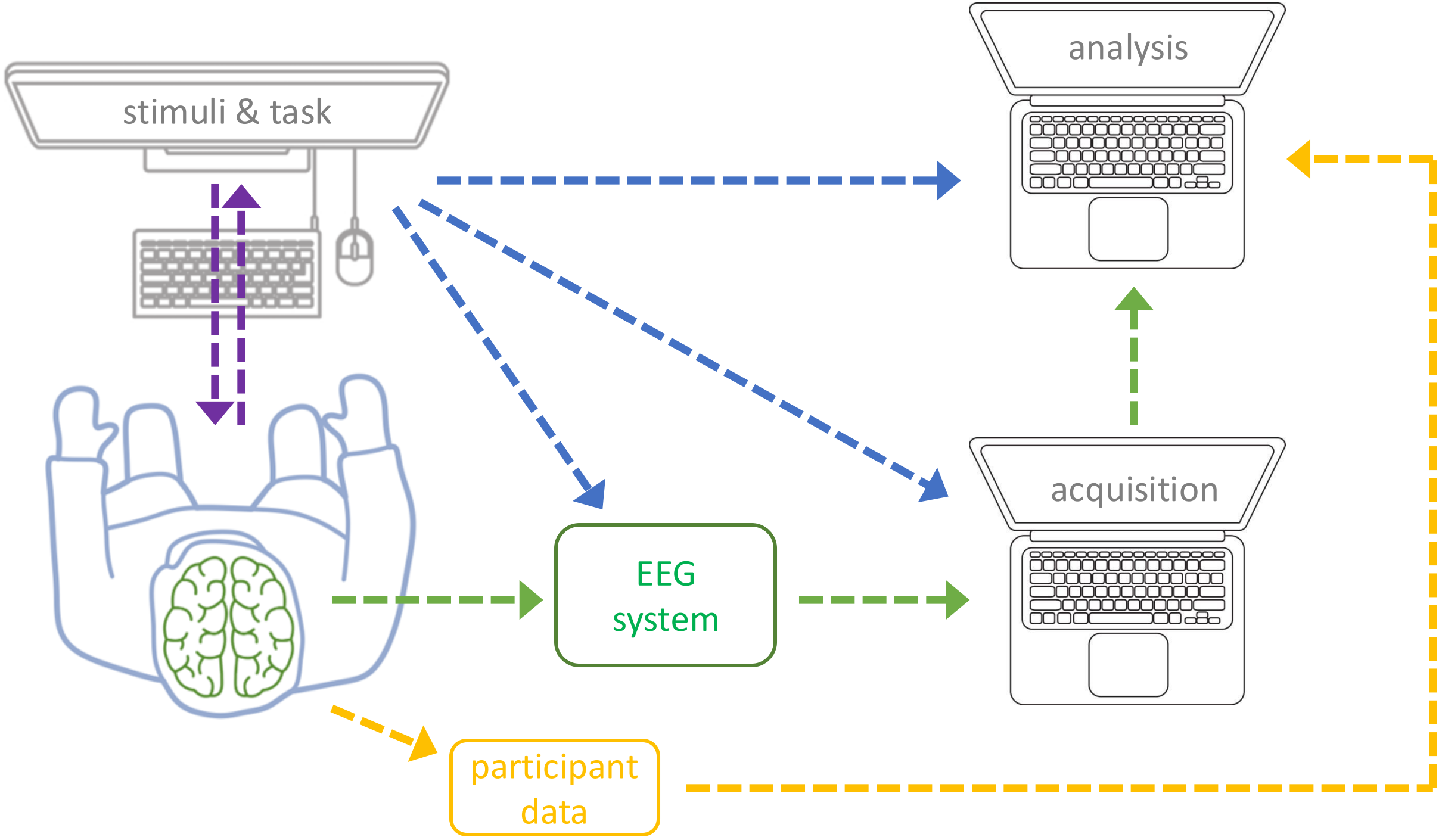
For research we work with voluntary participants who (in principle) do not directly benefit from the research.

For clinical diagnostics and treatment we work with patients that individually benefit.

Here I will only consider **research using EEG**, so with voluntary participants.

Note that volunteer = participant = subject

Research using EEG is not only about EEG data


stimuli & task
analysis
acquisition
EEG
system
participant
data

Outline and topics to cover

Ethics, Legal, Moral considerations

Declaration of Helsinki

Informed consent and screening form

Incidental findings and adversial effect

Lying to your participants

Privacy, GDPR, HIPAA

Data minimization

Anonymous versus pseudonymization

Data sharing or data use agreements

What data are we collecting? What are we doing to our participants?

We collect data

We do experiments

We manipulate our participants

We cause them potential discomfort

We cause them potential harm

During the experiment and afterwards

Declaration of Helsinki

A set of ethical principles for medical research involving human subjects, originally adopted in 1964 by the World Medical Association (WMA).

Emphasizes patient rights, ethical research conduct, and scientific integrity, ensuring that medical research prioritizes human dignity over scientific advancement.

https://www.wma.net/policies-post/wma-declaration-of-helsinki/

It is directed at medical researchers. Not all our EEG research is medical, but the principles still apply to our research.

Most important principles (page 1/2)

1. Primacy of Patient Welfare & Well-Being

The health and well-being of research participants must take precedence over scientific and societal interests.

Physicians must protect life, health, dignity, integrity, and rights of research subjects.

2. Informed Consent

Participation must be voluntary, with **freely given informed consent** (preferably written).

If consent cannot be obtained, approval from an independent ethics committee is required.

Participants must be informed of benefits, risks, and their right to withdraw.

3. Risk-Benefit Assessment

Research risks should not outweigh potential benefits.

Studies must be based on a thorough scientific evaluation.

4. Protection of Vulnerable Groups

Extra safeguards must be in place for vulnerable participants (e.g., children, prisoners, pregnant women, disabled persons).

5. Independent Ethics Review

Research protocols must be reviewed and approved by an **independent ethics committee** before starting.

Most important principles (page 2/2)

6. Respect for Privacy & Confidentiality

Participants' personal information must be kept confidential.

7. Post-Trial Provisions

If proven beneficial, participants should have access to the intervention after the trial.

8. Research Integrity & Transparency

Negative and inconclusive results should be published to avoid bias.

Research must be conducted with honesty and transparency.

9. Physician's Role & Responsibility

Physicians involved in research must ensure ethical standards are upheld, even if they are not directly conducting the study.

10. Prohibition of Placebo in Harmful Cases

A new intervention should generally be tested against the **best current proven treatment**, except in rare cases where placebo is ethically justified.

During the experiments

Informed consent

Informed = the participant knows in advance about what will happen

Consent = the participant agrees

We send an information brochure at least 24 hours in advance

- A general section on the recording technique (EEG, or MRI)
- A specific section on the particular study

In the lab we check whether the participant has any remaining questions, and whether they consent. If so, they sign a form.

We stress that the participant is free to stop at any moment, without negative consequences.

Informed consent

The informed consent form (with the name, date and signature) is stored at the administration and archived for a certain time. This is a legal requirement!

We **do not** keep the informed consent form lying around in the lab, as that might accidentally leak personal or health information from participants.

At the same time of the informed consent we also do the **screening form**.

Does the participant fulfill the study requirements? No medical or mental conditions, capable of doing the task, propre eye sight, etc.

Incidental findings and adversial effect

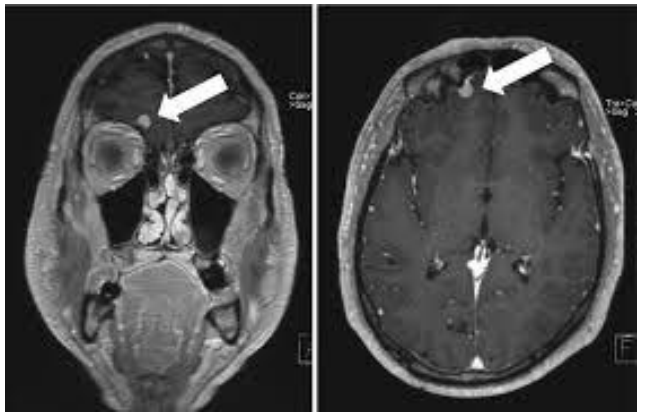
We notice something in the data that we were not looking for, but that may be clinically relevant. Mainly happens with anatomical MRI scans.

At the DCCN we make about 3500 MRI scans per year.

A few percent of those will show incidental findings.

One or two incidental findings per week.

We have a incidental findings procedure.



Not reporting it to the participant is not an option to us, as that is not ethical to the researcher.

Possible incidental findings with EEG: epilepsy, but also heart-rate irregularities

Incidental findings and **adversial effect**

Our intervention/experiment/measurement has an unexpected effect

For example

- the application of EEG gel causes a skin rash
- the participant becomes claustrophobic
- the participant accidentally gets hurt while in the lab

As part of the ethical approval for our studies we have an insurance for all participants.

Experimental tasks and being honest

We try to be **as honest as possible** to the participant. Sometimes we cannot disclose the purpose of the task, as then the participant would not do the task properly.

We tell the participant that they will score extra money if they perform the task very well: in the end they get the maximum amount anyway -> motivate the participant

We play with the participant's beliefs: telling that something is simple, whereas it is difficult -> study frustration.

We have the participant believe that an unplesant stimulus (electric shock) will come -> study anticpation and stress

Experimental tasks and being honest

Small lies to the participant are common and allowed.

For example telling that the task is to press a button upon a specific stimulus, whereas in reality that is just a distraction and the real stimulus of interest is another one.

Larger lies to the participant are evaluated by the ethics committee.

For example Milgram's experiment on social obedience
https://en.wikipedia.org/wiki/Milgram_experiment

After the experimental interaction

Privacy and personal data

We collect personal data from our participant

- Demographic data
- Potential health data
- Behavioral data
- Questionaires

It might cause **harm to our participant** if that data were known to external parties.

Data minimization

Pseudonimization

Blurring

Personal data

name

address

date of birth

phone number

license plate number

IP address

...

Crime Scene Investigation
http://www.abc.net.au/news/2017-09-19/csi/8960590

Biometric data

fingerprint

facial details

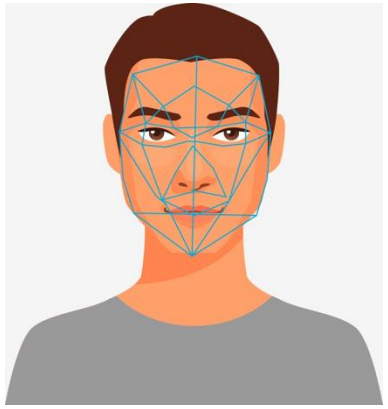
dental record

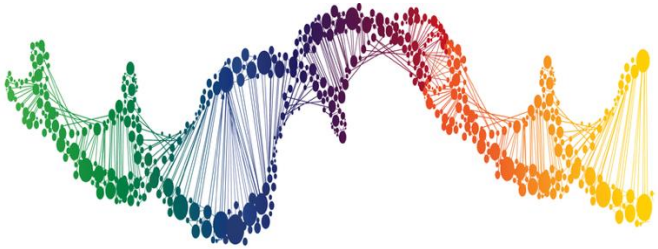
genetics

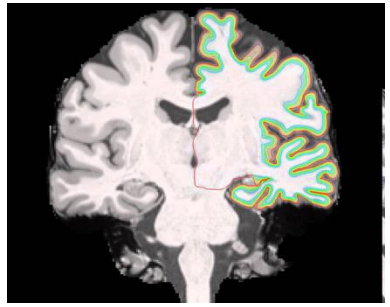
cortical folding pattern

responses to a questionaire

EEG







Personal Data – is needed and should be managed

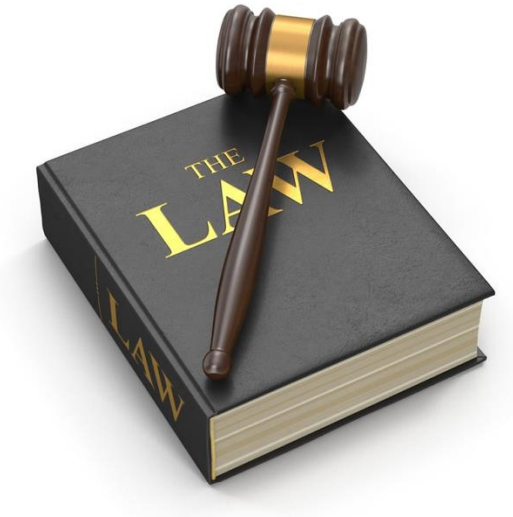
Required for **administration**

- Contacting your participants
- Paying your participants
- Follow up incidental findings

Often **not required** to address the research question

- Sometimes used as confound
- Check whether the sample is representative
- Possibly required to assess scientific integrity

Personal Data – record as much as needed, but as little as possible



Personal data

- Name, email address, date of birth
- Bank account number

Special personal data = “bijzondere persoonsgegevens in NL”

- Race
- Religion or beliefs
- Health
- Sexual activities
- Political preference, membership of a union
- Criminal record

Indirect personal data – identifies someone … ***when linked to another database***

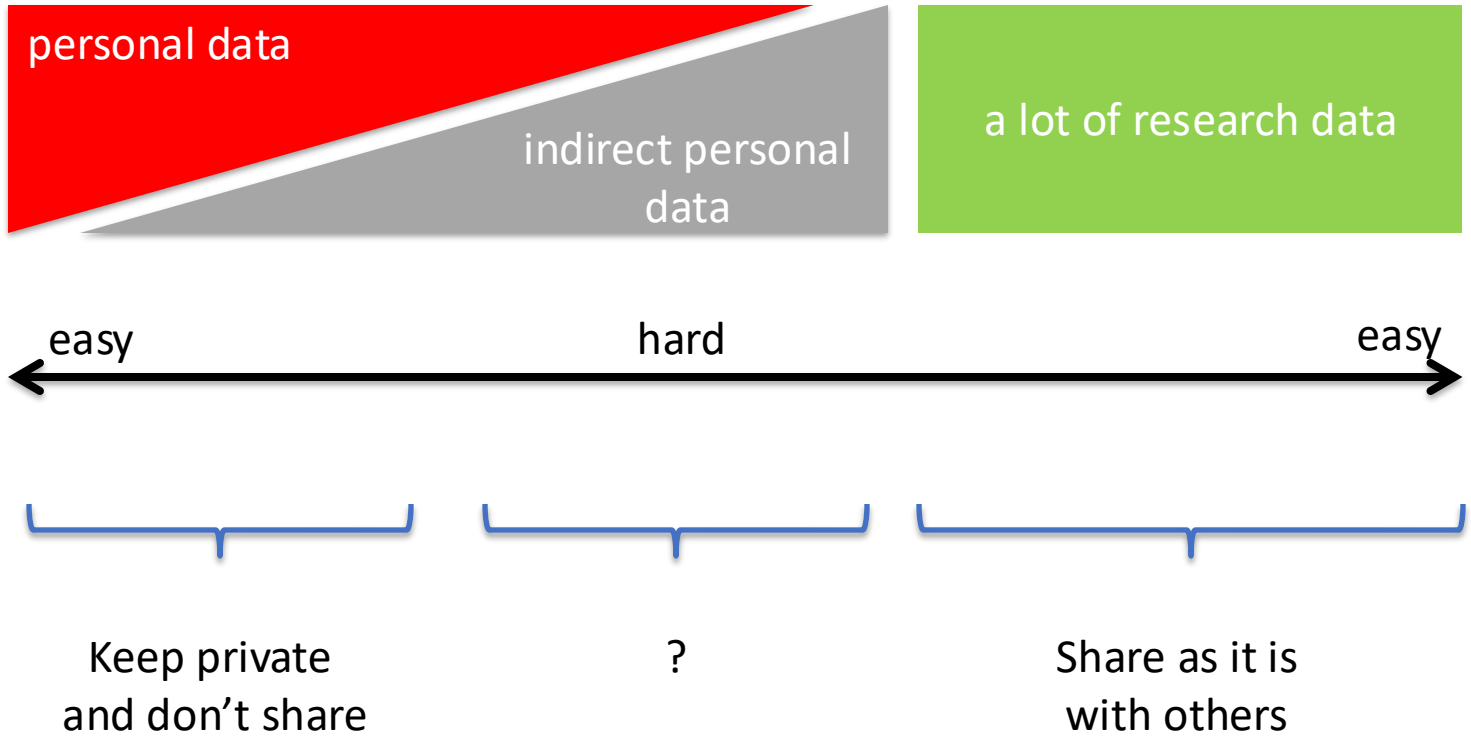
- Fingerprint, DNA, facial details
- Anatomical MRI
- Specific pattern of data (for example answers on a questionnaire)

https://autoriteitpersoonsgegevens.nl/nl/over-privacy/persoonsgegevens/wat-zijn-persoonsgegevens

Is EEG data itself potentially identifying?

Let’s have a short discussion on this …

Gradient between personal and research data



Limit possible identification

Anonymous

Nobody is able to identify the participant

Pseudonymization

Use a code instead of the participants name -> *already in the lab where the real name is only used on the informed consent and screening form, but nowhere else.*

De-identification

Remove (indirectly) identifying features

Store the age instead of date of birth

Blur the indirect personal data

- Deface anatomical MRI
- Use age bins instead of years
- Questionnaire outcomes rather than individual item scores
- …

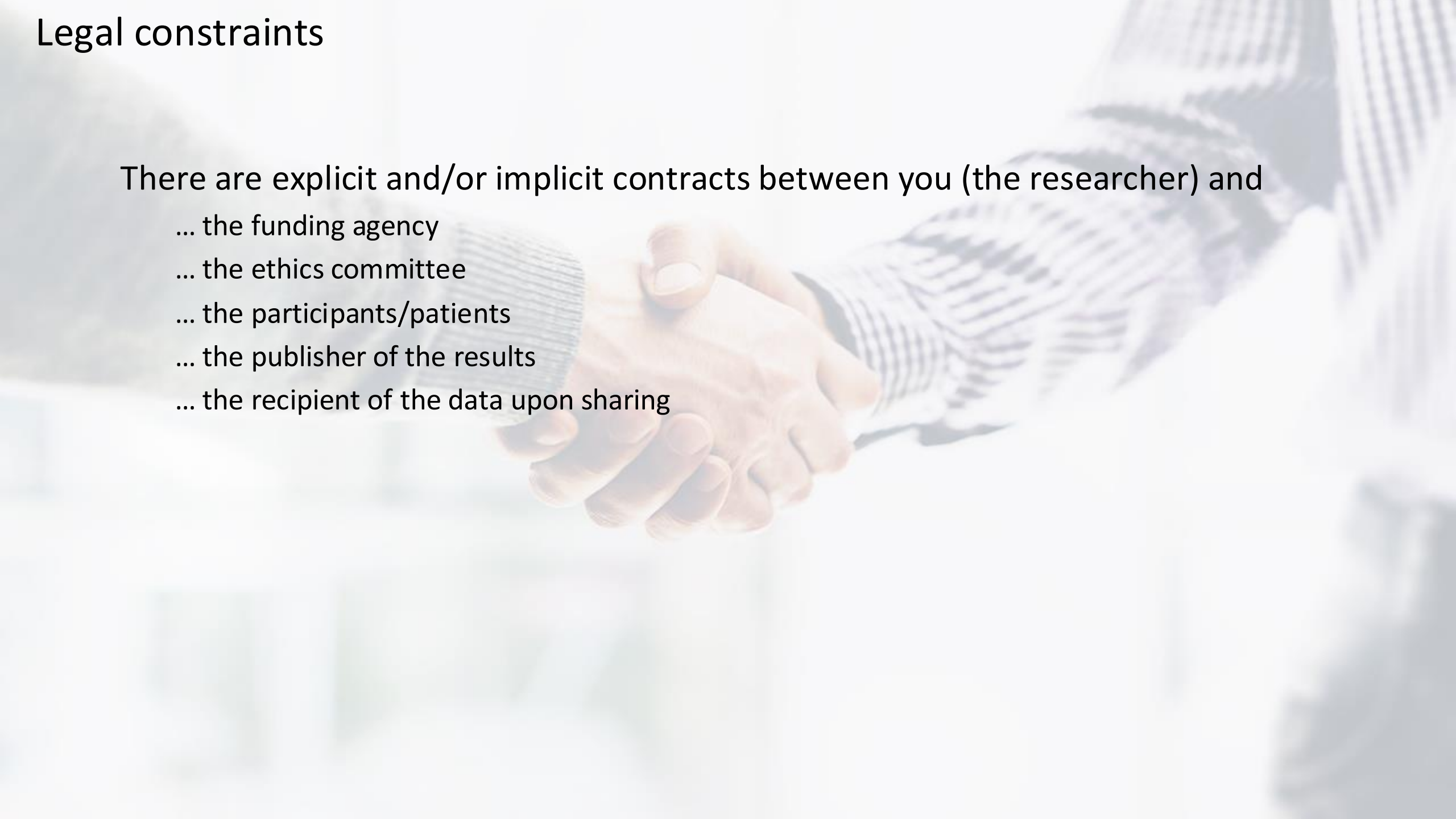
Appropriate blurring depends on the situation

… for example the age of the participant

1 month bins

10 year bins

Legal constraints



There are explicit and/or implicit contracts between you (the researcher) and

- … the funding agency
- … the ethics committee
- … the participants/patients
- … the publisher of the results
- … the recipient of the data upon sharing

Legal constraints – Informed Consent

participant → you → recipient

You inform the participant in advance what you will and will not do in the lab, but also with the data afterwards.

The participant consents.

If you want to use the data later or share it, make sure that the participant was informed and consented to it.

Legal constraints – Data Transfer or Use Agreement

participant → you → recipient

CC0 - Public Domain

No copyright.

*The person who associated a work with this deed has dedicated the work to the public domain by **waiving all of his or her rights** to the work worldwide under copyright law, including all related and neighboring rights, to the extent allowed by law.*

*You can **copy, modify, distribute and perform the work**, even for commercial purposes, all without asking permission.*

Donders Institute - Data Use Agreement for identifiable human data

*I will comply with all relevant **rules and regulations** imposed by my institution and my government ….*

*I will not attempt to establish the identity of or attempt to contact any of the included human subjects. I will **not link this data** to any other database in a way that could provide identifying information ….*

*I will **not redistribute** or share the data with others, including individuals in my research group, unless they have independently applied and been granted access to this data.*

*I will **acknowledge the use** of the data and data derived from the data when publicly presenting …*

*Failure to abide by these guidelines will result in **termination of my privileges** to access to these data.*

https://creativecommons.org/publicdomain/zero/1.0/
https://data.ru.nl/doc/help/helppages/best-practices/bp-selecting-dua.html

European Union - General Data Protection Regulation (GDPR)

Applies to all EU contries since 2014.

Implemented slightly differently over contries (in line with local law).

Interpreted differently by different instutitions/universities/departments, some take a more liberal, others a more constrained interpretation.

In the USA there is something similar but not as far-reaching: the Health Insurance Portability and Accountability Act (HIPAA, since 1996)

See Köhler et al. (2021) A survey of national ethics and bioethics committees. https://doi.org/10.2471/BLT.19.243907

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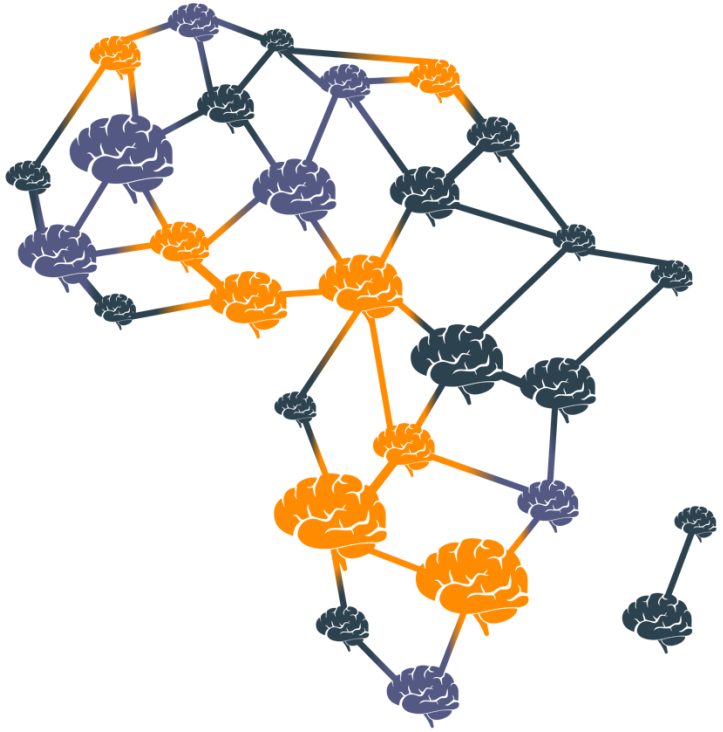

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