**Title:** Research data management in Education, Psychology and Sport Sciences at the Faculty of Human Sciences, University of Bern, Switzerland

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#### 1. Introduction

The Faculty of Human Sciences at the University of Bern includes three institutes: the Institute of Educational Science, the Institute of Psychology and the Institute of Sport Science.

<u>Research management (FOMA)</u> at the Faculty of Human Sciences aims to support researchers by strengthening excellent research and managing research data ethically in line with the Swiss federal laws and ordinances. **We advise** researchers where and how, and under which conditions and formats to store their research data, and provide consulting on requirements and best practices for metadata and documentation description, data monitoring and coding of variables. **We support** with the data management processes, continuous monitoring and updates related to data management plans (DMP), which are required by the Swiss National Science Foundation and EU-Commission. **We inform** researchers on the legal ordinance of the <u>Swiss Federal Act on Data Protection (FADP)</u> for the ethical management of sensitive data, on the <u>Findable</u>, <u>Accessible</u>, Interoperable, and Reusable (FAIR) data principles and on available IT-solutions in accordance to the <u>General Data Protection Regulations (GDPR)</u>.

# 2. Research Data

Data collection and sharing is part of the research projects conducted at the Faculty and therefore need to meet ethical and legal requirements. Collected are either related to clinical studies, which fall under the Federal Act on Research involving Human Beings (<u>HRA, Art. 118b § 1</u>) and require approvals from an ethics committee (e.g., <u>Cantonal Ethic Commission (CEC)</u> or <u>Swissmedic</u>), or studies that do not fall under the HRA and can be reviewed and evaluated by the <u>Ethical Committee experts at the Faculty</u>. Yet, most of the data are personal and health-related personal data, therefore, informed consent, case report forms and homogenized protocols should be taken into consideration in agreement with legislation in Switzerland.

Here we give some examples of the ethical data treatment according to good research practices. We face challenges, leverage strengths and create opportunities by providing data management within the human science disciplines in relation to:

**Personal and health-personal data:** Sociodemographic (date of birth, place of birth, civil status, nationality, old-age and survivor's insurance (OASI); Personality- and ability-related data (workplace-related problems); psychophysiological data such as electroencephalography (EEG) and functional magnetic resonance imaging (fMRI) recordings; mental health-related behaviors and attitudes; anthropometric data: Body Mass Index (BMI), waist circumference, bioimpedance data; cardiovascular data (blood pressure, pulse wave velocity, heart rate variability).

**Clinical data:** Symptom severity and changes during therapy; online-assessments; randomized online studies and surveys; confidentiality agreements; inform consent forms; study protocols; case report forms; monitoring reports.

**IT- and software applications:** Computer games; applications for kids; educational applications; self-help applications; phone applications; survey & interviews (Qualtrics, Atlas.ti); clinical trials and surveys (RedCap, Qualtrics); statistical software (R, Stata, SAS, SPSS).

**Data format and storage:** Anonymised scans (.tiff, .png); tables (.csv encoded in UTF-8); text documents (txt, A/PDF) coded as ASCII; audio (.wav, .mp4); video (.mov, .avi, .mj2, .mkv, FFV1 codec); graphics (HDF5, .svg). Password-protected access for the project principal investigators (PI) and project members. Traceable anonymized data transfer and password-protected access to the encoded data within the project partners. All tablet computers are password-protected, with the experimenters being the only persons to have password-protected access to the data. Information about data collection and documentation, ethical,

legal and security issues, data storage and preservation, as well as data sharing and reuse is provided in the data management plans, supporting researchers to design and conduct their projects according to the FAIR principles, legal ordinances and requirements of the national and international funding agencies.

### 3. Challenges

- Where and how to store the identifying data or personal participants' data additionally to separate database with anonymised encoded data?
- Possible delays in the study due to amendments to the ethics commissions.
- Where is the right place to store encrypted and password-protected video/audio interviews?
- Which is the most appropriate Software to use for surveys?
- Is it necessary to use licensing under continuous games integration?
- Where is the right place to store neurophysiological (EEG- and fMRI) data?
- What is the right criteria to use pseudonymisation vs. anonymisation? Encrypted and anonymised interviews are often needed to be pseudonymised (e.g. Olympic champions).
- How can video/audio images of interviews be anonymised? If not at all, then what are the possible solutions?

### 4. Strengths & Opportunities

- Use professional software that correspond to the GDPR and store the data within national Swiss data repositories or within European Union.
- Follow the <u>Good Clinical Practice (GCP)</u> and International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (<u>ICH</u>) rules and prepare applications for the ethics committees earlier enough by leverage better study planning.
- Use collaborative approach at the institutional level and with other research centers to strengthen network.
- Follow Open Science strategy by "open data as possible, as close as necessary" under legal
  ordinance of the <u>FADP</u> for the management of sensitive data ethically based on the <u>FAIR</u> data
  principles and on available IT-solutions in accordance to the <u>GDPR</u>.
- Identify the overall strategy for data management processes before the project starts. Apply for licenses for presentations, talks, developed games, phone applications etc.

# 5. Collaboration

The FOMA data management support at the Faculty is offered in collaboration with the Clinical Trial Unit (CTU, University of Bern); IT-persons of the three research institutes at the Faculty and Ethics Committee at the Faculty; and the Open Science Team at the University of Bern, Switzerland.