

# **Grant for Clinical Research - Swiss Society of Anaesthesiology and Reanimation -**

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## **FUNDING REGULATIONS\***

### **BASIC PRINCIPLES**

#### AIM

The Swiss Society of Anaesthesiology and Reanimation (SGAR-SSAR) supports multicentre clinical research projects that are expected to improve patient care.

#### FIELDS

The research projects may be in the area of anaesthesiology, intensive care, emergency medicine and pain medicine.

#### FUNDING

The scientific fund of the SGAR-SSAR is constituted through unrestricted donations by the industry and own funds of the SGAR-SSAR as approved by the general assembly of the society.

A single grant will be given per project, i.e. an application for the same project for additional funding is not considered.

The grant will be given for maximal three years.

### **REQUIREMENTS FOR THE SUBMISSION OF PROPOSALS**

#### PROJECT REQUIREMENTS

Only projects with the following characteristics will be considered:

- multicentre studies with the participation (i.e. data collection) of at least three Swiss anaesthesia departments;
- clinical, investigator-driven studies;
- subjects that fall into the above mentioned “fields” criteria;

Projects with the following characteristics will not be considered:

- industry-driven studies; co-funding by the industry is allowed, under the condition that the industry has no influence on study design, methods, data analysis, writing of the paper and publication; in case of industry co-funding, a copy of the contract has to be submitted with the application;
- explorative projects.

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\* Parts of this text were adopted from the regulations of the Swiss National Science Foundation (SNF), with approval of the SNF. The SNF, however, is by no means involved in this grant call.

Both new projects and project that have already been initialized can be considered.

#### PERSONAL REQUIREMENTS

Main applicant, sponsor and co-applicants:

- are individuals engaged in scientific research in Switzerland for non-commercial purposes;
- must be members of the SGAR-SSAR.

#### FORMAL REQUIREMENTS

The funding proposals must be submitted:

- in English;
- according to the formatting requirements outlined below;
- in electronic form;
- before the expiry of the deadline.

#### REQUIREMENT OF APPROVALS

Approvals from ethics committee and (whenever applicable) Swissmedic are not necessarily requested for submission. However, they are a condition for the release of the grant.

#### APPLICANTS

The research consortium is formed by one main applicant for the whole project, co-applicants and a sponsor. A maximum of two applicants (including the main applicant) for each participating centre is allowed. Main applicant, co-applicants and sponsor must be members of the SGAR-SSAR.

The main applicant is the coordinator of the study. He is the primary contact person between research consortium and Scientific Commission of the SGAR-SSAR. He reports Serious Adverse Events (SAE) to the Ethics Committee.

The sponsor is the “senior” researcher of the consortium. He establishes Standard Operating Procedures (SOPs) in conformity with regulatory requirements to ensure appropriate reporting, collects adverse events, and submits reports of Serious Adverse Events (SAE) to Swissmedic (if applicable).

The main applicant and the sponsor must show that they have successfully carried out research work for several years and must be capable of running a project under their sole responsibility. Young researchers may be included as co-applicants, provided that they can document experience in the conduct of research.

If researchers are involved in multiple applications, they can be main applicant or sponsor for only one application. The participation as co-applicant to more than one submitted project is allowed.

#### REQUIRED DOCUMENTS

##### COVER LETTER

The cover letter should:

- briefly explain the primary and secondary aims of the project;
- provide information on the status of the project;
- provide information on whether the study has been approved by local ethics committee(s) and, if applicable, by Swissmedic;
- be signed by the main applicant and the sponsor;
- list all delivered documents.

#### STUDY PROTOCOL

The study protocol must be submitted in English and must have the following structure:

1. Title page (with list of main applicant, co-applicants, sponsor, co-investigators, and, if feasible, a person who is responsible for data management and statistical analyses);
2. Structured summary (maximum 350 words), with following headings: Background, Aim, Methods, Relevance;
3. Background;
4. Aims or hypotheses (whichever applicable);
5. Primary and secondary endpoints;
6. Methods, including statistical analyses and sample size calculation;
7. Achievements of the applicants in the field of the proposal;
8. Feasibility (expected number of patients per time period that can be screened and recruited, availability of equipment and infrastructure);
9. Relevance (potential clinical implications of the results);
10. Ethical considerations;
11. List and Tasks of Contributors (who is doing what);
12. Time plan;
13. Reference list.

The study protocol must have the following format:

- No more than 20 pages, including title page, references, tables and figures;
- Font size: 12 pt.

#### CURRICULUM VITAE

The CV of main applicant, co-applicants and sponsor must be enclosed, with the following requirements:

- maximum 4 pages per applicant and sponsor, including publication list;
- list of grant awards;
- most relevant publications of the last five years;
- font size: 12 pt.

#### BUDGET

The following costs may be claimed:

- the salaries of scientific and technical project personnel working in the institutions of the main and co-applicants; the salaries of the sponsor, main and co-applicants are not funded by the SGAR-SSAR;
- material costs that are directly related to the realisation of the project, such as consumables;
- field expenses and travel costs;

- equipment necessary for performing the project, if the costs do not exceed a total of 10'000 Swiss Francs.

The requirements for the budget are:

- presentation of the overall budget, including all direct and indirect costs of the project;
- detailed description and explanation of the costs that have to be covered with the grant of the SGAR-SSAR;
- listing of additional grants and explanation on how the expenses not covered by the grant of the SGAR-SSAR are covered (global budget required);
- in case of department, hospital or university financing, letters of the chairmen or responsible persons that document commitment to financing have to be enclosed; these letters have to contain also commitments that the involved personnel receives protected time for research, if not financed by the grant of the SGAR-SSAR;
- in case of co-funding by the industry, a copy of the contract.

#### LETTERS OF SUPPORT

Letters of support from the chairmen of each applying centre have to be enclosed, containing the information specified in the above section.

## ASSESSMENT

#### SCIENTIFIC ASSESSMENT CRITERIA

Awarding of the grant is based on the following criteria:

- originality of research objectives;
- potential for improving patient care;
- adequacy of methods;
- feasibility of the project;
- scientific track record of the applicants;
- investigators' expertises in relation to the project.

#### ASSESSMENT PROCEDURE

Submitted proposals are screened by the SGAR secretariat for all the formal criteria and requirements of this regulation. If the criteria are not met, the proposal is rejected. Only in exceptional cases, the Scientific Committee of the SGAR-SSAR may request revision and reconsider the application.

The proposals are evaluated by all members of the Scientific Committee of the SGAR-SSAR. They do not evaluate proposals if members of their own research group are among the investigators. Proposals that do not reach minimal scientific standards will be rejected at this stage.

When a proposal reaches minimal validity and quality requirements, it will be sent for external peer review. For that purpose, two international (i.e. not in Switzerland active) peer reviewers will be chosen by the Scientific Committee of the SGAR-SSAR.

Peer review (both by members of the Scientific Committee of the SGAR-SSAR and external) will be anonymous (i.e. identification of reviewers, but not of applicants, will be blinded).

The final decision of acceptance or rejection belongs to the Scientific Committee of the SGAR-SSAR.

The president of the Scientific Committee of the SGAR-SSAR informs all applicants and the board of directors of the SGAR-SSAR about the final decisions.

## **RELEASE AND MANAGEMENT OF FUNDS**

The sum for the first year is released at the grantees' request, within a year of the date of the ruling. Extension of the deadline is possible in exceptional cases. If the release request is not submitted in time or if the relevant deadline is not extended, the grant expires.

The SGAR-SSAR may deny release of the sums for the following years if the projects are not progressing satisfactorily, according to the judgement of the Scientific Committee.

Grantees are obliged to settle any debit balance occurring on completion of the funded research work. Any credit balance, however, is to be refunded to the SGAR-SSAR.

## **REPORTING AND MONITORING**

The primary investigator must submit yearly intermediate reports about the progress of the project to the Scientific Committee of the SGAR-SSAR. The report should not exceed 4 pages, written with 12 points fonts, and should specify the following aspects: number of screened and recruited patients, adverse events, unexpected logistic problems, budget and time plan for the following period.

After completing the study, the main applicant must submit a final report to the Scientific Committee of the SGAR-SSAR.

All written reports must be submitted electronically.

Intermediate and final reports are presented yearly at the general assembly of the SGAR-SSAR by the main applicant or a representative of the research consortium. A last presentation is made after publication of the results in a peer-reviewed journal.

## **INFORMATION ON FUNDED RESEARCH WORK**

Study protocols of projects that are funded by SGAR-SSAR have to be published in one of the publicly accessible trial databases.

Grantees are obliged to mention the SGAR-SSAR as a source of funding:

- in all publications resulting from the granted project (“this project was funded by the Swiss Society of Anaesthesiology and Reanimation”);
- in the web-site of every institution of the main applicant, sponsor and co-applicants.

Document history:

- created by Michele Curatolo, December 2012;
- corrected and approved by the Scientific Committee of the SGAR-SSAR, December 2012;
- approved by the council of the SGAR-SSAR, January 2013.