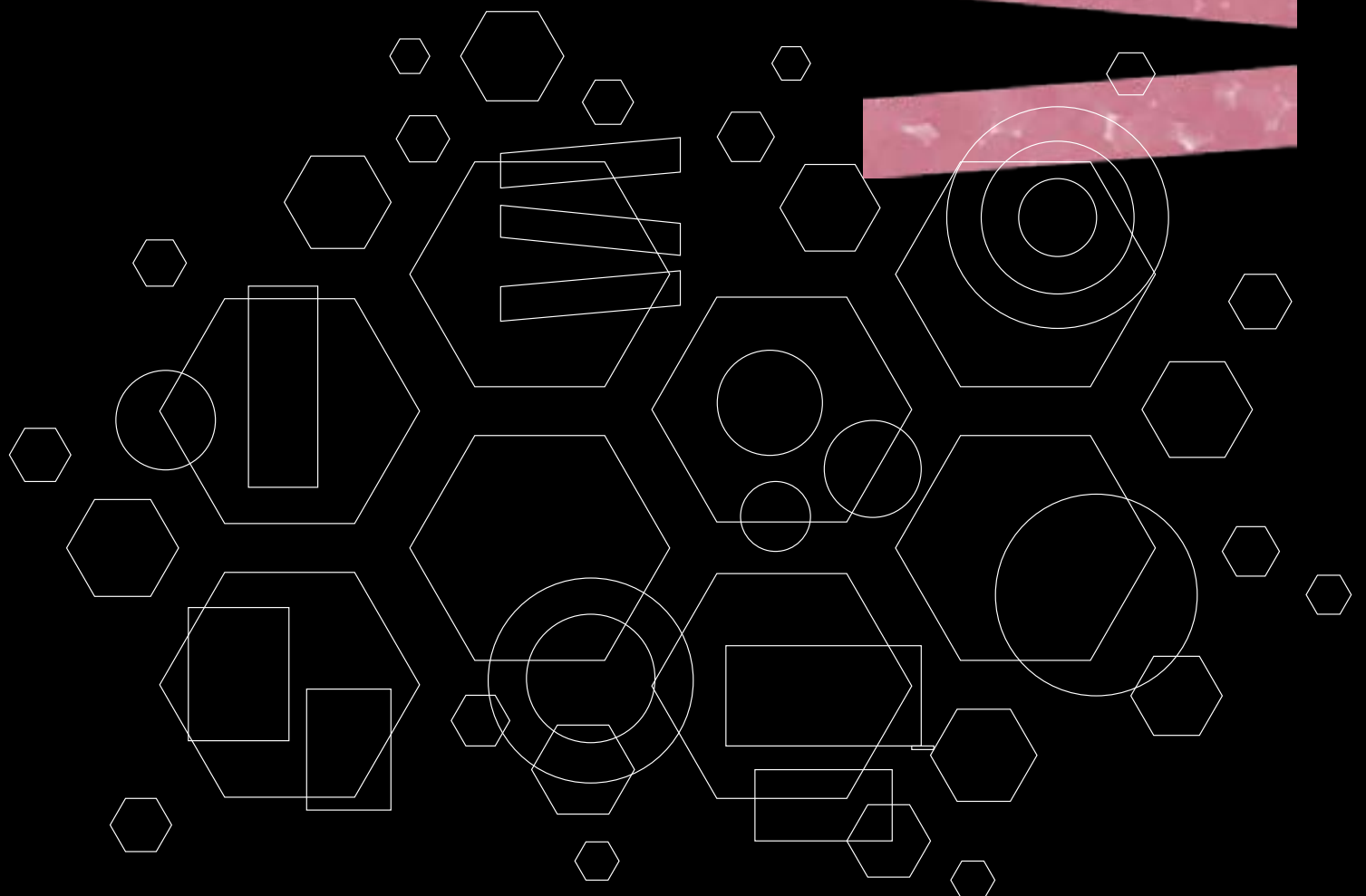
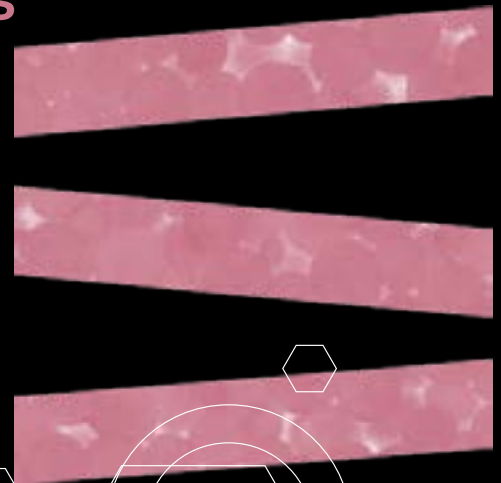


The new Federal Act on Data Protection (nFADP)

Guidance for clinical trials



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The new Federal Act on Data Protection (nFADP)

Guidance for clinical trials

On 1st of September 2023, the new [Federal Act on Data Protection \(nFADP\)](#)¹ came into force. The revision improves the processing of personal data and grants Swiss citizens new rights. The nFADP applies to all Swiss-based and international companies that provide goods or services to Swiss citizens and to organizations that process sensitive data, such as medical records and genetic material.

This short guide shall help you to understand whether the nFADP is relevant for your clinical research project and what the most important changes are as compared to the old FDAP.

Do I need to care?

The nFADP applies to data of natural persons processed by private persons and federal bodies² in Switzerland. A private person is defined as an individual, corporation, partnership, or other nongovernmental legal entity.

The nFADP does not apply

- to data processing carried out solely for personal use.
- to data processing by the federal parliament and their committees as part of their deliberations.
- to data processing by universities, except for federal institutions, or cantonal hospitals. (These institutions are governed by cantonal data protection law. Although each canton has its own data protection law, these will be aligned with the nFADP as far as applicable).
- to the processing of anonymised data if re-identification by a third party is impossible.

To determine which data protection law(s) (nFADP, cantonal data protection acts, European Union General Data Protection Regulation [GDPR]) apply to your research project, you may consult the decision trees below or get advice from the Data Protection Officer (DPO) of your institution.

¹ German: Neues Datenschutzgesetz (revDSG); French: Nouvelle loi sur la protection des données (nLPD); Italian: Nuova legge sulla protezione dei dati (nLPD). Note: The link refers to the English translation of the nFADP which is provided for information purposes only and has no legal force.

² Federal bodies are the administrative units of the Confederation, i.e. the departments, federal offices, their divisions and sections, and federal institutions such as the ETH, EPFL, EMPA, and SUVA. This also includes decentralised federal administrative units such as customs offices, military commands, federal armouries, etc. Not included is the federal parliament and their committees as part of their deliberations.

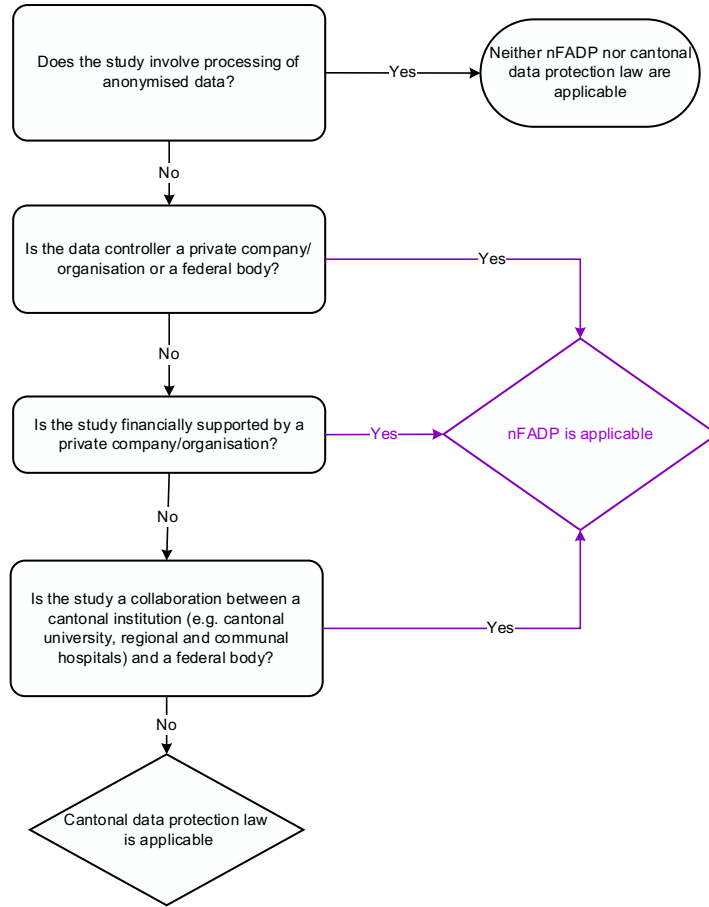


Figure 1: Decision Tree - Federal Act on Data Protection (FADP) vs. Cantonal Data Protection Law

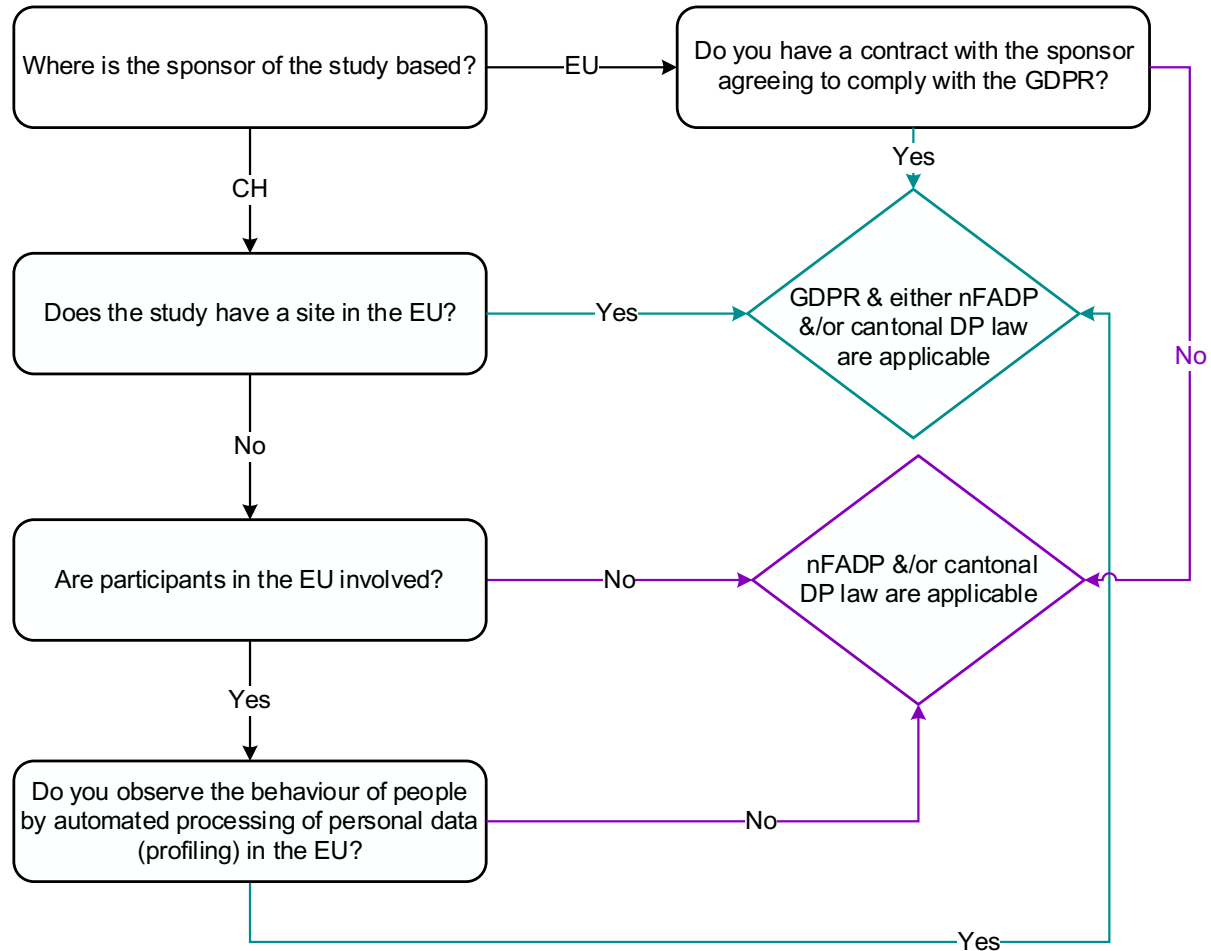


Figure 2: Decision Tree - European Union General Data Protection Regulation (GDPR) vs. Swiss Data Protection Act

Abbreviations: EU: European Union, CH: Switzerland, DPA: Data Protection Act including both federal and cantonal data protection law, GDPR: General Data Protection Regulation

What are the most important changes?

The main changes in the nFADP as compared to the previous FADP are listed below. For more detailed information, please refer to this [message](#) of the State Secretariat for Economic Affairs (SECO) and/or to the Guidance document “Das neue Datenschutzgesetz aus Sicht des EDÖB” (currently only available in German; accessible via this [link](#)) of the Federal Data Protection and Information Commissioner ([FDPIC](#)):

1. Only data of natural persons are concerned (Art. 2)
2. Principles of “Privacy by Design” and “Privacy by default” are introduced³ (Art. 7)
3. Genetic and biometric data are now classified as sensitive personal data (Art. 5c)

³ The principle of “Privacy by Design” requires developers to integrate the protection and respect of users’ privacy into the very structure of the products or services that collect personal data. The principle of “Privacy by Default” ensures the highest level of security as soon as the products or services are released, by activating by default, i.e. without any intervention from users, all the measures necessary to protect data and limit their use. In other words, all software, hardware and services must be configured to protect data and respect the privacy of users.

4. Appointment of a Data Protection Officer (DPO) is recommended (Art. 10)
5. Keeping a register of data processing activities is now mandatory (Art.12)
6. Associations authorised to safeguard the economic interests of their members may submit their codes of conduct to the FDPIC, which will state and publish his/her opinion on the codes of conduct (Art. 11)
7. A certification and a data protection quality mark will be introduced for data processing systems or programs (Art. 13)
8. The obligation to inform the data subjects⁴ (Art. 19) and their right to information (Art. 25) are extended
9. If data processing is likely to result in a high risk to the privacy or fundamental rights of data subjects, a Data Protection Impact Assessment (DPIA) must be carried out by the controller⁵ beforehand (Art. 22)
10. The data controller must consult the FDPIC before processing data when the DPIA reveals that, despite the measures taken by the controller, the proposed processing still poses a high risk to the privacy or the fundamental rights of the data subjects (Art. 23)
11. In the event of a data breach, the controller must inform the FDPIC quickly. The data subject concerned must also be informed if this is necessary for their protection or if the FDPIC requests it (Art. 24)
12. Data subjects may request to receive the data concerning them in electronic format (right to data portability) (Art. 28)
13. The disclosure of personal data abroad is allowed if an adequate level of data protection is guaranteed (Art. 16)
14. Private data controllers with their registered office or domicile abroad must appoint a representative in Switzerland to act as a contact point for the data subject and the FDPIC (Art. 14)
15. Reported potential violations of the data protection regulations will be investigated by the FDPIC (Art. 49)
16. The FDPIC can formally order federal bodies or private persons to adapt, interrupt, or stop data processing and deleted or destroyed the personal data (Art. 51)
17. The FDPIC may spontaneously comment and publish its opinion and assessment on new technologies, digitization, or processing practices (Art. 57)
18. The FDPIC will charge private persons for its services (Art. 59)
19. A fine up to CHF 250'000 may be imposed on private persons who violate their legal obligations (Art. 60)

Do I need to change anything regarding the currently ongoing clinical research project(s)?

First check if the nFADP is applicable to your project (see the decision trees above). It applies only to projects with private persons and federal bodies as the data controller/sponsor. If it applies, be sure your project aligns with the requirements of the nFADP (see the changes compared to the old law listed above).

⁴ Data subject means a natural person whose personal data is processed.

⁵ Controller means a private person who or federal body which, alone or jointly with others, determines the purpose and the means of processing personal data

For information as to how the nFADP may affect the content of the participant information document etc., please refer to the official communication of swissethics on their website under “[News](#)”.

Links

- New Federal Data Protection Act (nFADP): <https://www.fedlex.admin.ch/eli/cc/2022/491/en> (last checked September 2023)
- Federal Data Protection and Information Commissioner: <https://www.edoeb.admin.ch/edoeb/en/home/datenschutz/grundlagen.html> (last checked September 2023)
- Research and data protection: https://www.edoeb.admin.ch/edoeb/en/home/datenschutz/forschung_statistik/forschung.html (last checked September 2023)
- General Data Protection Regulation (GDPR) related information: https://commission.europa.eu/law/law-topic/data-protection/reform_en (last checked September 2023)
- General Data Protection Regulation (GDPR): <https://gdpr-info.eu/> (last checked September 2023)§