

SWISS TRANSPLANT COHORT STUDY GUIDELINES AND OPERATIONAL RULES FOR SCIENTIFIC PROJECTS

I. Introduction

The Swiss Transplant Cohort Study (STCS) welcomes all types of research projects related to transplantation. All projects must be submitted on regular STCS application forms and are subject to review by the Scientific Committee (SC) of the STCS. While every scientist is invited to submit research projects, proposals must involve STCS investigators of at least two of the six STCS centers. Each person actively involved in the recruitment or care of STCS patients or involved in the infrastructural work will be considered as potential STCS investigators. Projects that address important research questions in the area of organ transplantation, and projects strengthening the collaborative research within the STCS (e.g. involving all centers of a given program), national or international networks are more likely to be approved.

II. Submission of a research project

1. General principles

Any research project that plans to use data generated within the STCS has to be submitted to the Scientific Committee (SC) for approval prior to access to the data.

Open access is granted to data generated within the STCS by the own center and transplant program to the respective transplant program for internal use.

The STCS distinguishes 3 types of STCS research projects:

1. Nested projects that make use of preexisting STCS data/infrastructure.
2. Projects that make use of the STCS data/infrastructure but require collection of additional data.
3. Investigational trials that make use of the STCS

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data/infrastructure.

The STCS will not fund STCS research projects. Funding has to be obtained from outside sources including SNSF.

2. Who can submit

Every scientist who wants to conduct a research project related to transplant recipients included in the STCS is welcome to submit a proposal to the SC, in accordance to the rules mentioned above. In case of two competing projects the SC will invite both parties to propose a joint project. If no agreement can be reached and both projects are of equal scientific value, researchers who are formally involved and actively participate in the STCS will be favored.

3. Deadline and addresses

Letters of intent can be submitted without deadlines. Full proposals have to be submitted at least 6 weeks before the SC meeting. Deadlines and dates of SC meetings will be posted on the webpage.

All proposals need to be submitted electronically, by use of the STCS application template to the designated email address of the STCS for project submission: sc-stcs@uhbs.ch.

4. Types of Proposals

In order to simplify the procedure for the application of research projects, the SC supports the following two steps:

Letter of Intent (max. 2 pages)

Full Proposal (nested projects, SNSF-related projects, collaborative national or international projects)

At each step, the SC 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

A letter of intent is required before submission of a full proposal and

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informs the SC about a plan for a scientific project. Letters of intent are to be sent electronically to the EO who will send it to all members of the SC and the BOR who will give their feedback to the SC chairman. The SC chairman will provide a general statement whether the project should be submitted as a full proposal. Invitation to submit a full proposal does not imply acceptance of the full proposal.

The letter of intent will include a short general description of the research question, the rationale and the needed resources and where funding will be applied for. Minimum requirements include:

- A short introduction with 1 - 5 key references
- The study objectives and methods
- The study design, list of participating centers, requirements for data/samples
- A preliminary budget and funding

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. Submission has to be done with the STCS template form (www.stcs.ch). In general, proposals should consist of 10 pages or less. The following information is required.

Administrative information

The name of all investigators of each center involved in the project should be mentioned. Investigators must consent to take the role assigned in the project and to participate actively in the submitted proposal.

There must be a designated responsible investigator (RI) for each project.

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A full proposal consists of:

- Summary (structured, one page)
- Background
- Study Aims
- Study Design
- Research Plan (max 10 pages)
- Describe state of research in the field. Mention the most important publications written by other authors.
- For each applicant, elaborate on the research fields. Please mention the most important publications.
- Establish a detailed research plan. Please mention: Objectives and goal; methods of investigation; the available data; the data to be collected; data analysis with sample size analysis or power analysis.
- In particular: mention the exact type and amount of STCS samples needed.
- Note the timetable and milestones of the project.
- Explain the significance of the planned research to the scientific community and to eventual potential users.
- Study budget: Expected costs; indicate infrastructure; manpower available; what funds you applied for/are already available
- Other information: Status of ethical approval, how to disseminate the results (publication, thesis, conference)

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- References
- Attachments, if applicable: Covering letter; CV's, CRF, informed consent

4.3. Participation of centers

Study sites confirmation

The study center representative confirms the willingness to actively support the study locally. In particular, the center study representative agrees to fill in or ensure infrastructure for an external person to complete a CRF if applicable. Confirmation must be in written (email ok) and attached to the full proposal.

5. Evaluation and decision process:

The SC evaluates all submitted projects. There will be 2-4 SC meetings in a calendar year. At least two SC meetings should be two months ahead of the SNSF submission deadlines. Deadlines for submission of full STCS proposals are six weeks before the SC meetings. The Chairman of the SC will send the proposal to two members of the SC for review. The experts review the project and send a written structured comment to the Chairman of the SC in ten days. Experts should rate and comment on the scientific content, relevance and appropriateness of proposed methods and the budget of the projects and should identify eventual overlap with ongoing projects. All project including reviews will be distributed electronically to all members of the SC ten days before the SC meeting.

Projects will be presented at the SC meetings by the experts followed by an open discussion of the SC panel. Review comments will be forwarded to the responsible investigator in seven days.

The responsible investigator will be routinely invited to the SC meeting to defend the proposal. If the responsible investigator is a member of the SC, he/she can be present to support the proposal.

The SC may approve a project, provisionally approve with minor modifications to be verified by the chairman and the reviewers, request the

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submission of a revised protocol or reject a project.

A project is accepted or provisionally accepted with the approval of a 2/3 majority of votes of the members of the SC attending the meeting and if the following provision for additional data generation is fulfilled:

→ Whenever new datasets or samples are needed, all directly involved transplant programs, represented by their SC member, must approve the project.

The Chairman may request a secret vote if the opinions among the members diverge considerably.

The EO may request reevaluation of the approval by the SC in the case of potential conflict of interest or problems between centers, or if the project is against the principal rules of the SNSF or of the STCS, or standards of good research.

The responsible investigator will be informed about the decision within one week following the SC meeting and EO ratification.

Authors, who do not agree with the rejection of a project can appeal to the Executive Office within one month. The Executive Office and the Chairman of the SC will then take a final decision.

Allocation rules of STCS funds for accepted projects

1. The maximal sum allocated is 30'000.- per project. If samples of the cohort are used, 50'000.- can be attributed for small nested projects.
2. The first priority is given to small nested projects which are defined by a budget of less than 50'000.- and can be successfully and rapidly performed, i.e. they will result in a publication within the next two years. These projects are based on data and/or samples available within the STCS.
3. A PI of a larger project (defined as a project with a budget proposal of >50'000.-) can apply for additional funding by the STCS, if the following provisions are met:

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- the total of external funding (guaranteed with a confirmation letter) and the funding provided by STCS (max. 50'000.-) will cover the overall budget as outlined in the proposal.
- 4. 2/3 of the funds provided by the STCS are available after the decision of the Scientific Committee. The remaining 1/3 of funds can be requested after completion of the study (which is defined as a manuscript accepted for publication, and submission of all primary data on a stick/CD plus program code to the data center for storing).

Submission of a revised project :

Investigators invited by the SC to submit a revised protocol must provide a point by point reply in the respective section of the STCS submission form and mark all changes in the revised protocol and resubmit electronically. Revised protocols are then made available to the experts and the SC for re-evaluation and final decision at the next SC meeting.

6. Progress report

Adequate funding and study initiation has to be notified to the SC.

A progress report is due once a year. 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. Authorship and publication

7.1. General issues

Authorship requires a relevant contribution to the study and manuscript, according to international rules and must be in accordance with the 2013 guidelines of the Swiss Academy of Science. The STCS guidelines are based on the guidelines of the International Committee of Medical Journal

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Editors (ICMJE) ("Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication"), last update in October 2007, and published online: <http://www.icmje.org/>.

Authorship in a STCS projects includes active participation in the design and writing of the full proposal. The PI is responsible for a complete list of collaborators at time of submission and ensures that all co-authors have seen, revised and approved the proposal.

The last author is considered the senior author.

7.1. STCS Authorship rules

- **The order and names must be defined at time of submission of a full proposal**
 - New authors are added only exceptionally
- **One representative per center**
 - Except if several people from a given center are directly and actively involved in the specific project
- **First and last author** are the **initiators** of the project and clearly designated in the full proposal.
- **Order of other co-authors – points to consider**
 - Active involvement in the project of one center exceeding the involvement of the other centers
 - Priority may be given to the representative of a given center if there is a specific interest of that center in the topic of research
 - Otherwise by alphabetic order
- The wording to be used in all publications is "**XYZ, and the Swiss Transplant Cohort Study**".
 - Exceptions to this rule are considered upon request to the SC.
- **Footnote members**

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- Names of people with a particular intense involvement in the structure and activities must be listed in each manuscript as group co-authors of the paper and linked to the “STCS” so that they are identified in a Pubmed search.

These names include:

The active members of the EO

The active SNSF co-investigators

The active members of the BOR

The active members of the Scientific Committee

The active heads of the local data center

The central data management

The current names will be updated and accessible on the STCS website so that they can be integrated at the time of submission of each manuscript.

In case of disagreement regarding authorship or co-authorship, the matter will be referred to the president of the Scientific Committee, who will consult the Executive Office, and if necessary, the Board of Representatives for a decision.

7.2. Publication

Prior to publication any manuscript and conference abstracts using data originating from the STCS must be submitted to the Chairman of the SC for formal approval. Refusal for publication can be given if rules of the STCS access to data and/or publication policies have not been adequately followed.

For all publications using data from the STCS adequate acknowledgement of all funding sources is mandatory and should be mentioned as follows:

This study has been conducted in the framework of the Swiss Transplant Cohort Study, supported by the Swiss National Science Foundation and the Swiss University Hospitals (G15) and transplant centers.

Investigators involved in international collaborative research using data of

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the STCS must assure that the contribution of the STCS is appropriately reflected either by co-authorships or by listing the STCS in the study appendix. This has to be clearly established and mentioned at the time the full proposal is submitted.

7.3. Final report

Any accepted manuscript must be sent by e-mail by the project responsible to the EO of the STCS with the internal project number. In addition an electronic copy of the STCS data set at the time of final analysis together with an electronic copy of the final data analyses files must be sent on a CD to the STCS data centre. An electronic copy of the reprint of the final publication must be sent to the EO and the data centre.

The responsible investigator holds the final responsibility for the budget the research project and sends a copy of the final financial report to the EO.

7.4. Sharing of data

Data resulting from an STCS project must be shared with other researchers upon request in a collaborative effort. If a new project is planned, the regular process through the Scientific Committee needs to be followed.

8. The initial version of the 'Guidelines and Operational Rules for Scientific Projects' has been approved by the members of the Scientific Committee on November 5th 2008.

A revised version has been approved 06.04.2011.

On December 4th, 2013, the authorship rules have been amended and approved by the Scientific Committee.

Revised and approved by EO, BOR and SC on 18.06.2014.

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Footnote:

The active members of the EO
The active SNSF co-investigators
The active members of the BOR
The active members of the Scientific Committee
The active heads of the local data center
The central data management

Responsible for the Swiss Transplant Cohort Study: The current list can be requested from the chairman of the Scientific Committee (nicolas.mueller@usz.ch).