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**UNIVERSITÄT  
BERN**

# manage research data ethically

**Dr. Olga Churakova and Dr. Christine Krebs**  
Open Science, Research Data Management



Image: © UB UniBE

# Open Science

## Research Data Management Support



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[Dr. Christine Krebs](#)

*u*<sup>b</sup>

# Welcome

<https://www.menti.com/>

Code: 4887 1820



Some short questions to get an impression of who you are



# Outline

## **Ethics basics:**

Key principles and best practices

## **Ethics applied:**

Research data management life cycle

- Data collection and generation
- Data secure protection and storage
- Data ethical and secure sharing, backup, transfer
- Data publishing

$u^b$  **Ethics: Key principles**

**Value basis**

**Trust and reputation**

**Responsibility**

**Ethical decision making**

**Openness, where possible**

**Honesty**

**Reproducibility**

**Traceability**

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# Research on and with humans



## Potential harm to participants

- Conduct a **risk assessment**
- Adapt consent and information **procedures** where necessary

## Incidental findings

- Plan a head by drafting a **policy** for dealing with incidental findings
- Inform participants about the **limits of confidentiality**
- Be aware of the **legal context**

*u*<sup>b</sup>

# Ethical issues

Generally, ethical issues arise whenever research involves:

- Human participants, and /or their cells and tissues
- Personal data
- Animals
- Methods, materials or experiments that could harm the environment, research staff or participants



*u*<sup>b</sup>

# Internet and social media research



[Pixabay](#)

- **Terms and conditions of the platforms** to obtain your data
- Ensure **that the data are really public** (open platforms vs password-protected)
- **Avoid collecting data from children or vulnerable adults** without appropriate authorisations
- Consider the **potential sensitivity of the data**
- Questions? Consult [Data Protection Officer](#)

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# Research ethics

## Responsibilities to

Society

Funder/Research Agency

Discipline/Colleagues

Governments

Participants



[Research Ethics](#)

*u*<sup>b</sup>

# Research ethics

## Good practices

- Plan for inclusion
- Anticipate diversity
- Minimise harm
- Avoid 'over-researching'
- Collaborate with those being studied
- Make use of 'consultants'
- Facilitate research accessibility
- Exercise caution with the use of gatekeepers and proxies

*u*<sup>b</sup>

# Research on and with animals

3R principles (“Replace, Reduce, Refine”)

Harm-benefit analysis:

- Gain of knowledge
- Health (human health, animal health and welfare)
- Support of environment protection
- Improvement of quality of life
- 3R potential



**3 R** Swiss 3R  
**C C** Competence  
Centre

<https://swiss3rcc.org/>

*u<sup>b</sup>*

# Research on and with plants / seeds



Federal Office for the Environment [FOEN](#)  
Red Lists: Threatened species in Switzerland



Research Commission of the Swiss National Park (FOK-SNP)

FOK-SNP promotes and coordinates research projects in the Swiss National Park, in the Regional Nature Park Val Müstair and in the conservation and development zone of the Engiadina Val Müstair Biosphere Reserve. [more](#)

Image: Meisterfoto, stock.adobe.com

Research Commission of the Swiss National Park  
([FOK-SNP](#))

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# Research activities must respect

**Protection of the environment and human health**

**Physical and mental integrity**

**Protection of personal data**

**Equality and non-discrimination**

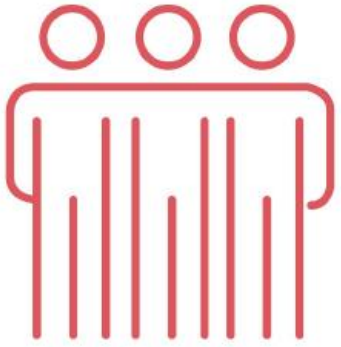
**Proportionality**

**Right to privacy**

*u*<sup>b</sup>

# Code of conduct for scientific integrity

## The four basic principles



Reliability



Honesty



Respect



Accountability

Slide from Prof Dr. Edwin Constable, Swiss Academies of Arts and Sciences ([Link](#))

# CARE principles

## scientific **data**

[Explore content](#) ▾ [About the journal](#) ▾ [Publish with us](#) ▾

[nature](#) > [scientific data](#) > [comment](#) > article

Comment | [Open Access](#) | [Published: 16 April 2021](#)

### Operationalizing the CARE and FAIR Principles for Indigenous data futures

[Stephanie Russo Carroll](#) , [Edit Herczog](#), [Maui Hudson](#), [Keith Russell](#) & [Shelley Stall](#)

[Scientific Data](#) **8**, Article number: 108 (2021) | [Cite this article](#)

**13k** Accesses | **36** Citations | **59** Altmetric | [Metrics](#)

<https://doi.org/10.1038/s41597-021-00892-0>







[DOI: 10.1126/science.1255484](https://doi.org/10.1126/science.1255484)

## Why preregister?

- Makes your science better by increasing the credibility of your results
- Allows you to stake your claim to your ideas earlier
- It's an easy way to plan for better research

## When can you preregister?

- Right before your next round of data collection
- After you are asked to collect more data in peer review
- Before you begin analysis of an existing data set

# $u^b$ Funder's requirements

## Swiss National Science Foundation (SNSF)

### ✓ Dos

- **Obtain permissions** at least at the time of project evaluation
- **Explain** anonymization / pseudonymization → Obligation to anonymize data whenever possible.
- Use **secure storage** space (e.g. locked room)
- **Share** anonymised data using a FAIR research data repository
- Collect **only data needed** for the purpose of your study

### ✗ Don'ts

- **Do not share** pseudonymised data openly → data protection regulations still apply
- **Do not apply** CC0 license to sensitive data
- **Do not share** sensitive data via Dropbox or Onedrive
- **Do not upload** any sensitive data on campus storage or campus cloud
- **Do not store** ID numbers and personal information at the same place

# $u^b$ Funder's requirements

## Ethics in Horizon Europe projects

### ✓ Dos

- **Proportionality (gender, equal opportunities)**
- **Right to privacy**
- **Right to protection of personal data**
- Right to the physical and mental integrity of persons
- The right to non-discrimination
- The need to ensure protection of the environment
- High levels of human health protection
- Exclusive focus on civil applications
- Respect of basic EU values

### ✗ Don'ts

- Human cloning for reproductive purpose
- Intend to modify the genetic heritage of human beings (except cancer research)
- Intend to create human embryos solely for the purpose of research or stem cell procurement
- Lead to the destruction of study subject

*u*<sup>b</sup>

# Publisher's requirements

## Research ethics statement

- Principles of scholarly freedom and scholarly responsibility
- Benefits and harms of research
- Studies involving animals and human research participants [editorial policy checklist](#)
- Human participants research [Declaration of Helsinki](#)
- Research on human populations
- Race, ethnicity and racism
- Sex, gender (identity/presentation), and sexual orientation
- Studies involving vulnerable groups
- Publishing images from human research participants
- Clinical trials
- Tumor marker prognostic studies
- Human biospecimens
- Human transplantation studies
- Studies involving human embryos, gametes and stem cells
- Dual use research of concern

[Nature portfolio](#)

# $u^b$ Artificial Intelligence (AI)



Shaping Europe's digital future

[Home](#) [Policies](#) [News](#) [Library](#) [Funding](#) [Calendar](#) [Consultations](#)

[Home](#) > [Library](#) > Ethics guidelines for trustworthy AI

REPORT / STUDY

## Ethics guidelines for trustworthy AI

On 8 April 2019, the High-Level Expert Group on AI presented Ethics Guidelines for Trustworthy Artificial Intelligence. This followed the publication of the guidelines' first draft in December 2018 on



[Link](#)

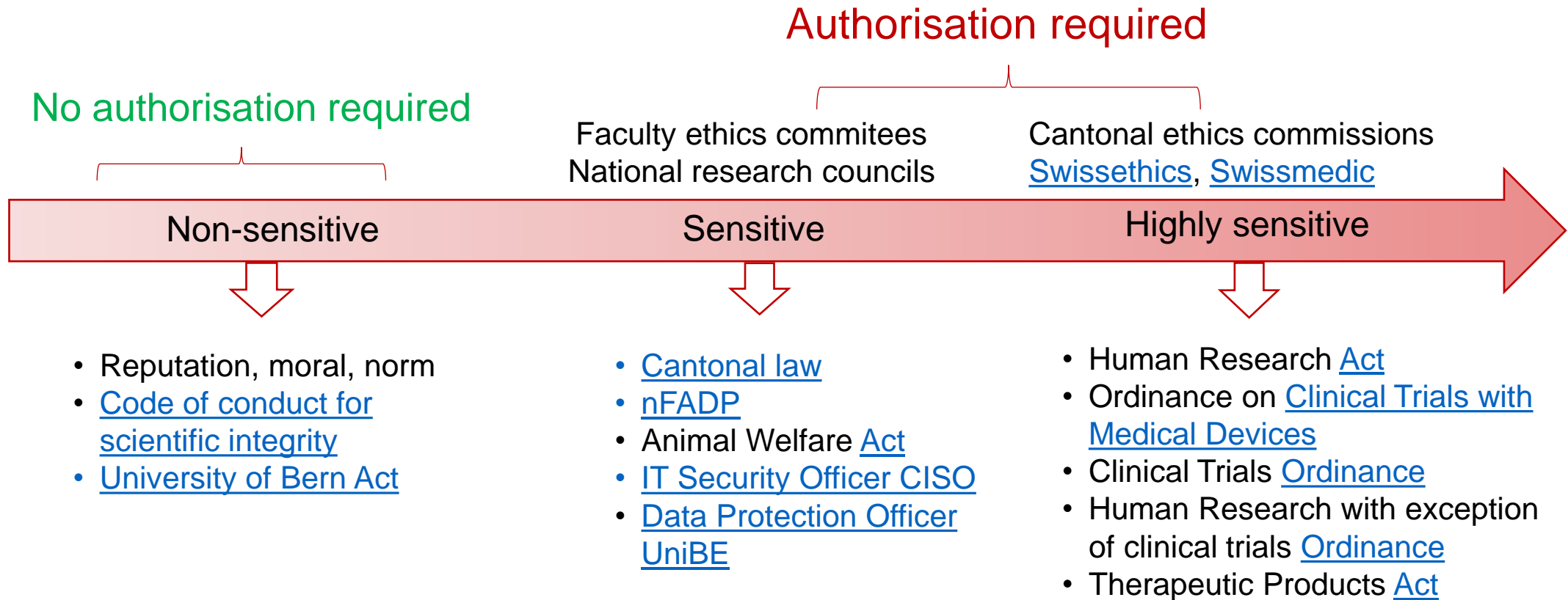
## 7 key requirements that AI systems should meet:

- Empower human beings
- Need to be resilient and secure
- Ensuring full respect for privacy and data protection
- Transparency
- Diversity, non-discrimination and fairness
- Societal and environmental well-being
- Accountability

“Ethics by Design” = addressing ethical issues during development. [Embedded Ethics Lab](#), Center for Artificial Intelligence in Medicine UniBE

# How to manage research data ethically?

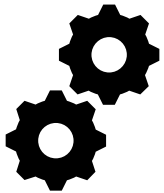
## Research (not) requiring authorisation



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# Data collection

## Sensitive and highly sensitive data



- Health-related data
- Data relating to religious, philosophical, political or trade union-related views or activities
- Data relating to health, the private sphere or affiliation to a race or ethnicity
- Genetic data
- Biometric data that uniquely identifies a natural person
- Data relating to administrative and criminal proceedings or sanctions
- Data relating to social assistance measures

*Data Protection Act, [FADP](#)*

# Data collection

## Informed Consent (IC)

A written, signed and dated form includes everything you plan to do with data:

- Purpose, nature and extent of data processing
- Duration of data storage (e.g., 10-years [SNSF guidelines FAQ o](#), Art. 5.1; 15-years for clinical studies, [swissethics](#)) and deletion (if applicable)
- Measures to protect data (anonymization, access control, etc.)
- Disclosure of data to third parties / data publication and sharing

*“Informed Consent (IC) is a process by which a subject **voluntarily** confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate.”*

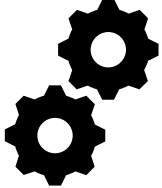


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# Data collection

## Electronic Informed Consent (eIC)

The **eIC** can make use of electronic media

- 
- Video / Audio interviews
  - Podcasts
  - Interactive Websites
  - Applications for tablets and smart phones, etc.
- 
- To convey the information, while the subject's consent must still be documented on paper with a **hand-written signature** of both the patient/**participant** and the **investigator**.

[Swissethics](#)

*u*<sup>b</sup>

# Data documentation



- ReadMe files [Readme\\_Template\\_EN.txt \(3KB\)](#)
- Codebooks
- Electronic Laboratory Notebook
- Laboratory Information Management System (LIMS, e.g., [OpenBIS](#))
- Research Electronic Data Capture [REDCap](#)
- For clinical studies GCP-compliant [secuTrial](#)

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# Data storage, security and back-up

## Pseudonymization



**!** Pseudonymised data is subject to data protection regulation

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# Data storage, security and back-up

## Anonymization



### Personal information

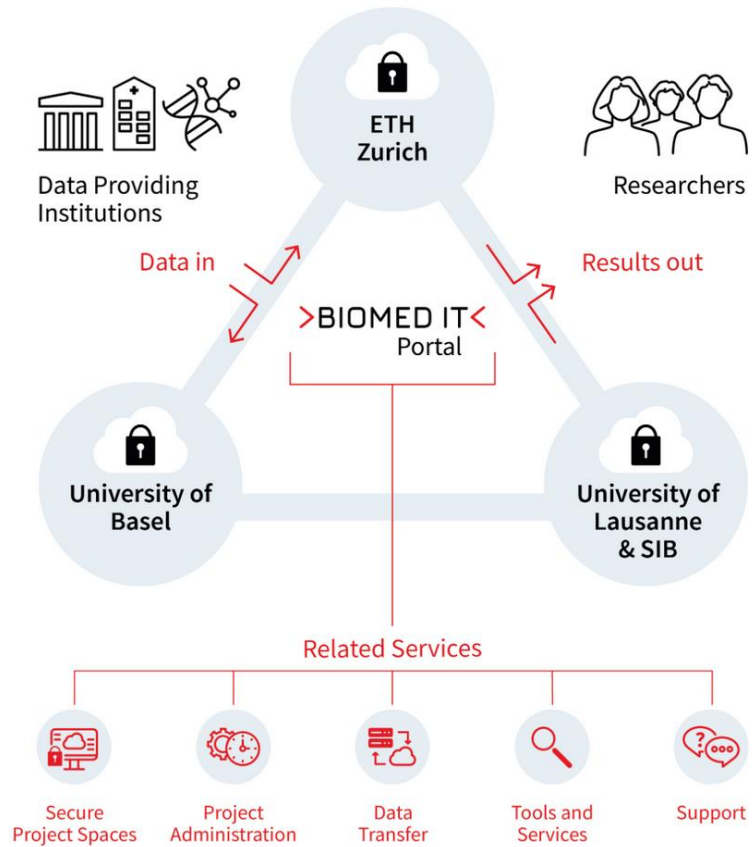
- Name, Surname
- Birthdate
- Gender
- Health data



### Anonymised data

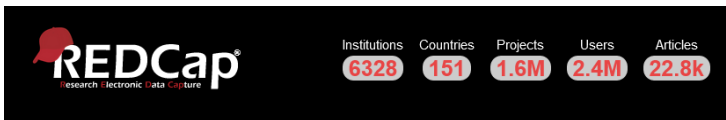
\*\*\*\*\*

# Data storage, security and back-up



- IT-Secure database
- Controlled access
- Explicit consent
- Adequacy decision
- Data transfer agreement with standard contractual clauses
- Binding corporate rules (approved by data protection authority)
- Recommended by the Cantonal Ethics Commission

<https://www.biomedit.ch/>



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# Ethical sharing research data and research outputs



Social media and platforms are not complying with Open Science Policy



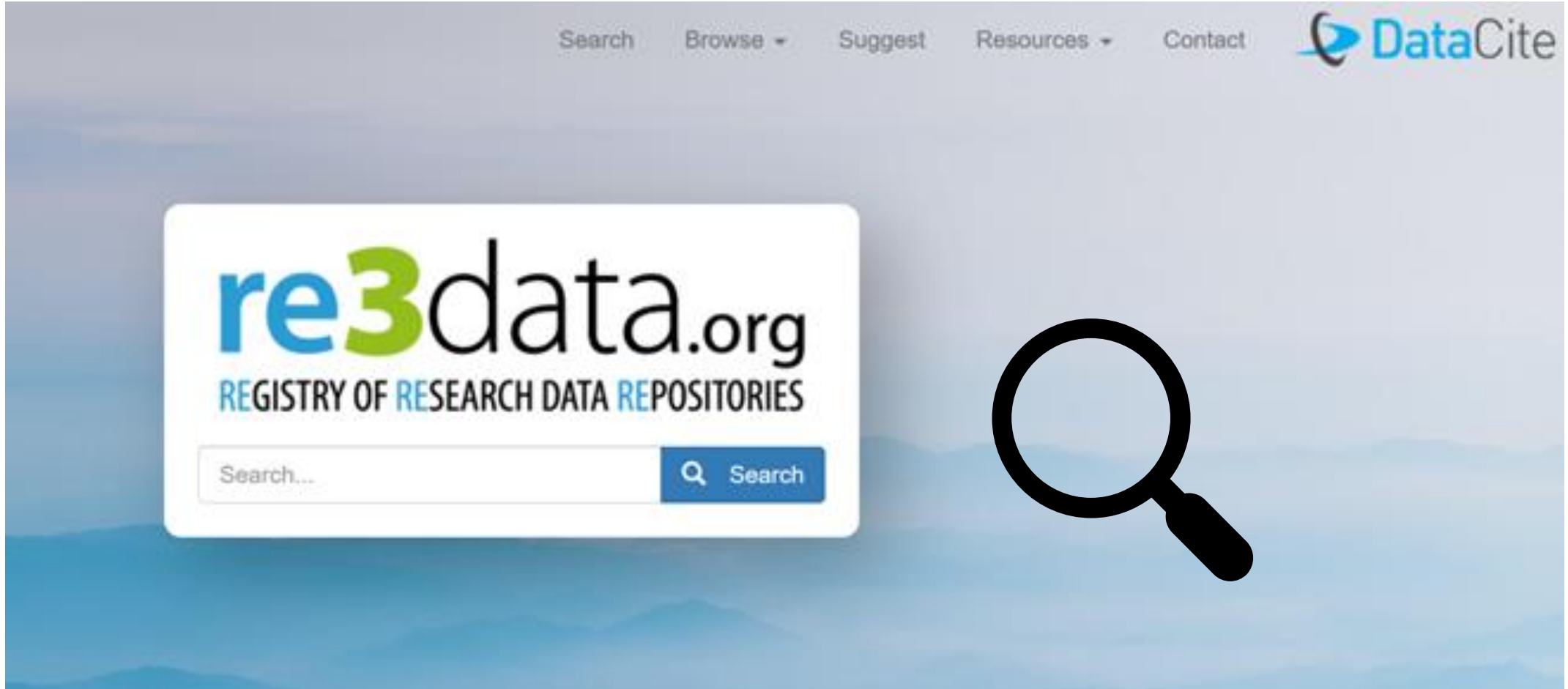
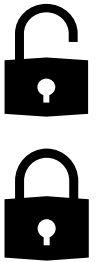
- Uncontrolled communication and dissemination of research results
- Password-protected access

- Intellectual property and Copyright issues

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# Data publishing

## Research data repository



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# Data publishing FAIR and CARE



## Discipline specific repository



## Cross-disciplinary



## Institutional repository



BORIS Portal

Research Data & Projects

## Generalist repository



<https://zenodo.org/>



# Data transfer and use agreement (DTA)



Colour code:  
Grey background = To be completed;  
Yellow background = the internal references to the contract (to be updated if necessary) or Optional text.

## DATA TRANSFER AND USE AGREEMENT

This agreement (hereinafter referred to as the "Agreement") is made and entered into by and between:

[name], [(registration number if any)], [address]

---

(the "PROVIDER")

and

[name], [(registration number if any)], [address]

---

(the "RECIPIENT")

Hereinafter jointly referred to as the "PARTIES" and individually as a "PARTY".

- Contract between data provider and data recipient person intending to re-use data
- Regulates the conditions under which data are disclosed to recipient
- Conditions may include guaranteeing appropriate confidentiality, integrity, availability and security of the systems used to process data

# Non-disclosure agreements (NDAs)



## **NDA**

To treat confidential information. The rules that will apply to the possible future collaboration will be negotiated in a separate research agreement.

## **NDA for Concept**

CONFIDENTIALITY AND NON-USE AGREEMENT – if your laboratory wishes to disclose a concept in order to enable your partner to grasp the economic and technical value of such concept before a possible technology transfer or cooperation agreement.

## **NDA bilateral**

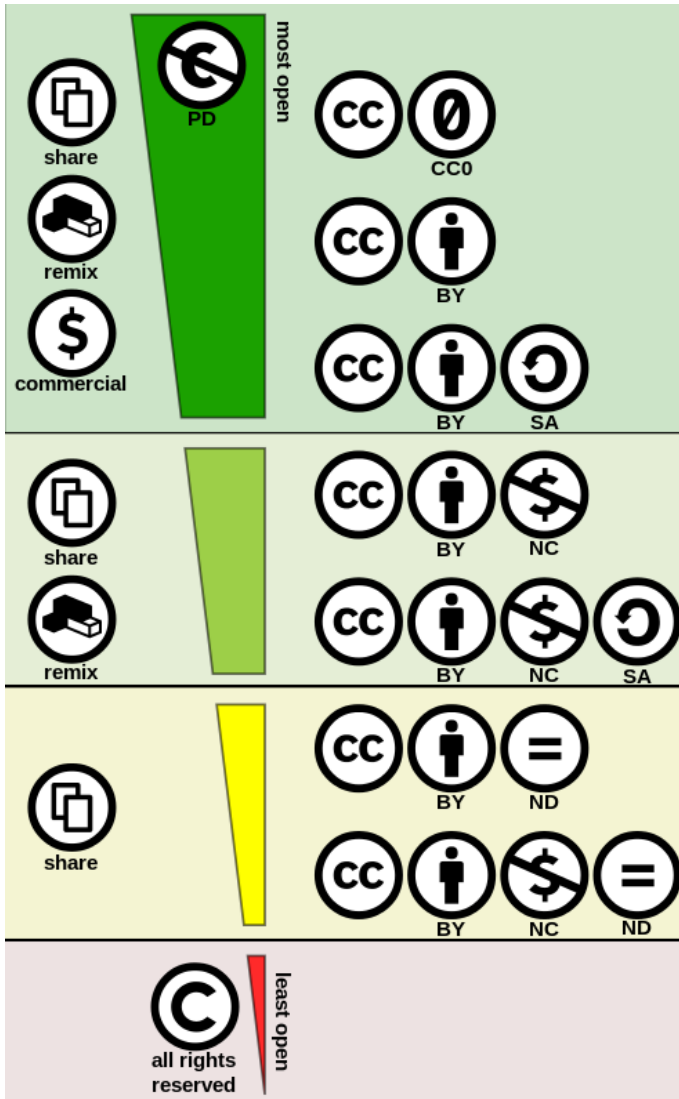
Your laboratory and your partner wish to exchange confidential information for a defined purpose.



Please get in touch with Legal Services Office UniBE  
[info.rechtsdienst@unibe.ch](mailto:info.rechtsdienst@unibe.ch)

u<sup>b</sup>

# Data, computer code, software publication



## To reuse data, take into account:

- Licenses
- Ownership (including joint ownership)
- Data transfer and use agreement



- If there are **NO** ethical, legal or contractual issues
- Metadata
- Supplementary material



- Some forms of processed data (e.g., elaborate visualisation)
- Data will be commercially exploited (patents)



u<sup>b</sup>

# How to Manage research data ethically

## Summary



**REDCap**  
Research Electronic Data Capture

**secuTrial**<sup>®</sup>  
for your clinical research



1

Ethics approvals  
[ISDS analysis](#)  
Information security management ([ISO](#))  
Password-protected access  
IT-UniBE support [helpdesk@id.unibe.ch](mailto:helpdesk@id.unibe.ch)

2

[Pseudonymisation tool](#)

3

Anonymisation tool  
[Arx.deidentifier](#)  
[Amnesia](#)

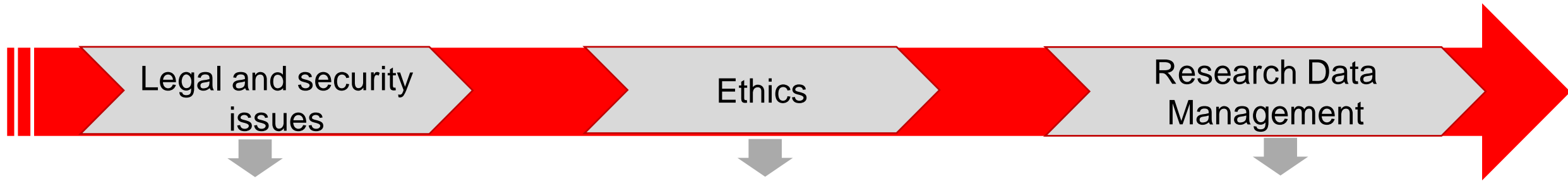
4

- Closed = No data → Metadata
- Embargoed
- Restricted
- [Data Transfer Agreement](#)
- Data documentation

*u<sup>b</sup>*

# Ethical, legal and security issues

## Summary

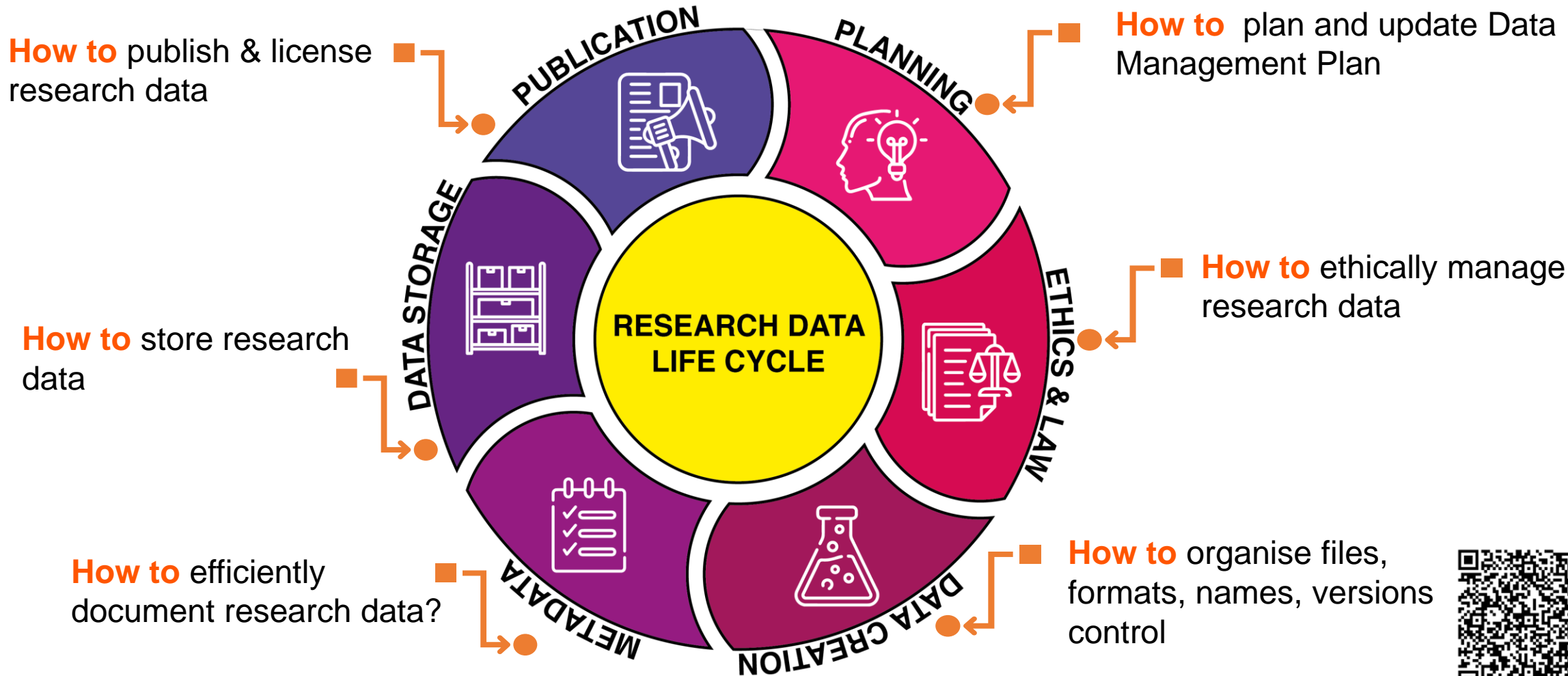


- Legal Services Office UniBE [E-Mail](#)
- UniTectra [E-Mail](#)
- Data sharing / Data Transfer and use agreements / Confidentiality agreements (DTA [here](#))
- IT-Service
- [Information security and data protection \(ISDP\)](#)
- Faculty/ Institute/ Department

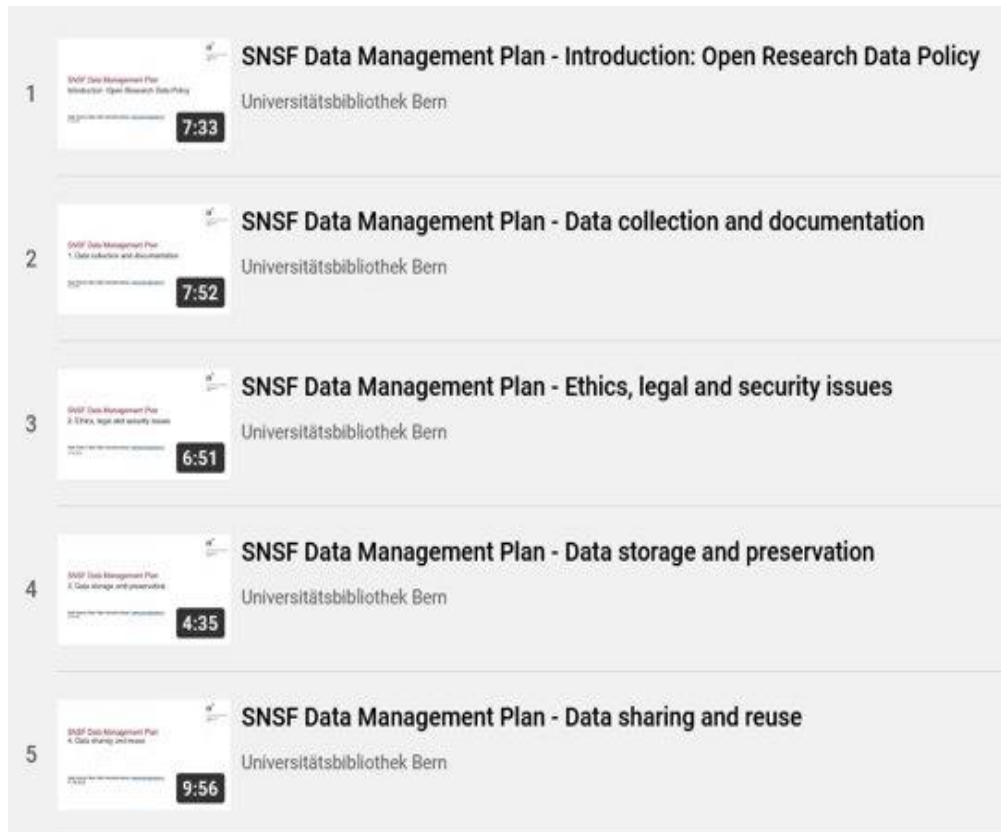
- [Ethics commissions](#) at the Institutes UniBE
- Cantonal ethics commission (for clinical studies, see [KEK](#), [HRA](#))
- [Animal Welfare Office](#)
- Federal Office for the Environment [FOEN](#) Red Lists: Threatened species in Switzerland
- Research Commission of Swiss National Parks ([FOK-SNP](#))

- [DMP review](#)
- [BORIS Portal](#): Research Data Repository
- [Training & Support](#)

# Support Training



# Data management plan review



1 SNSF Data Management Plan - Introduction: Open Research Data Policy  
Universitätsbibliothek Bern 7:33

2 SNSF Data Management Plan - Data collection and documentation  
Universitätsbibliothek Bern 7:52

3 SNSF Data Management Plan - Ethics, legal and security issues  
Universitätsbibliothek Bern 6:51

4 SNSF Data Management Plan - Data storage and preservation  
Universitätsbibliothek Bern 4:35

5 SNSF Data Management Plan - Data sharing and reuse  
Universitätsbibliothek Bern 9:56

Video modules [YouTube](#)

University Library of Bern UB

UB Research Services Faculty libraries About us

< Research Data Management

## Data Management Plan Review

Here you can upload your data management plan for review by the RDM team prior to submission to the research funding agency. If you are writing a DMP for the Swiss National Science Foundation SNSF, we recommend you to watch our short introduction in five short videos [on YouTube](#).

Alternatively you can send us your DMP by [mail](#).

Name \*

First name \*

Email address \*

Funder submission deadline  
TT . MM . JJJJ

Upload  
 Keine Datei ausgewählt.

Ideally, you should upload the document in Word format.

Comment

Data Management Plan review [online](#)  
Feedback within 1-3 working days

# Support Talks

**21** NOVEMBER  
17:15 - 18:00 UHR

EVENT  
OPEN SCIENCE

**Bern Data Talks - Preparing  
Data for Publication**

- [Prof. Dr. Tobias Hodel](#)  
University of Bern, Digital Humanities
- [Prof. Dr. Stefan Brönnimann](#)  
University of Bern, Institute of Geography
- [Thilo Hirsch](#)  
Bern University of Applied Sciences, Bern  
University of the Arts





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# Open Science Newsletter

- Funder's news
- Training sessions and courses
- Developments in Open Access and Research Data



**To subscribe:**

<https://www.unibe.ch/ub/osnews>



*u*<sup>b</sup>

# Research Data Management Support Survey

We would like to learn about your wishes and needs in order to optimize our training and consulting services.  
Thank you for participating in this short and anonymous survey!

[t1p.de/RDMsurvey](https://t1p.de/RDMsurvey)



*u*<sup>b</sup>

# Tools

- Law tool <https://dmlawtool.ccdigitallaw.ch/>
- Anonymization <https://amnesia.openaire.eu/>; <https://arx.deidentifier.org/anonymization-tool/>
- Pseudonymization [ERDRI.spider](#)

*u*<sup>b</sup>

# Useful Links

## Studies on and with humans

- Pre-registration <https://www.cos.io/initiatives/prereg>; [Registration Forms and Templates](#)
- [Swissethics](#)
- Clinical Trials Ordinance, [ClinO](#)
- [Templates](#) from Swissethics

*u*<sup>b</sup>

# Useful Links

## Studies on and with animals

- Pre-registration studies with animals <https://www.animalstudyregistry.org>
- [Swiss Animal Protection Act \(German\)](#)
- [Federal Food Safety and Veterinary Office \(FSVO\)](#)
- [Swiss Animal Welfare Ordinance \(German\)](#)
- [European Directive \(2010/63/EU\)](#)
- [Guidelines on Animal Testing; SAMS](#)

*u*<sup>b</sup>

# Useful Links

## Recommendations

- [Recommendation on research data documentation from the Open Science Team \(PDF, 141KB\)](#)
- [ELN vs. LIMS: How to Make a Choice?](#)
- [Research Data Repositories SNSF list](#)

# Useful Links

## Federal Law

- Data Protection Act, [FADP](#) in force from 01 Sept 2023
- Human research Act ([HRA](#))
- [Animal welfare Act](#)

## Cantonal Law

- [Cantonal law](#) on Data Protection (under formal consideration)
- Cantonal ethics commission ([KEK](#), for clinical studies on human)

## University Level

- Data ownership ([University of Bern Act](#))
- Faculty ethics commissions at UniBE ([Phil.-Hum.](#); [Phil.-Hist](#); [WISO](#), [Embedded Ethics Lab](#), [Center for Artificial Intelligence in Medicine](#))
- [Animal welfare Office](#)
- [Code of conduct for scientific integrity](#)

*u*<sup>b</sup>

# Useful Links

## Data Transfer

- Template for the Consortium Agreement (CA), Data Transfer and Use Agreement (DTUA) and Data Transfer and Processing Agreement (DTPA) of the Swiss Personalized Health Network (SPHN) (click [here](#)).



*u*<sup>b</sup>

# Useful Links

## Service and Support at UniBE

- [Open Science Team](#) Research Data Management
- [Legal Service Office](#), Data Protection Officer
- [Research Management Office](#)
- [UniTectra](#)
- [IT-Security](#)

# Contact

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Contact Point: Human Sciences

Psychology, Education, Sport



*u<sup>b</sup>*

Thank you

for your attention

**Open Science Team**

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