

# SNSF Data Management Plan

## 2. Ethics, legal and security issues

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## 2. Ethics, legal and security issues

### Key questions to address

2.1 How will ethical issues be addressed and handled?

2.2 How will data access and security be managed?

2.3 How will you handle copyright and Intellectual Property Rights (IPR) issues?

## 2.1 How will ethical issues be addressed and handled?

- What is the relevant protection standard for your data? Are you bound by a confidentiality agreement?
- Do you have the necessary permission to obtain, process, preserve and share the data? Have the people whose data you are using been informed or did they give their consent?
- What methods will you use to ensure the protection of personal or other sensitive data?

## 2.1 Ethical issues

### Research (not) requiring autorisation

No autorisation required

Non sensitive



- Reputation, moral, norm
- [Code of conduct for scientific integrity](#)  
Zenodo [link](#)

Requiring autorisation

Faculty ethics commissions  
National research councils

Cantonal ethics commissions  
[Swissethics](#), [Swissmedic](#)

Sensitive



- Federal Act on Data Protection, FADP
- [Cantonal law](#)
- [Human Sciences](#)
- [Business, Economics and Social Sciences](#)
- [Research Commission Federal Office](#)
- Swiss Animal Welfare [Act](#), [Office UniBE](#)

Highly sensitive



- Human Research [Act](#)
- [Animal experimentation](#)
- Ordinance on [Clinical Trials with Medical Devices](#)
- Clinical Trials [Ordinance](#)
- Human Research [Ordinance](#)
- Therapeutic Products [Act](#)

## 2.1 Ethics authorisation

# Swiss National Science Foundation guidelines

Copies of the authorisation or notification can be scanned and uploaded during the online submission.



Please note that **grants can only be paid out if all the necessary authorisations and notifications are available**. SNSF recommends that researchers **apply for these documents to the relevant authorities in parallel to the evaluation**.

## 2.1 Ethical issues

### Informed Consent (IC)

*“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.”* [ICH-GCP E6\(R2\)](#), 2016 Sec 1.28

**A written, signed and dated IC form includes everything (!) you plan to do with data:**

- Purpose, nature and extent of data processing
- Duration of data storage (e.g., 10 or 15 years [SNSF guidelines](#), Art. 5.1, [swissethics](#)) and deletion
- Measures to protect data (anonymisation, access control, etc.)
- Disclosure of data to third parties

## 2.2 How will data access and security be managed?

- What are the main concerns regarding data security, what are the levels of risk and what measures are in place to handle security risks?
- How will you regulate data access rights/permissions to ensure the security of the data?
- How will personal or other sensitive data be handled to ensure safe data storage and -transfer?

## 2.2 Data access

### Data security



[Anonymisation tools: Amnesia](#), [ARX tool](#)  
[Pseudonymisation tool](#)

[VeraCrypt](#) – Open source software  
for data encryption

- Identify level of risks for data security
- Information security and data analysis (ISDP)
- Information security management ([ISO](#))
- Data access rights, permissions
- Secure data storage and data transfer
- Secure database [REDCap](#), [secuTrial](#)
- International Standard Organisation (ISO) number
- Secure online surveys [LimeSurvey](#), [Qualtrics](#)
- Archiving for 10 or 15 years (depends on the study field [SNSF guidelines](#), Art. 5.1, [swissethics](#) and cantonal laws)



## 2.3 How will you handle copyright and Intellectual Property Rights (IPR) issues?

- Who will be the owner of the data?
- Which licenses will be applied to the data?
- What restrictions apply to the reuse of third-party data?

## 2.3 Copyright and Intellectual Property Rights

### Data owner

#### Rights to research results

- The rights to the research results gained in the course of research work funded by the SNSF are owned by the grantees and/or their employer.
- Grantees are obliged to define such rights together with their employer by no later than the time the funded research work is completed [SNSF Art. 44](#)

#### Act of the University of Bern

*“Intangible work products created by employees in the performance of their official duties as well as in the course of their professional activities shall be deemed to have been assigned to the University without further ado.”*

*“In the case of a service obligation for different employers, the right to the intangible results of the work shall be governed by contract.”* [UNIG Art. 70](#)



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## 2.3 Copyright and Intellectual Property Rights

### Copyright

- A legal term used to describe the rights that creators have over their literary and artistic works (literature, arts, computer programs, software).
- [Federal act on copyright and related rights](#)
- SNSF [Copyright](#)
- [Software](#) (Copyright / open source)
- Art. 70.2. BSG 436.11 University [Act](#)

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Shaddim, [Creative Commons](#)

## 2.3 Copyright and Intellectual Property Rights

### License



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



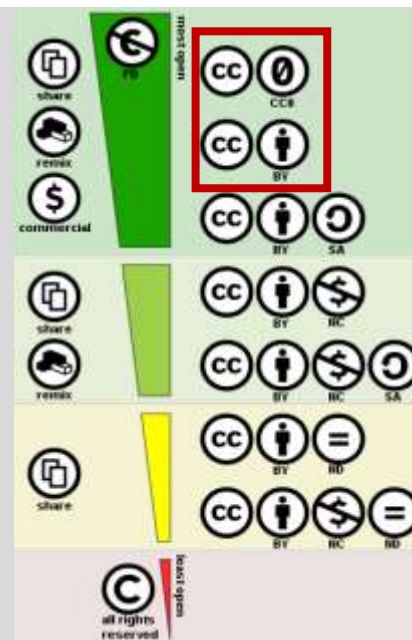
- CC-BY is recommended

## 2.3 Copyright and Intellectual Property Rights

### Third-parties data

#### Before data reuse please carefully check

- License
- Ownership / Copyright
- Written Joint Ownership Agreement (JOA)
- Data transfer agreement



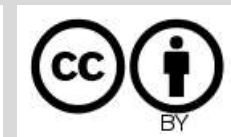
# Summary

## 2. Ethics, legal and security issues



**REDCap**  
Research Electronic Data Capture

**secuTrial**  
for your clinical research



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

[Pseudonymisation  
tool](#)

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

Closed data = No data →  
Open metadata (CC0)  
Embargo  
Restricted  
[Data transfer & use Agreement](#)