

HOW TO HANDLE DATA OF THE *SwissSarcomaRegistry*

I. Guidelines and Operational Rules for Scientific Projects

The *SwissSarcomaRegistry* welcomes all types of research projects linked to patients with sarcoma.

II. Submission of a research project

1. General principles

All grant submissions and communication with the Scientific Board (to be established) has to occur in English.

Any use of the *SwissSarcomaRegistry* data for research purpose has to be submitted to the Scientific Board. This applies even if no funding is requested, to avoid duplication and potential conflicts with other projects. Submission is required prior to the initiation of a project. Ongoing or finalized projects cannot be submitted for retroactive funding.

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

If a submitted *SwissSarcomaRegistry* project is nested within a research project financed by the SNSF, the two experts designated by the Scientific Board 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 2 weeks earlier than the usual deadline.

2. Who can submit

In principle, all researchers can submit projects to the *SwissSarcomaRegistry*. Specifically, there are two tracks for submission:

1. Researchers who are involved and actively participate in the *SwissSarcomaNetwork* may submit research projects.

2. Non- *SwissSarcomaNetwork* researchers also can submit *SwissSarcomaRegistry* projects if the project is endorsed by a *SwissSarcomaNetwork* member who supervises the project scientifically and takes the financial responsibility regarding the allocated *SwissSarcomaNetwork* budget (responsible investigator).

In both cases, *SwissSarcomaRegistry* authorship rules have to be followed.

3. Deadline and addresses

Letter of intent and full proposals have to be submitted at least 3 weeks before the Scientific Board Meeting (to be determined). See agenda on the *SwissSarcomaNetwork* website.

All proposals need to be submitted electronically to email of Scientific Board (to be added), from where they are automatically forwards to the Chair of the Scientific Board and the administrative office of *SwissSarcomaNetwork*.

4. Types of Proposals

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

- _Letter of Intent (1-3 pages)
- _Full Proposal

At each step, the Scientific Board 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 Board about a plan for a scientific project. A preliminary discussion of such a proposal will help the investigators to finalize their project within a major scope of the scientific agenda of the *SwissSarcomaRegistry*. The Scientific Board will also make suggestions for additional study aims or research groups 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
- _Apreliminary budget

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 10 pages or less. For proposals that only require the use of *SwissSarcomaRegistry* data but no financial support, 1-3 pages will usually suffice. The following information is required.

(To be defined)

4.2.1. ADMINISTRATIVE INFORMATION

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

unit/lab has to approve the proposal.

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

4.2.2. SUMMARY

150 words maximum. The author should provide a running title (or the complete title) for announcement on the Website of *SwissSarcomaNetwork* 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
- _Bio 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, Krebsliga, 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 project of the *SwissSarcomaNetwork*:

Note the 4 phases of a 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.

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.
- _Specification of samples and data to be used in the project

4.2.9. REFERENCES

4.2.10. ATTACHMENTS

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

- _A cover letter
- _Case Report File if relevant (i.e. key investigators not known to the Board)
- _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 board

5. Evaluation and decision process:

- _The Scientific Board has to evaluate all submitted projects. Its Chairman will appoint one or two members as “expert” for each submitted project.
- _The designated experts review the project and send a written structured comment to the Chairman of the Scientific Board. The designated experts are allowed to consult external experts, either in

Switzerland or abroad. The inclusion of an external expert in the evaluation has to be mentioned in the review. The investigator can list in the cover letter external experts who should not be contacted because of conflicts of interest. The designated experts must verify that there is no overlap with an ongoing project. Should this be the case, the expert must inform the Chairman of the Scientific Board who will contact the investigator.

- _The responsible investigator is invited to attend the Scientific Board meeting during the discussion of his project. A project is accepted with the approval of 2/3 of the members attending the meeting. The Chairman may request a secret vote if the opinions among the members diverge considerably.
- _The Executive Board ratifies the Scientific Board decision. The responsible investigator will be informed about the decision within three weeks following the Scientific Board meeting.
- _Authors, who do not agree with the rejection of a project, can appeal to the Executive Board within one month. The Executive Board will then take a final decision.

Submission of a modified project:

A project for which modifications have been required by the Scientific Board may be resubmitted:

- _A point by point reply to all comments of the Scientific Board 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 (to be added)
- _The modified protocol is sent to the experts who have initially reviewed the project
- _The project is discussed at the next Scientific Board 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 Board meeting would jeopardize the timely publication of the work (e.g. late breaker abstract, important publication in a very competitive situation)
- _Submissions have to be done as usual through the *SwissSarcomaNetwork* submission e-mail with request for rapid evaluation (to be added)
- _The Chairman of the Scientific Board will decide whether special circumstances are met
- _If accepted, the proposal is sent to all members of the Scientific Board by e-mail.
- _The proposal is first discussed by e-mail by all Scientific Board members using the Scientific Board address (to be added) during 7-10 days. The deadline is given by the Chairman.
- _After the discussion period, the SB Chairman will ask all Scientific Board members to vote by direct mail to (to be added): 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 Board 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 Coordination Center. 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

To be determined once funds are available

8. Publications

8.1. Authorship

- _The wording to be used is "**XYZ..., and the SwissSarcomaNetwork**".
- _Alternative wordings like "... for the „*SwissSarcomaRegistry*\" can only be used **with the approval of the Scientific Board**. If a rapid decision is needed, the request has to be submitted to the SB Chairman or to the President of the *SwissSarcomaNetwork*.
- _under *SwissSarcomaNetwork* in relation to authorship lists all delegates of the network at the time of submission, they are listed in alphabetical order.
- _Authorship guidelines follow the established rules of the Swiss Academy of Arts and Sciences (<http://www.akademien-schweiz.ch/en/index/Publikationen/Archiv/Richtlinien-Empfehlungen.html>).
- _Specifically, the sequence of authors reflects the importance of their contributions in descending order (Sequence determines credit).
- _First authorship is associated with the person who has invested most time in the project, two people can be listed as joint first authors if both contributed equally.
- _Last author is not associated with scientific seniority surpassing others, neither with bearing primary responsibility for the publication.
- _Corresponding author bears overall responsibility as represents the team vis-à-vis third parties.

8.2. Footnote

If applicable the wording includes: „This study has been financed within the framework of *the SwissSarcomaNetwork*, supported by the Swiss National Science Foundation (grant # XYZ) and by *SwissSarcomaNetwork project xyz*. The data are gathered by the members of the *SwissSarcomaNetwork*.

The members of the *SwissSarcomaNetwork* are available on www.swiss-sarcoma.net