GETTING STARTED – DOCUMENT 1

Contents

Sections

1. Requirements for applicants the BCIS peer review service

The service is available free-of-charge to any individual with current BCIS membership (of any type) at the time of application/submission for peer review. There are no other personal requirements for individuals. Applications are welcome from across our membership, regardless of profession or current role, or previous research experience (or lack thereof).

The researcher would normally be planning to undertake the research project within a department of an institution, typically either a hospital or university. Further details regarding departmental agreement are given in section 6 below.

2. Types of research project

The BCIS peer review service is happy to accept submissions for review of all types of project on topics of broad relevance to interventional cardiology.

This may include clinical science, basic science, population studies and other types of research.

3. Stage of development

It is envisaged that research plans and proposals sent for BCIS peer review will have been developed to some extent within the planned hosting department and through discussion with at least one senior member within that department (see section 6 below).

The proposal should be approaching a stage where sufficient detail has been incorporated that application to an ethics committee or a local funding source would be possible. (If members are unfamiliar with these processes, a number of helpful websites are listed at the end of this document).

Unfortunately it is not possible to accept for BCIS peer review, ideas which are still at an 'initial concept' or 'back-of-an-envelope' stage, for reasons which we hope are self-evident.

4. Format/layout of proposal

There is no fixed template for the layout or format of submissions for BCIS peer-review. The reason for this is to make access to the service as user-friendly and hassle-free as possible. This means that a proposal document for BCIS review can, to a large extent, be created by 'cutting and pasting' from other application forms which may have already been completed e.g. an IRAS form (for combined ethics and R&D approval).

We request that completed proposals are no more than 6 pages of A4 text, excluding any figures or references you may wish to include. We recommend focusing on your proposed work rather than providing very detailed background information. Additional information of importance can be included in appendices if desired.

5. Required content within the proposal

In order to provide useful review of a project proposal, we ask that the application contain a 'minimum dataset' of key pieces of information, as described here:

a) ADMINISTRATIVE –

i) Submitting applicant's name, contact details (email, postal address and telephone numbers) and current role/position

ii) Submitting applicant's current department and the proposed department and institution that will host the research (in terms of local governance)

iii) Name, contact details and role of a senior member within the department who has reviewed the proposal (see section 6 for further information)

iv) Number and (optional inclusion of) names of staff, other than the primary applicant, who will be involved in conducting the research, their roles/positions within the department (or elsewhere), their time available for this project.

(The above information should be included on all applications. Where blind review is requested, this information would be removed prior to transmission to our peer reviewers).

b) RESEARCH PROPOSAL -

i) Succinct research question or hypothesis (2 or 3 sentences maximum)

ii) Justification/rationale for the research - can be brief (half to one A4 page maximum)

iii) Planned target group if relevant and proposed recruitment technique (clinical projects only)

iv) Study structure/design; inclusion/exclusion criteria (if applicable)

v) Baseline and follow-up assessments/tests/interventions;
ideally (not mandatory) a pathway of subject 'flow' during study (clinical and basic science)

vi) Primary and any secondary outcome measures/endpoints (with definitions)

vii) Proposed statistical analysis of results; calculation of power/required sample sizes (clinical and basic science)

viii) Risks and any potential benefits of participation (clinical projects)

For those applicants seeking possible patient review, a non-technical description of the project including its rationale, structure, planned assessments and interventions, specific risks and benefits of participation, and any other deviation from usual clinical care should also be included. Patient information leaflets and a study consent form should be included.

6. Departmental details and local senior approval

a) Departmental Details

In order to make an evaluation of likely feasibility of a proposed project, it is important to have an understanding of the environment and the infrastructure within which it will take place. For this reason, we ask that applicants also supply a brief description (1-2 paragraphs) of the department, in particular outlining i) clinical activity relevant to the proposed project, ii) any previous and current research work, and iii) likely available support for the proposed project from other staff (e.g. nursing, IT, administrative etc).

b) Local senior approval

Successful projects will also usually require support from at least one senior member of the department (not necessarily medical staff, depending on the nature of the project). For this reason, we also ask that any research proposal for BCIS peer-review be shown in

advance to a senior member of the department who is able to give his/her agreement-in-principle to the project being conducted within the department.

The exact position/role of the senior figure may vary – for a possible MD or PhD project, the natural and most appropriate choice would be the primary supervisor for the project. For other types of project, there may not be such an immediately obvious choice, and in this situation any staff member of consultant-level (or equivalent, for non-medical professions) who has some knowledge of the field of proposed research and who would be agreeable to its conduct within the department, would be acceptable. (We understand that obtaining such approval from the head of department, e.g. a Clinical Director, may be time consuming and difficult, due to their busy roles, and hence we have specifically not required that the senior figure be the head of department).

This senior figure should provide a brief (e.g. 1 paragraph) statement confirming that he has read the research proposal (in its submitted form) and is agreeable to this project being conducted within the department.

7. Type of BCIS review available

a) Principal Review

The main component of BCIS peer review will comprise a thorough evaluation of the research proposal by 2-3 reviewers chosen for their knowledge of the research area involved. Reviewers will typically be consultants or honorary consultants drawn from within the BCIS membership and will be approached by the BCIS Research committee. For projects involving non-medical professions in the primary area of focus, relevant senior figures in the appropriate profession will be approached (again, this will typically be from within BCIS).

For occasional projects whose proper assessment would require expertise not currently available from within BCIS, external review will be sought on behalf of applicants by the BCIS Research committee. However this external review cannot be guaranteed, since this will not be entirely within our control and unfortunately very limited funding is available).

b) Additional Specialist Review

Applicants may request additional specialist review in the following domain:

i) Specialist statistical review

Due to previously-mentioned funding constraints for this peer review service, specialist review of protocols by a statistician cannot be routinely offered. However, for specific cases where complex statistical methodology is an essential part of the planned analysis and where relevant expertise is not available from within BCIS, we will commission external review by a professional statistician. It is anticipated that, in such projects, some statistical input will already have been obtained locally by the applicant, in order to develop the methods for the initial submission.

The BCIS research group will seek to commission these services for selected projects that are at an advanced stage of development and that are deemed, from the main review, to be close to finalisation.

Applicants not selected for immediate specialist review may re-apply as their project matures, for example after resolution of key issues raised in the principal review.

8. Blind review requests

In order to encourage submissions to the peer-review service from those who might otherwise feel intimidated (for whatever reason), we are agreeable to passing proposals to reviewers in an anonymised form (i.e. 'blind review'), if the submitting authors wishes. In this situation, the details of the submitting author, the relevant department and the senior supporting departmental member would be seen by the peer-review coordinator(s) involved but not by any of the reviewers.

However, please note that we generally encourage submitting authors to opt for 'open'/non-blind review unless they have strong feelings on the matter, as it allows a more complete evaluation of feasibility and other practical issues.

9. Requests for exclusion of specific departments or individuals as reviewers

For various reasons, applicants (submitting authors) may have specific departments or individuals by whom they would not wish their proposals to be reviewed (even in an anonymised manner).

Up to 3 reviewers or departments for exclusion may be given. No explanation for the reasons underlying these choices is required.

10. Outcomes of review process – nature of feedback to members

The results of the main peer reviews, and where applicable second-stage reviews, will be fed back as collated verbatim reports from individual reviewers, together with any relevant additional comments in the form of a covering letter from the peer-review team. This documentation could then be provided to ethics, R&D departments, funding sources etc. as evidence of formal external review.

Please note: There will NOT be any form of overall project 'approval' or 'rejection' by BCIS as an outcome of the BCIS peer review process.
Peer review is intended to help our members and is NOT designed to act as any kind of licensing or regulatory scheme for research projects.

Project proposals that have been reviewed by the service may be re-submitted if major changes were suggested and have then been undertaken.

11. Terms and conditions for submitting BCIS members

Beyond what has been described in the sections above, there is little else in the way of requirements for submitting authors. Specifically, there is no requirement for the suggestions made by reviewers to be followed by submitting authors, although these may also be raised by other agencies (e.g. ethics or funding committees) and hence appropriate justification for not following suggestions should be carefully considered.

12. Useful sources of information

The following sites contain valuable information and background to those planning to undertake research:
https://www.myresearchproject.org.uk/
https://www.bhf.org.uk/research/information-for-researchers/how-to-apply
http://www.nihr.ac.uk/funding/
https://www.gov.uk/government/news/attributing-the-costs-of-health-social-care-research-development-acord

The sites below are useful to find out what research is already in progress in your planned area of investigation:
https://www.clinicaltrials.gov/
http://www.isrctn.com/