Regulations concerning the Scientific Review and Selection of Clinical Cohort Studies

Call 2008

Proposals for Clinical Cohort Studies (CCS) are submitted according to the guidelines defined in the call 2008 for proposals for clinical cohort studies published by the Swiss National Science Foundation in October 2007.

They are subject to the following evaluation procedure:

1) The Committee for Patient-Oriented Clinical Research (PaKliF) and the Scientific Secretariat of the SNF shall examine whether the CCS proposals fulfil the formal criteria to be met for admittance to the scientific review process (especially completeness of information given). If necessary, applicants may be asked to provide additional information at short notice.

2) An International Panel consisting of 5 to 7 members from outside Switzerland, renowned as scientific experts in conducting CCSs, shall be proposed by the PaKliF-Committee to the Presidial Board of the SNSF National Research Council (NRC). Once elected by the Presidial Board, they shall form the CCS Panel and fulfil the tasks described hereafter. It is expected that CCS Panel members shall openly declare potential conflict of interest, i.e. direct scientific links with the authors or any form of benefit from the funding of the proposals. In such a case, the CCS Panel member shall abstain from taking part in the decision-making process and from voting on the proposal in question.

3) CCS proposals shall be subject to a 2 step-evaluation process. In a first step, outline proposals for CCS shall be submitted. Based on the results of their scientific evaluation, described in paragraph 6, and based on the recommendations of the CCS Panel, the NRC shall invite authors of the top ranking projects to submit a full proposal.

4) In all steps of the evaluation process, proposals shall be assigned to one member of the CCS Panel and one member of the PaKliF-Committee, who shall each write an appraisal to be distributed by the Scientific Secretariat before the evaluation meetings in April 2008 (outline proposals) and October 2008 (full proposals) to both bodies. The assignment of the proposals shall be made jointly by the President of Section B of the NRC Division III, the President of the PaKliF-Committee and the Scientific Secretary of Division III (Steering Committee).

5) In addition, each CCS full proposal shall be sent out to international experts for scientific review. The experts to be contacted shall be determined by the Steering Committee. In doing so, the Steering Committee shall take into account potential experts proposed by the members of the CCS Panel and the PaKliF-Committee. The reviewers shall establish a written evaluation report until end of September 2008. At least two independent evaluation reports should be presented for every CCS proposal.

6) In their written appraisals, the members of the CCS Panel and the members of the PaKliF-committee shall present a comprehensive written report on the CCS proposals assigned to them. In so doing, they shall take into account the evaluation reports established according to paragraph 5 and give their opinion with respect to the evaluation criteria specified in the Call, with special emphasis on following aspects:

a) Scientific quality of the CCS proposal
b) Importance of the proposed CCS for public health in Switzerland
c) Relevance of the proposed CCS for clinical research in Switzerland
d) Available infrastructure
e) Ability of the applicants to set up an extensive CCS network
f) International integration and co-operation of the proposed CCS
g) Interdisciplinary co-operation of the researchers involved in the proposed CCS
h) Experience of the applicants in the management of cohort studies and multi-centre projects as well as in data management
i) Cost-benefit-ratio of the proposed CCS

The members of the PaKliF-Committee shall concentrate in particular on points b), c) and d).

7) The Scientific Secretariat of the SNSF shall be present throughout the meetings to provide regulatory, administrative and executive advice, and establish the minutes of the meetings.

8) The evaluation meetings for outline proposals and full proposals shall both follow a 2 steps procedure. Evaluation meetings shall be chaired by the President of Section B of the SNSF NRC Division III who shall have no right to vote. First, a joint meeting of the PaKliF-Committee and the CCS Panel shall be held. The members of the CCS Panel and the PaKliF-Committee shall briefly present their written reports on the CCS proposal(s) assigned to them, followed by a short discussion aiming at identifying and discussing open issues. During this meeting the members of the PaKliF-Committee shall inform the CCS Panel about conditions and prerequisites for conducting cohort studies in Switzerland that may not be known to the international experts but might be of importance for the evaluation of the proposals.

9) Following the joint meeting, the CCS Panel shall reconvene without the PaKliF-Committee and discuss the proposals in details. Based on these deliberations, the Panel shall establish a ranking list amongst the outline proposals or full proposals. The President of the PaKliF-committee shall be present at the meeting but shall have no right to vote.

10) Based on the ranking of the proposals, the Steering Committee shall establish a selection and funding proposal to be presented to the SNF NRC Division III. In so doing, it shall be bound by the ranking of the CCS Panel, and shall take into account the financial means available.

11) The NRC Division may accept or reject the selection proposal. In case of acceptance, it shall be forwarded to the Presidial Board of the NRC for final decision. In case of rejection, the Steering Committee may establish a new selection proposal, taking into account the instructions given by the NRC Division III.

12) The applicants of the CCS proposals shall be informed of the final decision of the Presidial Board of the NRC. In case of a positive decision, the notice of acceptance shall contain or refer to the terms and conditions to be observed in the establishment and execution of the CCS.