



Swedish Infrastructure for Medical Population-Based
Life-Course and Environmental Research

Rules and Guidelines for Database and Biobank



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1. Introduction

SIMPLER, Swedish Infrastructure for Medical Population-Based Life-Course and Environmental Research, is an infrastructure for epidemiological research. A consortium consisting of Uppsala University (host), Karolinska Institutet, Chalmers University of Technology and Örebro University is responsible for development, operation and management of SIMPLER. Database and biobank are open for and accessible to scientists in academia or business and project requests should be handled smoothly in an open process. Instructions for project requests can be found at www.simpler4health.se.

2. Accessibility database and biobank

Projects must be approved by SIMPLER in order to acquire data or samples. Approval includes confirmation of approved ethical review and verification by responsible PI of funding for the project. In addition, fee for data and/or samples must be paid and personal data user agreement signed before data/samples are released.

Application

- All project requests must follow the procedure for application.
- A project must have an explicit and well defined hypotheses/research question besides using relevant and motivated analyses. For biological samples, the choice of biomarker must be motivated.
- Each project must have an ethical approval from a valid ethical review board.
- If the director of SIMPLER reject a project request, the applicant can appeal to the steering committee of SIMPLER for a second review.

Availability

- Project requests with similar hypotheses/research question will be approved, but the projects will be informed of each other and encouraged to collaborate. However, if a project has financed analyses of biological samples there will be a one year waiting time from the day when the analysis is finished before data is shared with other projects.
- Since the biological samples are a finite resource, and SIMPLER has a responsibility towards participants and funders, requests for samples from the entire sub-cohorts or with high scientific value that supply the infrastructure with informative, not previously analysed biomarkers, are prioritized.
- All processing and storage of data must be done in an application safety classified for sensitive personal data provided by Uppsala University. Users get access to this application when data is handed out in a project specific folder. Data must not be moved from this folder, users are only allowed to download result files from the application.
- If SIMPLER is wound up, users should be informed well in advance concerning the changed terms for the infrastructure.

Delimitation of a research project

A project is delimited to up to three adjacent and specific research questions and with a durability of up to 5 years and a scope of up to 5 publications/manuscripts.

A longer duration or more publications/manuscripts within the same project demands a new application and user fee. Also, if already requested and received data and/or biological samples are desired to be used in an extension of the project or in another project, an additional application must be completed. The additional application must be approved before analysis can begin.

Prolongation of a project after 5 years can be requested if a researcher has been prevented from working on the project due to parental leave or a longer sick leave for one self or for a close relative. This is also valid for members of vital importance for the project such as graduate students.

Delimitation of a student project

The following requirements must be met for a project to be counted as a student project:

In the application to SIMPLER the syllabus for the work and the student's register extract or equivalent documentation must be attached in addition to the mandatory information.

The scope of the work must be such that it can generate a maximum of one scientific publication in addition to the written report that may be asked for by the course syllabus.

3. User obligations

- Users must return variables, i.e. biomarkers, obtained at analysis in order to benefit the infrastructure. This is done in collaboration with SIMPLER's data manager.
- On request from SIMPLER's office, responsible PI must give feedback on project progress once a year for SIMPLER's annual report and report to SIMPLER's funders.
- The main funder, the Swedish Research Council, may do a scientific evaluation of the infrastructure, and must on request be given access to the complete research material of all SIMPLER projects.

4. Publication of results

- At publication and other dissemination of results based on data and/or samples from the infrastructure, the infrastructure must be acknowledged by stating the infrastructure name and the Scientific Research Council grant no, 2017-00644. At publications of scientific articles this should be done under the heading "Acknowledgement" or equivalent. This obligation is valid for infrastructure staff as well as other users of the infrastructure. Example: "We acknowledge SIMPLER for provisioning of facilities and experimental support and we would like to thank x, y and z for assistance. SIMPLER receives funding through the Swedish Research Council under the grant no 2017-00644."
- Also, the host of the computational resources needs to be acknowledged. Example: "The computations were performed on resources provided by SNIC through Uppsala Multidisciplinary Center for Advanced Computational Science (UPPMAX) under Project SIMP XXXX/Y-ZZZ."
- Research results must be available as open access within six months after publication. This is preferably done by publication in an open access journal. Please do notice that journals with open access as optional may have a time lag for open access publication.
- Some journals demand/ask for publication of data in connection with publication of the article. This is not in accordance with the general data protection regulation and this requirement cannot be met. Users are obliged to inform the journal about this, and can for example state "Data are available from SIMPLER (www.simpler4health.se) for researchers who meet the criteria, i.e an ethical approval is demanded, for access to de-identified SIMPLER data."
- Abstracts of manuscripts must be approved by SIMPLER's director before the manuscript is submitted to a journal. If in doubt, the director can ask for a second review from SIMPLER's steering committee.

- The manuscript, in particular material and methods, must be reviewed by SIMPLER's statistician before it is submitted to a journal. The statistician has the authority to perform control calculation/analysis of data handed out from SIMPLER.
- There is no general request from the director or the steering committee of SIMPLER for co-authorship on publications including data from SIMPLER. Co-authorship is discussed if the concerned persons have significantly contributed to the publication, i.e. with their knowledge on the cohorts; see the Vancouver-rules.
- In the case where rules are violated, the steering committee of SIMPLER will decide on what action to take. The seriousness of the infringement determines action, the scale of action goes from a reminder to follow the rules, to suspension from the infrastructure and data access.

5. Fees

Reduced fee

Student projects has a reduced fee corresponding to the application fee provided that they meet the requirements for student projects under point 2.

Project requests regarding biological samples from the entire cohorts and requests that enrich the infrastructure have the possibility to get a reduced fee. This is decided by the steering committee of SIMPLER on a case by case basis.