Title of project

Short title

Authors (including principle investigator, responsible investigator, study site representatives and other co-authors):

Author’s institutions:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Administrative and summary information

|  |  |
| --- | --- |
| **Type of project:** | [ ]  Regular project[ ]  Amendment**1**[ ]  BSc/ MSc/ MD thesis **1**[ ]  International collaboration **1** [ ]  Monocentric study **1** |
| **Principle investigator:** |  |
| **Responsible investigator:** |  |
| **Coordinating Center:** |  |
| **Beginning of the study:** |  |
| **Study duration:** |  |
| **Budget, overall:** |  |
| **Samples required from STCS:**(if yes, type of samples) |  |
| **Case report form planned:**(If yes, it must be part of the initial submission) |  |
| **Number of patients expected:** |  |
| **Date of first submission:** |  |

1 Simplified evaluation procedure may apply according to STCS Guidelines

# Categories

Please indicate which categories apply to your project:

|  |  |
| --- | --- |
| **Organ (multiple possible)** | **Topic (max. 3 selections)** |
| [ ]  HSCT [ ]  Heart[ ]  Islets[ ]  Kidney[ ]  Liver[ ]  Lung[ ]  Pancreas[ ]  Small bowel[ ]  Multiple SOT | [ ]  Allocation research[ ]  Biomarker[ ]  Clinical risk factors and outcome[ ]  Data Science/ Machine learning[ ]  Drug treatment[ ]  Endocrinology and Metabolism[ ]  Genetics[ ]  Genomics[ ]  Immunology[ ]  Infectious Diseases[ ]  Oncology[ ]  Patient-reported outcomes[ ]  Pediatric transplantation[ ]  Physiology[ ]  Psychosocial aspects[ ]  Randomized controlled trial[ ]  Transplant epidemiology |

# Study sites confirmations

**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**.

|  |  |  |  |
| --- | --- | --- | --- |
| **Center** | **Name of representative** | **Confirmation of representative (y/n)** | **Confirmation attached (y/n)** |
| Basel |  |  |  |
| Bern |  |  |  |
| Geneve |  |  |  |
| Lausanne |  |  |  |
| St.Gallen |  |  |  |
| Zürich |  |  |  |

# Agreement

[ ]  I confirm, that I have read the STCS guidelines for the submission of a project and that the project fulfills all necessary requirements (http://www.stcs.ch).

*Any issue that might interfere with the guidelines should be discussed in a cover letter.*

[ ]  I confirm, that all study site representatives have been asked to confirm their willingness to actively support the study locally and all confirmations are attached

☐ I confirm, that all co-authors have seen the current version of the project and agreed

with the submission

[ ]  I hereby agree to provide a project report (Guidelines; Chapter 6.) to the STCS 18 months after acceptance of the full proposal.

 *A template for the progress report can be requested from the STCS office (sc.stcs@usz.ch).*

[ ]  I hereby comply to send any manuscript prior to publication to the STCS to be checked for compliance with the STCS acknowledgment rules (Guidelines, Chapter 7.)

 *A current author list is available upon request to the STCS.*

[ ]  I hereby comply to send any accepted publication and corresponding lay summary to the STCS, for publication on its website. The lay summary will be reviewed by the Patient Advisory Board for comprehensibility.

 *A template for the lay report is provided by the STCS office (**sc.stcs@usz.ch**).*

[ ]  I hereby agree to inform the STCS about any other scientific communication (theses, conference abstracts and/or presentations etc.)

# Revision

If this version is a revision of a previously submitted proposal, please, give a point-by-point reply to the comments received from the Scientific Committee and highlight the resulting relevant changes in this proposal with yellow.

|  |  |
| --- | --- |
| Date of resubmission: |  |
|  | [ ]  Point-to-point reply attached |
|  | [ ]  Revised sections of the proposal highlighted |

# Summary (two pages)

## Background

(…)

## Study Aims

(…)

## Study Design

(…)

## Lay summary (for publication on www.stcs.ch and potential patient involvement)

(Please use active and simple everyday language. Describe with short, concise sentences.)

* Descriptive, plausible title (may deviate from the study title to enhance understanding)
* Main goals/questions of the study (do NOT describe methods and analyses)
* Short, relevant information about why the study is of interest
* What benefit or significance is expected from the results for patients and professionals?

## Details of Amendment

(If the submission is an amendment of an existing STCS proposal:)

* Name and FUP Number of original accepted STCS proposal
* Status of Ethical Committee approval
* Detail differences of amendment to original study

# Research Plan (max 10 pages)

## State of research

(Describe state of research in the field. Mention the most important publications written by other authors.)

## Research fields for each applicant

(Elaborate on the research fields. Please mention the most important publications.)

## Detailed Research plan

* Objectives
* Origin of data
* Inclusion/exclusion criteria of the data
* Methods (excl. statistics, see below)
* Statistics: Data analysis with sample size analysis or power analysis
* Exact type and amount of STCS samples needed

## Timetable and Milestones of the project

(…)

## Significance

(Explain the significance of the planned research to the scientific community and to eventual potential users.)

## Patient involvement

(If an involvement of patients in the study is considered, please get in contact with the STCS office (sc.stcs@usz.ch). We will provide you with the relevant contact details. Involvement can be in all steps: 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.)

## Study budget

(Expected costs; indicate infrastructure; manpower available; what funds you applied for/are already available)

## Publication plan and declaration of interest

(Including transfer of results to patients; publication, theses, conferences, etc.)

## Other information

(e.g. status of ethical approval, if applicable)

## References

# Attachments

[ ]  Covering letter (if applicable)

[ ]  CV’s

[ ]  Written confirmation of each study site representative (e-mail acceptable)

[ ]  CRF (if applicable)

[ ]  Informed consent (if applicable)

# Checklist

[ ]  Principle and responsible investigator named (cf. section 1.)

[ ]  Coordinating center named

[ ]  Study site representatives are contacted and named

[ ]  All co-authors/PI have committed to the study and are named

[ ]  Budget stated

[ ]  Number of patients expected named

[ ]  If applicable: Requirement of samples from STCS stated and type of samples defined

[ ]  **Patient involvement considered (cf. section 7.6)**

**Please submit the full proposal to:** **sc.stcs@usz.ch**