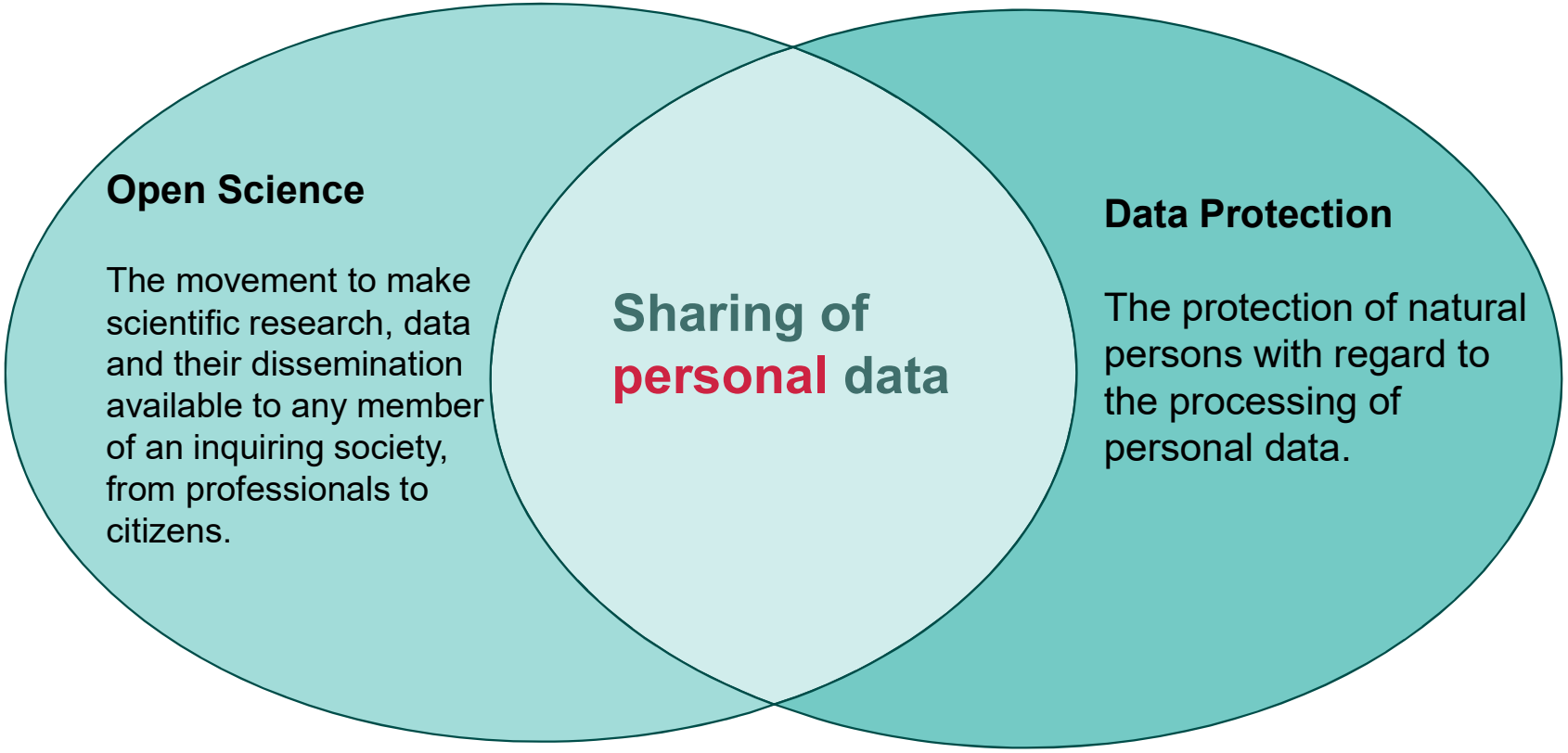
MAX PLANCK GESELLSCHAFT

OPEN RESEARCH DATA AND GDPR

Heidi Schuster

Data Protection Officer of the MPG

WHAT IS IT ALL ABOUT?



SHARING SCENARIOS

Within an existing project collaboration

- inside the EU / EEA
- outside the EU / EEA

Without an existing project collaboration

- Data service center / repository
- Internet platform
- Restricted /controlled recipients?
- Unlimited recipients?

What kind of personal data?

PERSONAL DATA

any information relating to an identified or identifiable natural person (‘data subject’).

identified person: person can be clearly determined from the data available

identifiable person: person can be identified, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;

PERSONAL DATA

To determine whether a natural person is identifiable, account should be taken of all **objective factors**, such as the costs of and the amount of time required for identification, **available technology** and technological developments.

A group less than or equal to three is never anonymous.

The differentiation between identified and identifiable person is irrelevant for the protection of the law.

PERSONAL DATA

special kinds of personal data (sensitive data)

- racial or ethnic origin (NOT nationality)
- political opinions
- religious or philosophical beliefs
- trade union membership
- health
- sex life
- genetic data
- biometric data for the purpose of uniquely identifying a natural person

These data is particularly worthy of protection.

PERSONAL DATA IN RESEARCH

contact data

- name, address, email, phone number

characteristics

- blood pressure, left-/right-handed, medical history, age, date of birth, capability to undergo MRI, EEG, etc., native language

experimental data

- examinations (medical, questionnaires, etc.), interview outcomes, imaging data (photos, MPI, X-Ray, CT, etc.), laboratory results, video-/audio recording

In case these data types **are linked by an ID**, there is always a connection to a person.
Characteristics and experimental data are on their own always seen as **pseudonymized data.**
They **might** become **anonymous** when contact data and connecting link are deleted.

LAWFULNESS

The processing of personal data is generally prohibited.

under the conditions of Art. 6, 9 GDPR or national law permitted

Art. 6: lawfulness of processing

Art 9: processing of special categories of personal data

- necessary for the performance of a contract / for pre-contractual measures
- **consent**
- on the basis of a balancing of interests
- […]

important:
all legal bases have remained the same
all legal bases are equivalent

CONSENT

‘consent’ of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a **statement** or by a **clear affirmative action**, signifies agreement to the processing of personal data relating to him or her;

formal aspects

- the existence of consent has to be proofed
- signature, email; electronic consent: opt-in
- documented oral consent -> documentation by recording or by procedure
- **minors (in any case under 16 years of age): consent of the legal guardians**

WITHDRAWAL

The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal.

Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent.

Withdrawal is only relevant if the data is not anonymous.
if data is coded only (= pseudonymised) withdrawal is relevant

INFORMED CONSENT

purpose of the data processing

- „broad consent“: data subjects can give their consent to **certain areas** of scientific research when recognised ethics standards are met
- linkage with administrative data has to be explicitly mentioned

method of storing and processing data

- contact data, characteristics, research data
- explicit reference to special categories of personal data
- information about the data separation and coding list
- combination with data from other sources?

Data Sharing scenarios

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DATA SHARING

Legitimacy

- First step: Sharing as such regardless of the recipient country -> consent
- Second step: transfer to data outside the EU / EEA -> it depends

EU „Whitelist“

- Adequacy decision of the commission
- Andorra, Argentina, Australia, Faroe Islands, Guernsey, Israel, Isle of Man, Japan, Jersey, Canada (only companies), Switzerland, Uruguay, New Zealand, UK

All other countries:

- Contracting EU Standard Contract Clauses (SCC) with the recipient
- Consent with the **explicit information about possible risks** of such transfers due to the absence of an adequacy decision and appropriate safeguards

PUBLICATION OF DATA

Section 27. Data processing for purposes of scientific or historical research

[…]

(4) The controller may publish personal data only if the data subject has provided consent or if doing so is indispensable for the presentation of research findings on contemporary events.

What kind of data will be publishes?

- Legally anonymous data?
- Or “not identifiable” data?

“No contact data will be published. Identification will not be possible on the basis of the research data to be published.”

TEMPLATES

https://max.mpg.de/Zentrale-Beauftragt

- Max Planck Newsletter
- Best Practice
  - Handling of photographs
  - Templates of data protection information
  - Data erasure and destruction
  - Proposals for good practice in high-risk human research
  - How to Data Protection
  - Fill-in Help SCC
  - Declaration of consent - template for human research
  - Works Agreements
  - International Offices
- OHB XVII - Data Protection
- DPC-Teamroom

DECLARATION OF CONSENT

Template for human research

As part of the development of the Castellum data base, a set of consent modules is made available that can be used either in the present manner or adapted to the needs of the individual MPIs and the conditions of the individual studies. All text modules are editable.

Aktuell öffentliche Dokumente

Template for the declaration of consent - englisch version

Developed during the CASTELLUM Project

05/18/2021 12:37

Template for the declaration of consent - german version

Developed during the CASTELLUM Project

05/18/2021 12:36

TEMPLATES

CASTELLUM
Datenschutzkonforme Probandendatenbank

Annotated template for study information and consent.
Developed during the CASTELLUM Project

Katrin Schaar in close consultation with Heidi Schuster, 28.02.2019. *Subject to a*

The general template has been reviewed and commented by members of the Neurosciences (MPICBS, Dr. Jöran Lepsien, Maria Paerisch), MPIB (Dr. Nadin Meder, Thomas Feg), MPIP (Dr. Norma Grandi) & MPIA (Dr. Cornelius Abel).

TEMPLATES

Data transfer [if applicable, MANDATORY]: is the research data also passed on to other scientists?[23]

[0] If no data transfer is planned

The data will only be analyzed by the scientists/science groups mentioned here, [AND/OR] exclusively at the MPI of [XY] within the framework of the research project [IF APPLICABLE, IF MENTIONED UNDER "PURPOSE" ABOVE:] and further research [IF APPLICABLE and teaching].

[1]If data will be passed on within a collaboration project

The study is a collaborative project with [XY NAME(S) & INSTITUTE(S)] [24]The data will be exchanged and analyzed [only] by the scientists/science groups [or institutes] mentioned here within the framework of the research project [IF APPLICABLE: Within the research network, the research data may also be scientifically analyzed for related questions [SPECIFY AREA IF APPLICABLE, FURTHER EXPLANATIONS IF APPLICABLE]]. [IF PROJECT PARTNERS OUTSIDE THE EU OR IN A THIRD COUNTRY NOT RECOGNIZED BY DATA PROTECTION LAW ANALYSES

[xv] "The broad consent of donors is only possible under certain conditions. In particular, it should only be requested if the biobank's orientation does not allow for a limitation to certain indication areas, research purposes or investigation methods. Where a time limit is provided, donors must be informed of what will happen to the materials and data after the end of the intended period of use" The explanation as well as the variants inserted in the following are taken from the model of the Working Group of Medical Ethics Committees 10.6.16, p. 3. Reference to the broad consent: Broad consent should be justified and only in the event that actual use of biomaterials is planned and necessary outside a specific research project. This means that it should not be a standard formulation. The justification should be documented.

[4] If data transfer within Europe is planned

It is planned to transfer the research data to [CONCRETE DATA SERVICE CENTER OR NAMED STORAGE LOCATION OR WEB ADDRESS] for archiving and further scientific use after completion of the data collection. This will enable other scientists to evaluate the data in relation to other scientific issues. [EXPLANATION, IF APPLICABLE, OF HOW THE DATA IS TO BE PREPARED FOR THIS PURPOSE, E.G. COARSENING/NOISE GENERATION OF THE DATA // NO RAW DATA, ONLY ANALYSIS DATA, CERTAIN ANONYMIZATION PROCEDURES.] [ONLY IF APPLICABLE: Checks will be carried out there to ensure that the research data no longer contains any personal references.] If applicable, the [INSERT: CONCRETE DATA SERVICE CENTER] will take additional measures so that the research data cannot be associated with your person. The Data Service Centre will make the [processed/anonymized/noisy/(...)] data available to researchers at home and abroad for exclusively scientific purposes. Since it will no longer include any personal references, it will no longer be possible to delete your research data from the data records.

[5] If data storage on an Internet platform is planned[xvii]

It is planned to publish research data which will not be able to identify you directly on the Internet platform [SPECIFY XY: Web Address] [IF APPLICABLE ALTERNATIVE GENERAL: It is planned to upload research data to data platforms [HOWEVER: SEE NOTE AT HEADING]]. This will enable other scientists to access the research data and to analyzes it in a supplementary manner, post-process it and repeat analyses or use it to answer further scientific questions. [IF APPLICABLE, PLEASE ADJUST:] Data platform XY is located within/outside the European Union / [OR IN GENERAL: Data platforms may be located outside the European Union]. Once placed there, the data will be made publicly available worldwide, i.e. It will be possible for interested parties to view, download and use the data [IF APPLICABLE after logging on to the portal]. This also means that the data will leave the area covered by European data protection law. This also means that it is possible that you may not be able to assert your rights as a person affected. From the time of publication on the platform, this data can no longer be controlled, or subsequently restricted its use or delete it everywhere.

TEMPLATES

[x] General note for data transfers

Your contact details will only be used within the research project [or XY/within the MPIXY]. We will only pass on research data to external scientists without your consent, and not your contact data . Individual participants will no longer be recognizable. For external researchers, research data will not relate to you [IF APPLICABLE, FURTHER SECURITY MEASURES SUCH AS APPLICATION PROCEDURES, SUBMISSION OF DATA PROTECTION CONCEPTS, DATA USAGE AGREEMENTS] ARE DESCRIBED HERE.

Publication [DESIRABLE, or MANDATORY, if personally relevant results will be published [xviii]:[25] How will the results be published?

[1] General

The results of the study will be published exclusively without any direct reference to individuals [IF APPLICABLE: and can also be used as a basis for teaching]. If study results are published, your identity will remain confidential. This means that it will not be possible to tell from the results which person provided the information, nor will it be clear from the research data that you participated in an investigation, unless you separately agreed to a publication of your personal data.

[2] If publication in journals is planned which require the deposit of data

IF, FOR EXAMPLE, RAW DATA, MRI DATA, ETC. WHICH CANNOT BE COMPLETELY ANONYMIZED ARE TO BE PUBLISHED]

It is planned to publish the results in scientific journals, which demand that the underlying research data is also stored so that the results can be verified by other scientists. It is therefore possible that associated research data without names and contact data will be submitted to the journals and published there. Please note that this scientific data will be made available worldwide. This also means that the data will leave the area covered by European data protection law. This also means that it is possible that you may not be able to assert your rights as a person affected.

THANK YOU FOR YOUR ATTENTION

Please do not hesitate to contact me!

Heidi Schuster
Datenschutzbeauftragte

Max-Planck-Gesellschaft zur Förderung der
Wissenschaften e.V.
Hofgartenstr. 8, 80539 München

Telefon + 49 89 2108-1554

E-Mail heidi.schuster@gv.mpg.de

www.mpg.de