

Role of the SBAC in the evaluation of applications to EHDN Seed Funds – review procedure and assessment criteria

Anne Nørremølle and the Scientific and Bioethics Advisory Committee (SBAC)

The Scientific and Bioethics Advisory Committee (SBAC) of the European Huntington's Disease Network (EHDN) is responsible for reviewing research projects submitted to the EHDN in order to obtain funding under the seed fund scheme. The SBAC provides recommendations to the Executive Committee (EC), who takes the final decision on which projects to support. Seed funds up to a limit of €50,000 are intended to fast-track pilot studies required to apply for larger grants from other organizations or to estimate the statistical power needed for larger studies (e.g., in clinical trials) (<http://www.ehdn.org/it/hd-clinicians-researchers/seed-funds/>). This applies particularly to new lines of research when very preliminary data to support a working hypothesis are insufficient. In the following, we will describe the procedures used, as well as the criteria by which the SBAC assesses the applications. In addition, we will give some advice regarding how to write the application.

The EHDN calls for Seed Fund applications twice a year and receives on average 10 to 30 applications per round.

Review procedures

Each SBAC member reads every application briefly in order to define their knowledge in the field (expert/basic knowledge or outside their field) or if they have a conflict of interest. Conflict of interest occurs when the SBAC member is either an applicant or co-applicant on the seed fund proposal, or when he/she is a member of a consultancy or advisory board of a company involved in the project. In addition, EHDN expects the SBAC members to reveal any other relations to the applicants or project that could cause a conflict of interest. A SBAC member with a conflict of interest will not review the particular project and will be excluded from discussions on the proposal.

Based on the response from the SBAC members, the SBAC chairs will assign a minimum of two SBAC members to each proposal; preferably, this will be one reviewer with basic knowledge, and one with expert knowledge, of the particular field of research. These two members will do a thorough review of the application, basing their assessment on the criteria described below. The reviewers will write comments to the application and give a score. This information is then

shared with the rest of SBAC, after which the committee discusses the applications and reviews at a telephone conference. The SBAC members aim to agree on which proposals that are suggested for funding (on average 2-5 applications).

The score and comments from the SBAC reviewers, as well as a full report of the SBAC discussions, will be provided to the EC along with the SBAC's suggestion on which proposals to fund.

Assessment criteria

Formal criteria

Only European projects are eligible; the main PI has to be an EHDN regular member, based in Europe, and at least 50% of the funds must stay in Europe.

If you have previously received funding from the EHDN Seed Fund scheme, you cannot receive a new seed funding until you have finished the previous project and handed in the final status report for this.

Is it a seed fund project?

The first question asked to the proposed project is whether it is indeed a seed fund project. We define these as projects that are exploiting new and original ideas and therefore hold the potential to move HD research in novel directions. Reflecting this, the potential impact of the project leading to a new understanding of the disease and its treatment has high priority in the assessment. We welcome projects that are "thinking out of the box".

A seed fund project does not necessarily lead to the full elucidation of a hypothesis, but should hold the potential to generate results based on which additional (more extensive) funding can be obtained. The potential to generate more regular additional funding based on the help with the proposed grant should be outlined.

To show the novelty of the project, and to assure that the applicants are familiar with the HD literature, a review of the background for the project including reference to the work of others is necessary.

Preliminary data may be included in the seed fund proposal to demonstrate the outcome of tested approaches using small sample sizes and to provide proof of concept or evidence to support a working hypothesis. Preliminary data may further be included to demonstrate the suitability and applicability of novel methodologies and technologies and the technical ability and competence of the research team.

Projects that are merely aiming to add more samples to a preliminary study using an already defined study design, or projects that are clearly a development of a previous publication basing on the same hypothesis, are examples of projects that are not considered to be seed fund projects.

Is the aim of the project clear and the design appropriate?

The aim of the project should be clear and feasible to conduct with the applied funding. The rationale and the design of the project should be described, including which approaches will be applied, the number of samples or patients to be analyzed, and the methods used. Statistical analyses to be used should be described. If possible, an estimation of the number of samples expected to be necessary in order to obtain significant results should be included (power calculation).

The applicants should demonstrate that resources and expertise needed for the project are available. This is especially important for applicants who are new to the HD research field.

In clinical projects using HD patient samples, the patient cohort should be accessible to the applicant(s), and the exclusion and inclusion criteria should be described in the proposal. One problem often encountered in cohort studies is the large variability in various disease parameters; when this variation has potential impact on the results it may be necessary to either choose a homogeneous patient group (e.g. same CAG repeat length) or increase the number of samples. It is essential that the applicants have considered ethical issues including obtaining ethical approvals for the project if needed.

Does the application describe everything clearly?

Write the application in a way that it is easy to understand for the reader (e.g. avoiding too many abbreviations). Follow the headlines provided in the application template and the suggested number of characters in each paragraph. Make sure that appendices are short and relevant (e.g. preliminary results).

It is important that all relevant information is provided in the application, as there will be no opportunity for the SBAC to ask the applicants for clarification.

Response from the SBAC and EC

Based on the reviews from the SBAC members and the discussions in the SBAC and EC, the applicants will receive a response letter. In case of rejected applications, the response letter is meant to provide the applicants with a brief explanation for the rejection, hopefully in a way that will aid the writing of future applications. Please remember that the percentage of seed fund applications that are funded can be as low as 10% per round meaning that very good projects might be rejected, because others are just slightly better. In case of rejection, when investigators re-apply for the same project in the following round, the project will be considered as a new submission. It is, however, important that all of the issues raised by the reviewers are addressed, as the applications will be compared.