

SWISSIBD cohort study

GUIDELINES AND OPERATIONAL RULES (SOPs) FOR SCIENTIFIC PROJECTS SUBMISSION AND REVIEWING

I. Introduction

The Swiss IBD Cohort Study (SIBDCS) welcomes and encourages all types of research projects linked to patients with IBD and related diseases. However, preference will be given to projects likely to benefit from the SIBDCS infrastructure (databank, biobank, clinical research network) and including at least two of the major SIBDCS centers (research on large number of patients and/or necessitating recruitment from more than one center).

II. Submission of a research project

1. General principles

All submissions and communication with the **Scientific Committee** has to occur in English.

For any use of the SIBDCS data for research purpose, a protocol has to be submitted to the **Scientific Committee**. This applies also if no funding is requested, in order to centralise information linked to research projects to avoid duplication and potential conflicts with other projects, and to track them. Protocol submission is required prior to the initiation of a project. Ongoing or finalized projects cannot be submitted for retroactive support or funding.

If a submitted SIBDCS project is nested within another research project financed by the SNSF, two experts designated by the **Scientific Committee** must have the possibility to read the grant submitted to the SNSF and have full knowledge of its decision.

In order for the experts to gather this information and study the documents, such a project has to be submitted to the Scientific Committee **2 weeks earlier** than the usual deadline of the SNSF.

2. Who can submit ?

All researchers who are formally involved and actively participate in the SIBDCS may submit research projects.

Any project which is submitted by a non SIBDCS researcher has to be **endorsed and supported by a SIBDCS member** who will supervise the project scientifically and will have the financial responsibility (responsible investigator).

3. Deadline and addresses

The **Scientific Committee** meet 4 times a year. Research protocols have to be submitted at least 5 weeks before the **Scientific Committee** meeting. The dates are regularly posted on the webpage (<http://www.ibdcohort.ch>).

All research protocols need to be submitted electronically to sibdcs-submission@chuv.ch, from where they are automatically forwarded to the **Chair of the Scientific Committee** and the **Head of the Datacenter** of the SIBDCS.

4. Protocol content requirements

The detailed description of the study should concisely present all the information necessary to permit a complete assessment of the proposal. In general, it should consist of 6-10 pages. A template for protocols is available on the homepage.

4.1. Administrative information

The name of all investigators of each center involved in the project should be mentioned. It is understood that they have all agreed to participate actively in the submitted proposal.

For each project, a responsible investigator has to be identified (see point 2)

4.2. Summary

- 300 words maximum.

4.3. Background

- Present state of knowledge in the area of the proposed research with key references

4.4. Study hypotheses

- The hypothesis which this project proposes to test

4.5. Study aims and objectives

- Objectives of the project in relation to state of knowledge
- The scientific and practical significance of the proposed research

4.6. Own research in the field

- Including relevant experience and a list of publications
- Relevant background information on the other investigators

4.7. Material and methods

- Inclusion and exclusion criteria for the selection of the study population
- Sample size calculation
- Epidemiological methods
- Laboratory methods
- List of outcomes and exposure variables requested to answer the objectives
- List of complementary data acquisition questionnaires, investigations or tests to be performed in patients (**see also point 5.**)

- Statistical methods

4.8. Time frame

- Time-frame for the project (including explicit and detailed research tasks to be performed within the credit and the duration of the project)

4.9. Status of Ethics Approval

- Mention of the ethics approval or amendment this research protocol refers to
- Ethical committee to contact (if applicable)

4.10. Study budget

- Indicate infrastructure and manpower already available for the study
- Indicate what funds you expect to obtain from other sources (industry, SNFS, foundations, etc...)
- The budget should include appropriate details as well as external funded expenses.
- For personnel, the requested position(s) and duration should be justified by a description of the tasks
- The budget of the study should take into account only costs not already covered by the core research projects of the SIBDCS and the cohort infrastructure.

Specify the following costs: personnel, laboratory tests, specimen retrieval, reimbursement to the participating centers, special tasks requested from the **Datacenter**, diverse.

- The budget may be modified by the **Scientific Committee** and has to be approved by the **PI of the SIBDCS**. If the authors do not agree with the allocated budget, they should immediately notify the PI of the SIBDCS, particularly if they think that the whole project cannot be fully carried out with the allocated funds. In principle, supplement funding at a later stage will not be possible.
- The budget must comply with the rules of the Swiss National Science Foundation

4.11. Other information

- Interim analysis (if applicable)
- How you imagine disseminating your results (publication in scientific journal, thesis, internal report, conference, etc.)
- A proposal for authorship should be part of each submitted project.
- National or international collaborations (if applicable)
- DTA or MTA (if applicable)

4.12. References

Please attach whatever information you feel would help to support the submission. Such information includes:

- A covering letter
- The curriculum vitae of the principal investigator (if not already sent before)
- An informed consent form for drug trials

- Approval of the sponsoring institution's and/or the university's ethics review Committee

5. Complementary patient self-reported data acquisition

If the research project intent to collect additional data through questionnaires addressed to patients, the following information has to be considered:

- The **template** for patient questionnaires has to be completed and submitted with the proposal, this comprises:
 - An introduction (title, rationale for the study)
 - The name of a contact for additional information or questions
 - The list and format (continuous, categorical, binary) of each variables
- The template is requested in both German and French. The translated version should be sent to the head of the Datacenter **within 6 weeks** after the approval of the research project.
- The investigators of the project are responsible for the translation. No translation will be performed at the Datacenter.
- The maximum length of additional questionnaire is 3 pages.
- The deadline for proposal requesting additional questionnaire is the spring meeting of the **Scientific Committee** (i.e. usually in March)
- Additional questionnaires will be put together in one sole document, and sent only once per year (i.e. usually in September)
- The **Scientific Committee** is responsible for selecting which additional questionnaires will be sent, if their total number is too high for one year. The selection will be made through a ranking process during the spring session. The questionnaires unselected for one year will be sent a year later.

6. Evaluation and decision processes

The Scientific Committee is elected by the general assembly of the SIBDCS.

The cohort PI, the PIs of the core projects, the head of the Datacenter, the head of the biobank, the head of the IBDnet and a person representing the SMCCV are part of the members of the Scientific Committee.

The head of the Scientific Committee is not identical to the cohort PI

- The **Scientific Committee** evaluate all submitted projects. The head of the **Scientific Committee** appoint two members as reviewers for each submitted project.
- The reviewers send a written structured comment to the Head of the Scientific Committee. They must together with the head of the Datacenter verify that there is no overlap with an ongoing project. Should this be the case, the reviewers/head of the Scientific Committee or the head of the Datacenter must contact and inform the corresponding and responsible investigators of the project.
- The responsible investigator is invited to attend the Scientific Committee meeting during the discussion of his project if necessary
- A project is accepted if approved by 2/3 of the members attending the meeting. The Head of the **Scientific Committee** may request a secret vote if the opinions among the members diverge considerably.

- The cohort PI is informed of the Scientific Committee decisions
- The responsible investigator is informed about the decision within 3 weeks following the Scientific Committee meeting
- Authors who do not agree with the decision on a project can appeal to the Scientific Committee within 1 month. The Scientific Committee will then take a final decision.

Submission of a modified project:

A project for which modifications have been required by the Scientific Committee may be re-submitted:

- A point by point reply to all comments of the Scientific Committee is requested from the investigators (like for publications)
- The modified protocol, with relevant changes highlighted in yellow, and the point by point reply (filled into the specific text box of the full proposal template) have to be sent to the usual address (Sibdcs-submission@chuv.ch)
- The modified protocol is sent to the reviewers who have initially reviewed the project
- The project is discussed at the next Scientific Committee meeting
- Submissions have to be done as usual through the SIBDCS submission e-mail with request for rapid evaluation (Sibdcs-submission@chuv.ch)

7. Progress report

6 to 8 months after having initiated the project, the corresponding / responsible investigator has to send a short progress report to the secretary of the Datacenter.

8. Publications

8.1. Authorship

See: SIBDCS_SOP01.02-v3.1-Authorship_policy.doc.

All manuscripts conducted in the frame of the SIBDCS should include the cohort grant number.

8.2. Any submitted or published manuscript

With mention of the project number, should be sent by e-mail to the head of the Datacenter