Scientific Committee

STCS SWISS TRANSPLANT COHORT STUDY

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Guidelines and operational rules for scientific projects and the STCS Scientific Committee

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List of abbreviations

FUP	Full proposal
HFG	Humanforschungsgesetz – English: HRA, Human Research Act
HFV	Humanforschungsverordnung - English: HRO, Human Research Ordinance
MB	Management Board
LOI	Letter of Intent
PI	Principle investigator
RI	Responsible investigator
SC	Scientific Committee of the STCS
STCO	Steering Committee of the STCS

Definitions

STCS Investigator	Person who is either a member of one of the STCS bodies or working groups
Principle investigator (PI)	Responsible for the submission and implementation of the project
Responsible investigator (RI)	Responsible for administration, finances and the scientific report
Study center representative	Responsible in the individual centers, who actively supports the study locally

Contact details

STCS website:

www.stcs.ch

https://www.stcs.ch/index.php?p=documents

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PRACTICAL GUIDANCE FOR STCS PROJECTS

1 INTRODUCTION

The Swiss Transplant Cohort Study (STCS) is a nationwide effort to collect standardized medical data about all solid organ transplantations (SOT). All six transplantation centers in Switzerland (Basel, Bern, Geneva, Lausanne, St. Gallen, Zurich) provide high quality longitudinal clinical and laboratory data of SOT recipients. Beside the medical data, the STCS focuses on infectious diseases, bio-banking, psychosocial and behavioral factors at time of listing and during follow-ups. The data collection process starts with the transplantation or the moment when the islets are injected into the recipient. After a baseline assessment that contains all patients- and transplant-relevant data, all patients are mandatorily followed up in their respective transplant centers.

With is comprehensive data collection, the STCS provides a unique instrument for comparative effectiveness research and all medical professionals are encouraged to utilize the STCS database for their research.

2 SUBMISSION OF A RESEARCH PROJECT

2.1 General Principles

The STCS welcomes all types of research projects related to transplantation. Projects are more likely to be approved, if they address important research questions in the area of organ transplantation and/or strengthen the collaborative research within the STCS, national or international networks. The goal of the STCS is to foster studies involving more than one center.

Generally, scientists have to submit a proposal of their research project to the STCS to gain access to the STCS database. The proposal will undergo a review process by the Scientific Committee (SC) of the STCS.

As an exception, data generated by the individual centers and transplant programs within the STCS is available for internal use by the respective transplant programs.

Any STCS research project shall comply with ethical principles and legislation. Ethical committee procedures according to HFG (Human Research Act) and HFV (Human Research Ordinance) have to be followed. Upon acceptance by the Scientific Committee, each STCS project must be submitted to the lead ethics committee and requires approval before the start of the project.

2.2 Proposal types

The following types of proposals can be submitted:

- Nested projects that make use of preexisting STCS data/ infrastructure with or without samples
- Nested projects that make use of the STCS data/ infrastructure but require collection of additional data with or without samples.
- Investigational trials that make use of STCS data/ infrastructure
- Request for international collaborations
- Nested projects planned as BSc, MSc, MD theses
- Monocentric studies
- Single patient data and sample request
- Amendments of existing STCS projects

2.3 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.

While every scientist is invited to submit research projects, the STCS recommends to involve at least one STCS investigator in the project (see 2.5).

In case two competing projects are submitted, 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.

2.4 Project investigators

An STCS investigator is defined as either being a member of one of the STCS bodies or working groups.

The principle investigator (PI) is responsible for the submission and implementation of the project.

A designated responsible investigator (RI) for each project has to be named, who is ultimately responsible for administration, finances and the scientific report.

It is mandatory to cooperate with local study site representatives at the individual transplant centers, if STCS data from these centers is used in the proposed study (see 2.6).

All investigators of each involved center have to be named in the proposal (see Author list, 6.2).

In principle, the order and names of the investigators/authors at the time of the submission of the full proposal pre-determines the ranking of the authorship in a later scientific publication (see 6.2).

Investigators must consent to take the role assigned in the project and to participate actively in the submitted proposal (including the responsibility for conducting the local site part, e.g. CRF).

They must have seen and approved the proposal.

2.5 Participation of centers – Study site confirmation

Before a proposal is submitted, it is mandatory that the PI contacts study site representatives from each transplant center that provides data for the proposed study.

A study site representative is a member of the transplant center, who confirms the willingness to actively support the project locally. In particular, the study site representative agrees to fill in or ensure infrastructure for an external person to complete a CRF, if applicable.

Depending on the research question, medical and surgical representation must be carefully evaluated for the proposal.

The study site representatives must be included as co-authors in the writing and approval of the proposal.

Confirmation must be in writing (e.g. email is sufficient) and attached to the full proposal.

2.6 Patient involvement

The STCS encourages the authors to actively involve patients in the projects. If an involvement of patients in the study is considered, please get in contact with the STCS SC office. It will provide the relevant contact details.

Patients can be involvement in all steps of the project: Developing the research question or aims, consultation for specific aspects e.g. relevant outcomes, recruitment, feasibility or ethical aspects, direct contribution of data, discussion and interpretation of results, joint presentation of study results, etc.

2.7 Deadlines

Generally, the SC evaluates submitted proposals at the STCS SC Meetings. These will take place 2 to 4 times per calendar year. Deadlines for the submission of proposals and dates of SC meetings are published on the STCS webpage (see Contact details). Meetings can be held in-person or virtually.

All documents have to be submitted electronically to the STCS SC office (see Contact details).

3 DATA AND SAMPLE POLICY

3.1 Available data of the STCS

The STCS provides metadata of the collected and available dataset via a web-based codebook. It consists of a curated catalogue of collected variables and corresponding value sets, definitions, ranges and versions.

Investigators can request access by registering on the STCS website:

https://www.stcs.ch/index.php?p=contact/registration

Once activated the same account grants access to the codebook:

https://codebook.stcs.ch/codebook/variables

3.2 Access to STCS data and samples

STCS data (in the form of a comprehensive downloadable file or as a result of post-processed ad-hoc selection) or biological blood samples (viable cells, plasma and DNA) are available for use in research projects. The data and samples are available under the condition that the project has been submitted and approved by the STCS Scientific Committee (SC) and by the competent research Ethics Committee.

The STCS Data Center and the Head of the biobank require the following documents for your data or samples request to be processed:

- Approval letter of the project issued by the STCS Scientific Committee
- The final proposal as approved by the STCS Scientific Committee
- Approval letter of the project issued by the responsible Ethics Committee
- The final proposal as approved by the responsible Ethics Committee

The local bio banking labs will only release STCS samples based on the sample ordering list generated and verified by the STCS Data Center and the head of the STCS biobank.

3.3 Archiving project data

After termination of the project the raw data have to be kept. For archiving and re-use purposes, all primary data including add-on data plus program code have to be transferred to the STCS data center for storing. The applicable procedure is determined by the STCS data center.

Data resulting from an STCS project must be shared with other researchers upon request in a collaborative effort.

Sample procedures are regulated by separate guidelines issued by the laboratory working group. The “sample feed back questionnaire” must be sent to STCS SC office.

4 APPLICATION PROCEDURE

A concise overview about the types of projects, their requirements and submission process can be found in the STCS How-to Manual, which is available on the STCS website.

Depending on the scope of the planned project, different types of application procedures apply.

Regular proposals follow the procedure described below.

The simplified application procedure for international collaborations, nested projects planned as BSc, MSc or MD theses, monocentric studies, amendments of existing projects or single patient data and sample requests is described in section 3.3.

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

The application procedure for regular proposals consists of two steps:

1. Letter of Intent (LOI)
2. Full Proposal (FUP)

4.1 Letter of Intent

A letter of intent is required before submission of a full proposal and informs the SC about a plan for a scientific project.

The letter of intent must include a short general description of the research question with 1-5 key references; maximum 2 pages.

Minimum requirements include:

- Names of principle and responsible investigators as well as other investigators
- The study objectives and methods
- The study design
- List of participating centers
- Requirements for data/samples
- A preliminary budget and funding

Letters of intent must be send electronically and in Word/PDF format to the STCS SC office. The document will be distributed to all members of the SC and the Steering Committee (STCS) of the STCS. Afterwards the STCS SC office will provide a statement to the investigator, which includes the comments by the SC and STCS members, and whether the project can be submitted as a full proposal.

Invitation to submit a full proposal does not imply acceptance of the full proposal.

If the project is submitted for an international collaboration or as a BSc, MSc or MD thesis (see 3.3i and 3.3ii), no letter of intent is necessary.

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.

A template for the full proposal is provided by STCS SC office or can be downloaded on the STCS website.

A full proposal consists:

- Principle and responsible investigators as well as other investigators are named in correct order
- Summary - ***max. 2 pages*** *including:*
    - Background, Study Aims and Design, Lay summary, Details of amendment
- Research Plan - ***max. 10 pages*** *including:*
    - State of research
    - Research fields for each applicant
    - Detailed Research plan
    - Timetable and Milestones of the project
    - Significance
    - Patient involvement
    - Study budget
    - Publication plan and declaration of interest
    - Other information
    - References
- Necessary attachments:

- Covering letter (if applicable),
- CVs
- written confirmation of each center involved
- CRF (if applicable)
- informed consent (if applicable)

Full proposals can be submitted after the STCS SC office requests it and the evaluation of the LOI is completed. The official deadlines apply for the submission of the full proposal and it should be send to the STCS SC office electronically.

4.3 Simplified Application procedure

A simplified application procedure may apply for international collaborations, BSc, MSc, MD theses, monocentric studies, amendments of existing STCS projects or single sample requests, if the following conditions are met:

i. International collaborations

- No LOI is necessary
- only clinical data can be requested
- no samples are used
- if a CRF is required, all members of the working group are in favor and commit to collecting the data (no additional workload outside of a specific working group).
- if a working group for the topic exists, it has given consent
- if data from more than one center is used, each center has to approve its use

A full proposal has to be submitted to the STCS SC office respecting the regular deadlines and an external research plan may be attached.

A template for the full proposal is provided by STCS SC office or can be downloaded on the STCS website.

ii. BSc, MSc and MD thesis

- No LOI is necessary
- no samples are used
- if a working group for the topic exists, it has given consent
- if data from more than one center is used, each center has to approve its use

Full proposals for BSc, MSc and MD theses can be submitted regardless of the published STCS deadlines. CRF are the thesis author's responsibility. The full proposal has to be labelled as BSc, MSc or Medical thesis and submitted to the STCS SC office.

A template for the full proposal is provided by STCS SC office or can be downloaded on the STCS website.

iii. Monocentric studies

- Only data from one STCS center is requested
- no samples are used
- if a working group for the topic exists, it has given consent

A LOI clearly labelled as monocentric study has to be submitted respecting the regular deadlines. After invitation to submit a full proposal, it can be submitted regardless of the published STCS deadlines.

A template for the full proposal is provided by STCS SC office or can be downloaded on the STCS website.

iv. Amendments of existing STCS projects

- Based on an existing, previously approved STCS project
- if a working group for the topic exists, it has given consent
- if data from more than one center is used, each center has to approve its use

A LOI clearly labelled as amendment has to be submitted respecting the regular deadlines. After invitation to submit a full proposal, it has to be submitted respecting the regular FUP deadline as well.

A template for the full proposal is provided by STCS SC office or can be downloaded on the STCS website.

v. Single patient data and sample request

If the request for single patient data or sample is made in the context of a clinical/treatment issue (no scientific, but clinical need) an e-mail request to the chairman of the SC is sufficient.

If the single patient data and sample request arises in the context of a single case publication, a LOI is necessary.

A LOI clearly labelled as a single patient data and sample request has to be submitted respecting the regular deadlines.

The LOI has to demonstrate the usage and value of the particular case, and ensure proper acknowledgment of the STCS.

5 EVALUATION AND DECISION PROCESS

5.1 Regular projects

The SC evaluates all submitted projects. For regular projects[1], the SC chairman will send each proposal to two members of the SC for a scientific review, as well as to a statistician for a statistical review. The experts review the project and send a written structured comment to the Chairman of the SC within a set timeframe. Experts will rate and comment on the scientific content, relevance, suitability of proposed methods and the budget of the projects. Additionally, they will identify an eventual overlap with ongoing projects. All full proposals as well as the reviews will be distributed electronically to all members of the SC before the STCS SC meeting.

The submitted projects will be presented at the SC meetings by the experts, followed by an open discussion of the SC panel. The PI will be invited to the SC meeting to defend the proposal. If the PI or RI is a member of the SC, he/she/them can be present to support the proposal.

The following decisions can be taken by the SC panel:

- Acceptance of a project
- Pre-acceptance with minor revisions
- Resubmit proposal with revisions
- Rejection

The SC members attending the SC meeting approve the decision with a simple majority of votes. Whenever new datasets or samples are needed, all directly involved transplant programs, represented by their SC member, must approve the project.

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

The Management Board (MB) may request the SC to reevaluate the decision in case of a potential conflict of interest or problems between the centers. It also applies if the project is against the principal rules of the SNSF or of the STCS, or general standards of good research.

[1] Does not apply to BSc, MSc, MD theses, international collaborations, monocentric projects, amendments and single sample requests (see 4.2)

The PI will be informed about the decision within one week following the SC meeting. Additionally, the reviewer comments will be forwarded to the PI within seven days of the SC meeting, if the project needs revisions.

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

5.2 Simplified evaluation procedures

Simplified evaluation procedures may apply for international collaborations, BSc, MSc, MD theses, monocentric studies, amendments of existing projects and single patient data/sample requests, if the previously conditions are met (see 3.3):

i. International collaborations

The SC chairman will send the proposal to the SC without previous expert review as part of the regular agenda. The SC will take a final decision at the SC meeting and can request a regular review process and a Q/A session with the PI.

ii. BSc, MSc and MD thesis

If all conditions are fulfilled, then approval by presidential decision is possible. The chairman may require a decision by the SC board without previous expert's review. The SC can request can request a regular review process and a Q/A session with the PI.

iii. Monocentric studies

Given all conditions apply, then a presidential decision is possible. The chairman may require a decision by the SC board without previous expert's review. The SC can request can request a regular review process and a Q/A session with the PI.

iv. Amendments of existing STCS projects

The SC chairman will send the proposal to the SC without previous expert review as part of the regular agenda. The SC will discuss and take a final decision at the SC meeting. The PI is invited to attend the Q/A session at the SC Meeting.

v. Single patient data and sample request

The chairman of the SC can grant access to single patient data and sample requests in case of a clinical/treatment issue.

If the request arises in the context of a single case publication, the SC will discuss the request at the regular SC Meeting. If the request is urgent and only as an exception, the decision can be taken by circular vote. The STCS has to be acknowledged accordingly (see 6.2)

5.3 Rules for revision

If a proposal is pre-accepted with minor revisions, the PI has to provide a point-to-point reply and an amended proposal with the changes marked to the STCS SC office. The STCS SC office will re-submit the documents to the reviewers. Afterwards and if the reviewers and the SC Chairman approve of the revision, the PI is informed immediately, and the project can be initiated.

If a proposal requires major revisions, the PI is invited to resubmit the adapted full proposal. The PI has to provide a revised proposal with the revisions marked and a detailed point-to-point reply to the STCS SC office. For resubmission, the published full proposal deadlines apply. The STCS office will send the revised proposal to the previous reviewers and the SC for re-evaluation. The final decision will be taken at the following SC meeting.

6 PROGRESS REPORT

The progress report is due 18 months after receiving the approval letter.

The template for the progress report can be downloaded on the STCS website or is provided by the STCS SC office.

It should contain the following elements:

- Introduction with the objective of the study
- Scientific results with quantitative figures if appropriate, information on data and sample requests
- Qualitative information on objectives achieved, if applicable (presentations, preparation of publications etc.)
- Deviations from the research plan and explanation of delay in the initial time schedule including a revised time schedule if necessary (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 recommendations of the Swiss Academies of Arts and Sciences.

http://www.swiss-academies.ch/en/index/Schwerpunkte/Wissenschaftliche-Integritaet.html

The STCS authorship guidelines are based on the guidelines of the International Committee of Medical Journal Editors (ICMJE) ("Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals"), and published online: http://www.icmje.org/.

Authorship in a STCS project 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 of the full proposal to the STCS SC office and ensures that all co-authors have seen, revised and approved the proposal. The last author is considered to be the senior author.

Depending on the individual contribution of the authors, the order might change at the time of publication and additional authors can only be added exceptionally.

7.2 STCS Authorship rules

In case of disagreement regarding authorship or co-authorship, the matter will be referred to the SC Chairman, who will consult the MB, and if necessary, the STCO for a decision.

These rules have to be followed, when a STCS administered project is submitted and published:

- The order and names must be defined at the time of submission of a full proposal
  - New authors are added only exceptionally and the SC chairman has to be notified as soon as possible
  - Exceptions to this rules are considered upon request to the SC
- Minimum one study site representative per center has to be included
  - One member of the clinical and surgical division should participate

- 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 labeled as such 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

- To acknowledge the STCS association in all publication use the wording "XYZ, and the Swiss Transplant Cohort Study" or "XYZ, Swiss Transplant Cohort Study"

- Footnote members
  - Names of people with a particularly high involvement in the STCS structure 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.
  - The current list of names is available at the STCS SC office.
  - These names include:
    - Active SNSF co-investigators
    - STCS Local project leaders
    - Active members of the STCO
    - Active members of the small MB
    - Active members of the SC
    - Heads of the STCS working groups
    - Members of the Central Data Management
    - Active heads of the local data center

7.3 STCS – ORCID number

The STCS association should be acknowledged by adding the OCID number when publishing in a journal:

ORCID Number: 0000-0002-6369-819X

7.4 Publication

Prior to publication, it is mandatory that any manuscript or conference abstract, using data originating from the STCS, is 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, the acknowledgement of all funding sources is mandatory and should be mentioned as follows:

This project (FUP #) has been facilitated by the Swiss Transplant Cohort Study.

The Swiss Transplant Cohort Study is supported by the Swiss National Science Foundation, Unimedsuisse and the Transplant Centers.

For international collaborations using data of the STCS, investigators must ensure 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 to the STCS SC office.

Any accepted manuscript must be sent to the STCS SC office.

The project responsible has to mention the internal FUP number and has to attach a lay summary for online publication to the accepted manuscript.

In case no journal publication results from a thesis project, the thesis document is sufficient and has to be send to the SC office to complete the STCS project. We recommend to attach a Lay Summary for the thesis, however, it is not mandatory.

7.5 Lay summary for publications

When an accepted manuscript is reported to the STCS, it has to be accompanied by a lay summary. The lay summary template is available on the STCS website.

The lay summary will be proofread by the Patient Advisory Board of the STCS and published on the STCS Website to make the research results accessible to patients and the wider public.

7.6 Open Access Policy

The SNSF requires that STCS publications are made available in an open access (OA) publication or database either by the green or gold standard.

https://www.snf.ch/en/MDecEyLJgpSTk0cU/page/open-access-information-for-researchers

Furthermore, depending on the journal, APCs of publications resulting from STCS projects can be covered by the Chronos hub.

https://www.snf.ch/en/ozKDc97zu0ZBwCfJ/funding/open-access-article-publications

7.7 Final report

In case no publication results from a project, a final report on the study findings and justification for non-publication has to be handed in.

7.8 Data archiving and publication

After a project is finished, the project`s data has to be kept. Please refer to section 3.3 for further details.

GOVERNANCE – STCS SCIENTIFIC COMMITTEE

1 ORGANISATION AND TASK

The Scientific Committee is responsible for the review of research projects submitted to the STCS.

The Scientific Committee is responsible for defining the guidelines and operational rules for the submission, evaluation and acceptance of scientific projects.

The chairman of the Scientific Committee is responsible for the organization of the committee meeting, the writing of a protocol for each meeting, and for the transmission of information to the STCS Management Board.

A decision in the Scientific Committee Meeting is taken by simple majority of the members present. In case of disagreement or if a PI does not agree with the decision, the submission is discussed by the STCS Management Board, which will finalize the decision.

2 SCIENTIFIC COMMITTEE MEMBERS

The Scientific Committee is formed of representatives from each active organ transplant program, and other additional bodies, with a total of 36 voting members.

Each transplant program is represented by two members, one standing in for the clinical and one for the surgical division. Both have equivalent rights, but have only one combined vote in the Scientific Committee Meetings. In case both attend the meeting, one representative will vote for both (combined one vote) with the other one abstaining.

The exact composition is the following:

- 6 votes for each kidney transplantation program represented by 12 members (2 from Basel, 2 from Bern, 2 from Geneva, 2 from Lausanne, 2 from St. Gallen, 2 from Zurich)
- 3 votes for each allogeneic stem cell transplantation program represented by 6 members (2 from Basel, 2 from Geneva, 2 from Zurich)

- 3 votes for each liver transplantation program represented by 6 members (2 from Bern, 2 from Zurich, 2 from Geneva (includes the small bowel transplantation program)
- 3 votes for each heart transplantation program represented by 6 members (2 from Bern, 2 from Lausanne, 2 from Zurich)
- 2 votes for each lung transplantation program represented by 4 members (2 from Lausanne, 2 from Zurich)
- 2 votes for each pancreas islets transplantation program represented by 4 members (2 from Geneva, 2 from Zurich)
- 2 votes for immunology represented by 4 members
- 2 votes for infectious diseases represented by 4 members
- 2 votes for psychosocial medicine represented by 4 members
- 2 votes for the patient advisory board represented by 2 members
- 1 vote for dermatology represented by 2 members
- 1 vote for hematology-oncology represented by 2 members
- 1 vote for pediatric transplantation represented by 2 members
- 1 vote for genetics represented by 1 member
- 1 vote for a non-transplant physician represented by 1 member
- 1 vote for the biobank represented by 1 member
- 1 vote for Swisstransplant represented by 2 members
- 1 vote for the members of the STCS Data center and statistics
- 1 vote for the members of the STCS Management Board

3 SCIENTIFIC COMMITTEE MEETINGS

At least two meetings will take place two months before the respective SNSF submission deadlines. Deadlines for the submissions of LOIs and FUPs are at least 6 weeks before the SC Meetings. They must be publicly available and are published on the STCS website.

RATIFICATION OF THESE GUIDELINES

05.11.2008	Initial version of the 'Guidelines and Operational Rules for Scientific Projects' approved by the members of the Scientific Committee.
06.04.2011	Revised version approved.
04.12.2013	Authorship rules have been amended and approved by the Scientific Committee.
18.06.2014	Revised and approved by EO, BOR and SC
13.11.2019	Amended, revised and approved by EO, BOR and SC.
28.04.2021	Revised and approved by EO
25.11.2024	Amended, revised and approved by Extended MB
12.11.2025	Data access and data storage after publication have been amended and approved by N. Müller, head of the SC