

# SWISS IBD cohort study

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

For any use of the SIBDCS data for research purpose, a proposal 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. Proposal submission is required prior to the initiation of a project. Ongoing or finalized projects cannot be submitted for retroactive support or funding.

In case of simultaneous submission to the Swiss National Science Foundation (SNSF) and the SIBDCS, the Scientific Committee has to give a first opinion/advice, which will be transmitted to the investigator and to the SNSF.

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

A “letter of intent” (3 pages) can be submitted any time. The letter of intend will be reviewed by two members of the Scientific committee and discussed at monthly telephone conferences. The decision will be made public to the applicant at longest 6 weeks after submission.

The **Scientific Committee** will meet four times a year. The dates will be posted on the webpage. Full proposals have to be submitted at least 3 weeks before the **Scientific Committee** meeting.

All proposals need to be submitted electronically to <mailto:Sibdcs-submission@chuv.ch>, from where they are automatically forwarded to the **Chair of the Scientific Committee** and the **National Coordinator** of the SIBDCS.

### 4. Types of Proposals

In order to simplify the procedure of application for research projects, the Scientific Committee supports the following two steps in research proposals:

- **Letter of Intent** (1-3 pages)

A letter of intent usually will be sufficient if no funding is required. However, the Scientific Committee has the right to request a Full Proposal if there are any concerns regarding the Letter of Intent.

- **Full Proposal** (6-10 pages)

At each step, the **Scientific Committee** will get back to the investigators in order to avoid unnecessary efforts if a project is not felt to be worth pursuing or if coordination with other projects is necessary.

#### *4.1. Letter of Intent*

The purpose of a letter of intent is to inform the **Scientific Committee** about the plan for a scientific project. A preliminary discussion of such a proposal will help the investigators to perform their project within a major scope of the scientific agenda of the SIBDCS. The **Scientific Committee** may also make suggestions for additional study aims or additional research groups/researchers to be included in the final project.

The letter of intent will include a short general description of the research question, the rationale and the resources likely to be needed. Minimum requirements include:

- A short introduction with 1 - 5 key references

- The study objectives
- The study design (power calculation if appropriate)
- A preliminary budget

For a project which needs only data sets and no financial support, the decision can be taken on the basis of a letter of intent. For funding, a full proposal has to be elaborated.

## *4.2. Full Proposal*

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 full proposals will be given on the homepage.

### 4.2.1. 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)

### 4.2.2. Summary

One page maximum.

The author should provide a running title (or the complete title) for announcement on the website of the SIBDCS in case of acceptance

### 4.2.3. Background

- Present state of knowledge in the area of the proposed research with key references
- Objectives of the project in relation to state of knowledge

### 4.2.4. Own research in the field

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

### 4.2.5. Study aims and objectives

- The hypothesis which this project proposes to test
- The scientific and practical significance of the proposed research

### 4.2.6. Study design and research plan

- Investigations and tests to be performed in patients
- Laboratory methods
- Follow-up evaluation; patient management issues
- Statistical methods
- Time-frame for the project (the research tasks to be performed within the credit and the duration of the projects should be explicitly mentioned)

### 4.2.7. 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 :

Specify costs according to the 4 phases of the project: preparation, operation, data analysis, manuscript writing.

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

- The budget may be modified by the **Scientific Committee** and has to be approved by the **Steering Committee**. 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 ([www.snf.ch](http://www.snf.ch))

#### 4.2.8. Other information

- Ethical committee to contact
- 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.
- DTA or MTA if necessary

#### 4.2.9. References

#### 4.2.10. Attachments

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

- A covering letter
- CRF if relevant (i.e. key investigators not known to the Sc Committee)
- 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. Evaluation and decision process:

The Scientific Committee will be elected by the general assembly of the SIBDCS. It is recommended that the cohort PI, the PIs of the core projects, the National Coordinator, the head of the datacenter, the head of the biobank, the head of the IBDnet and a person representing the SMCCV are members of the Scientific Committee. The head of the Scientific Committee should not be identical to the cohort PI

- The **Scientific Committee** has to evaluate all submitted projects. The head of the **Scientific Committee** will appoint two members as "expert" for each submitted project.

- The two experts review the project and send a written structured comment to the Head of the Scientific Committee. They must together with the National Coordinator verify that there is no overlap with an ongoing project. Should this be the case, the experts/head of the Scientific committee or the National Coordinator must inform the cohort PI who will contact the investigator.
- The responsible investigator is invited to attend the Scientific Committee meeting during the discussion of his project if necessary
- A project is accepted with the approval of 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 Steering Committee ratifies the Scientific Committee decision
- The responsible investigator is informed about the decision within three weeks following the Scientific Committee meeting
- Authors who do not agree with the decision on a project can appeal to the Steering Committee within one month. The Steering 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](mailto:Sibdcs-submission@chuv.ch))
- The modified protocol is sent to the experts who have initially reviewed the project
- The project is discussed at the next Scientific Committee meeting

Urgent decision needed:

- Rapid decisions may be taken by e-mail but they are limited to very special circumstances :
  - Temporal delay of the decision to the next Scientific Committee meeting would jeopardize the timely publication of the work (e.g. late breaker abstract, important publication in a very competitive situation)

- The suggested budget for the proposed work is less than CHF 5'000.-
- Submissions have to be done as usual through the SIBDCS submission e-mail with request for rapid evaluation ([Sibdcs-submission@chuv.ch](mailto:Sibdcs-submission@chuv.ch))
- The Head of the Scientific Committee will decide whether special circumstances are met
- If accepted, the proposal is sent to all members of the Scientific Committee by e-mail.
- The proposal is first discussed by e-mail by all Scientific Committee members using the Scientific Committee address ([Sibdcs-submission@chuv.ch](mailto:Sibdcs-submission@chuv.ch)) during 7-10 days. The deadline is given by the Head of the Scientific Committee.
- After the discussion period, the Head of the Scientific Committee will ask all Scientific Committee members to vote by direct mail to ([Sibdcs-submission@chuv.ch](mailto:Sibdcs-submission@chuv.ch)): 7 days turnaround time. The decision is final if all voting members accept the proposal. If this is not the case, the project will automatically be put on the agenda of the next Scientific Committee meeting.

## 6. Progress report

6 to 8 months after having initiated the project, the responsible investigator has to send a short progress report to the National Coordinator. It should contain:

- Quantitative figures if appropriate (% of objectives reached)
- Delay in the initial time schedule should be explained and a revised time schedule has to be presented (termination, manuscript, publication).

## 7. Allocation of the funds

The following rules will be applied for the allocation of the funds:

- 20 % of the budget on approval
- 30 % of the budget on receipt of a scientific intermediate report and of the expense proofs corresponding to 50%
- The remaining amount but not more than 50% of the approved budget on receipt of the required documents :
  - a financial report including original expense proofs
  - a publication or a manuscript accepted for publication. In case of repeated rejections, a scientific report must be sent
  - a CD Rom including the final study protocol, the raw data and the statistical programs used for the analysis

- a list of the requested blood samples with mention of their quality and availability.

If the allocated budget does not exceed CHF 10'000.- 50% of the amount is paid on approval.

## 8. Publications

### 8.1. Authorship

See: SIBDCS\_SOP01.02-v3.1-Authorship\_policy.doc.

### 8.2. Footnote

The SIBDCS member list has to be included as a footnote.

### 8.3. Any submitted or published manuscript

With mention of the project number, should be sent by e-mail to the National Coordinator