***Instruction for use***

**Project title**

**Project Leader:** Academic title, first and last name, affiliation

**Study personnel:** Academic title, first and last name, affiliation

Academic title, first and last name, affiliation

 Academic title, first and last name, affiliation

**Planned start of project**: Day, Month, Year

**Planned termination of project** Day, Month, Year

**Further information:** Text

The project leader approves the research plan version X (Day, Month, Year)

**Project Leader:** Academic title, first and last name, affiliation

Signature

 Place, Date

# ETHICAL AND REGULATORY ASPECTS

## Participant Information and Informed Consent

Explain that participants will be informed about the research project (when, how, by whom) and that consent is sought from each participant; mention of compensation if any are foreseen and that informed consent may be sought for general and further use of data.

# INTRODUCTION

## Background

Describe the research question, including any scientific data on which the research project is based (published / unpublished). Any statements that rely on existing knowledge or published information shall be adequately referenced.

## Rationale for the research project

Provide a clear statement on the rationale and justification of the research project, potential new findings, and choice of investigation and the project population.

* 1. Risk-Benefit Assessment
* *Assess the risk for project participants against the potential benefit (risk-benefit statement). Risk also includes the risk of unauthorised data access and/or unwanted identification of project participants. Describe key aspects regarding the rationale to include particularly vulnerable participants.*
* *For studies without immediate benefit to the project participant, a rationale should be provided stating how the results of the project could benefit future participants. If necessary, a description of how risks to project participants are minimised and if applicable how post-project protection is implemented.*

# PROJECT DESIGN

* 1. Type of research and general project design
* Provide a description of the type of the project (qualitative, observational, fundamental, sampling or collection of data without research question at present), the project setup (e.g. multicentre / single centre; national / international).
* Describe the design of the research project and the rationale for the choice of design. Provide a discussion of the known or potential problems and limitations of the design, if applicable.

## Recruitment, Screening, and Reimbursement

* Describe procedures for participant recruitment, e.g. “participants are contacted by letter and telephone” or “participant recruitment through advertisement placed in xx”; provide all relevant details (e.g. such as dates or location).
* Please describe the reimbursement of participants, which should be justified with regard to effort and duration of the project for individual participants.

## Procedures

Provide a description of intended procedures (assessments, measurements, project visits, interviews, etc.) and stages, the expected duration of participants’ participation, description of the sequence and duration of all research project periods, refer to schedule of assessment. If possible as flow chart.

## Objectives

State principle project objective(s) as pre-specified hypotheses.

## Outcome variables

* Describe the outcome (dependent) variable(s), i.e. how it was measured/observed (e.g., questionnaire, tests), and which metric was used (e.g., change from baseline, final value, time to event).
* For repeated-measures designs: indicate all time points and which of these were included in the analysis.
* Specify all related processes (methods) to promote data quality, e.g. duplicate measurements, training of assessors etc.
* If applicable, describe primary outcomes (for which the study was designed and effects sizes estimated prior to power analysis) and secondary endpoint/outcome(s) (additional outcomes for which the study was not specifically designed). The primary endpoint/outcome is the main variable that is measured at a precise time-point or at end of the investigation/observation to answer the primary research question. It should be measurable and should give information towards the project objective(s)).

## Predictor variables

Describe predictor (independent) variables being included in the analysis to answer the specific research hypotheses.

## Other study variables

Describe, if applicable, other study variables, e.g. covariates, potential confounders/effect modifiers, including how these will be assessed.

# PROJECT POPULATION and SAMPLE

* Describe the target population on which the sampling is based
* Describe the planned project sample: number of participants, age range, gender distribution etc.

## Inclusion criteria

* Describe in detail the inclusion criteria for the participants’ eligibility for the project. Create a list of criteria and be as specific as possible.
* List all project inclusion criteria, for example: target population, age (e.g. age ≥ 18 years), ethnic / socio-demographic background, life style factors (e.g. exercise, smoking history).

## Exclusion criteria

Describe in detail the exclusion criteria for the participants’ eligibility for the project. Create a list of criteria and be as specific as possible, for example: pregnant or lactating women, specific medication(s) or treatment(s), other clinically significant concomitant diseases, life style factors and addictions such as drug or alcohol abuse, inability to follow procedures (e.g. due to psychological disorders or dementia), insufficient knowledge of project language, etc. (depending on research project question, additional or other criteria may apply).

## Criteria for withdrawal / discontinuation of participants

Describe reasons for which a participant needs to discontinue from the project, e.g. withdrawal of informed consent, non-compliance, etc. and describe procedures to follow in these cases (HRO Art.10).

# STATISTICAL METHODOLOGY

## Determination of Sample Size

Describe the statistical rationale for sample size in terms of the power of the test to detect a given difference or attain a given precision in the primary endpoint/main hypotheses. If this is not possible, the planned sample size should still be justified.

## Handling of missing data

Describe how missing data and data of drop-outs will be handled in the analysis (i.e. completer analysis, available cases, multiple imputation, maximum likelihood approach). Ensure that an adequate number of participants will be evaluated, e.g. by compensating for expected drop-outs or by replacement.

# DATA AND QUALITY MANAGEMENT

*Describe measures taken for data collection, handling, management and quality control: e.g. that project personnel are trained on all important project related aspects and that internal audits are planned.*

## Data handling and record keeping / archiving

Describe how data are handled and that all study related documents are archived (essential documents and site documents)

## Confidentiality, Data Protection

* Data generation, transmission, storage and analysis of personal data within this project will follow strictly the current Swiss legal requirements for data protection.
* Data protection: project data shall be handled with uttermost discretion and only be accessible to authorised personnel. Describe how data are handled confidentially and that all study related data are protected.

## Coding

* Describe the coding procedures of personal data, the storage location of the coding key and who has access to the key. The code may only be broken if it is necessary to avert an immediate risk to the health of the person concerned or to guarantee the rights of the person (e.g. in revoking the consent) or a legal basis exists for breaking the code.

## Debriefing

*Research participants should be informed about the aims of the research project (content, results, conclusions etc.)*

## Archiving and Destruction

* Specify time-period and location of storage of data. If applicable, describe how data will be destroyed after project termination and how this will be documented or if there is any further use planned, in which case describe planned use and duration.

# FUNDING AND SUPPORT

Provide a brief statement of sources and types of financial, material, and other support for the project. If applicable, make reference to other places or contracts/documents where this information is captured.

Declare any conflict of interest if applicable and the role of the funders in the research project; otherwise provide a statement of no conflict of interest (independence, intellectual, financial, proprietary etc.)

# REFERENCES

Provide a list of the references cited in the project plan.

# APPENDICES

Add any appendices here if relevant. For documents that change very frequently consider mentioning as separately provided documents with a link included here.