



Efficacy and Mechanism Evaluation Programme

APPLICATION FORM GUIDANCE NOTES FOR APPLICANTS SUBMITTING STAGE 1 APPLICATIONS

(On-line NIHR Stage 1 Standard Application Form (SAF))

Version: 1.4

Last updated: 08 August 2018

NIHR Research Application Form

Stage 1 Application Form

1. Application Summary Information

Host Organisation

Please give details of the organisation who will be the contractor if the project is funded.

Research Title

The project title should state clearly and concisely the proposed research. Any abbreviations should be spelled out in full.

Research Type

Select the appropriate research type. If your proposed project includes any element of primary research, please select 'Primary Research'. If you are carrying out new analysis of existing data, select 'Secondary Research'. If you are not sure which category to select, choose the closest match to your project as this can be adjusted later.

Proposed Start Date

Note this should be from 1st of the month regardless of whether this is a working day or not. Please be realistic about your possible start date taking account of the necessary contracting, and staff recruitment prior to starting your project. HRA approval will not necessarily need to be in place before the start date. Funds can be released prior to ethical approval being obtained.

Research Duration (months)

Ensure you include sufficient time to complete all aspects of the research including applications for regulatory approvals (where required) and the final report.

End Date

This field will automatically populate once you have saved the research duration information.

Estimated Research Costs

Enter the total amount of research costs requested (not including NHS Support & Treatment costs).

Estimated NHS Support & Treatment costs or external (not NHS) intervention costs

Enter the total amount of NHS support and treatment costs associated with this proposal.

For the EME Programme you should only need to include costs in the Research costs and NHS Support and Treatment costs boxes. Non-NHS intervention costs are similar to excess treatment costs but mainly apply to Public Health Research.

2. Lead Applicant CV

Complete your name, contact details and other requested information.

3. Lead Applicant Research Background

Publication record

Provide details of a MAXIMUM of 6 of your most recent / relevant publications (in the last 10 years) relevant to this application (using Vancouver or Harvard citation format) listed one after another with a blank line between each one. Please use DOI reference numbers if needed.

Research Grants Held

This should include research grants held (as a named applicant) CURRENTLY or IN THE LAST 5 YEARS as well as any additional previous grants, relevant to this application. Please include who the grant is with and the amount of each grant. If no grants are held please enter N/A (as this is a mandatory field).

Has this application been previously submitted to this or any other funding body?

Select 'Yes' or 'No' from the drop down box to indicate whether this or a similar application has previously been submitted to this or any other funding body. For more information about resubmission of a research/trainee funding application, or joint funding please contact the appropriate NIHR research funding programme.

Applications Submitted to other NIHR programmes

Where this application or a similar one has been submitted to this or another NIHR programme or elsewhere please click the 'Add' button and complete the necessary information.

We are keen to know if the application has been submitted elsewhere and you must be as open about this as possible. This includes, but is not limited to, any facts that, should they come to light at a future date, would embarrass either the programme or the individual who withheld the fact (e.g. if a member of the team holds a patent or has a financial interest within the research area).

Failure to disclose accurately or fully will be considered by the programme as academic misconduct and treated accordingly. You should also include in this section information on whether this or a similar application has been submitted to any programme previously, or to any other funder including other NIHR programmes. You should name, and provide dates and outcomes of these. Please indicate whether you hold or have ever held an NIHR programme contract which has been terminated prior to completion, extended in time or in terms of funding. Indicate which of the NIHR funding streams you are applying to.

4. The Research Team

Specify your (lead applicant) role in this research

Explain in addition to your role as Lead Applicant, the role that you will be undertaking in the research, e.g. co-ordination and project management, analysis, methodological input etc.

% FTE

Commitment: This refers to the percentage of your time that you will commit to this project.

Co-Applicants

Add details of all co-applicants and their specific role in the project. The number of co-applicants is calculated automatically. Do not include collaborators, who should be mentioned (if necessary) in the Research Plan section of the on-line application form.

Co-applicants are those individuals with responsibility for the day to day management and delivery of the project. Co-applicants are considered part of the project team and are expected to share responsibility for its successful delivery. Collaborators normally provide specific expertise on particular aspects of the project but who do not share in the responsibility for the delivery of the project.

5. Plain English Summary of Research

The importance of a plain English summary

A plain English summary is a clear explanation of your research.

Many reviewers use this summary to inform their review of your funding application. They include clinicians and researchers who do not have specialist knowledge of your field as well as members of the public. If your application for funding is successful, the summary will be used on National Institute for Health Research (NIHR) and other websites.

A good quality plain English summary providing an easy to read overview of your whole study will help:

- those carrying out the review (reviewers and board and panel members) to have a better understanding of your research proposal
- inform others about your research such as members of the public, health professionals, policy makers and the media
- the research funders to publicise the research that they fund.

If it is felt that your plain English summary is not clear and of a good quality then you may be required to amend it prior to final funding approval.

It is helpful to involve patients / carers / members of the public in developing a plain English summary.

Content

When writing your summary consider including the following information where appropriate:

- aim(s) of the research
- background to the research
- design and methods used
- patient and public involvement
- dissemination.

Further guidance on writing in plain English is available online at NIHR Make it Clear www.involve.nihr.ac.uk/makeitclear.

For further support and advice on writing a plain English summary, please contact your local Research Design Service (where applicable). www.rds.nihr.ac.uk.

6. Research Plan

Using all of the headings (in the order presented) and guidance below, please use this section to clearly explain your proposed research. **As this is the main part of your application which will be considered by the reviewing committee you should ensure that the information is accurate, succinct and clearly laid out.** The overall amount of information that you can provide at this stage is limited to 3 - 5 pages (dependent on the type/complexity/scale of study proposed).

The NIHR expects appropriate and relevant involvement of patients and the public and other key stakeholders in the research it supports. It is essential to set out your plans to involve patients and the public in the Stage 1 application. Your patient and public involvement plans will be assessed by the funding panel/board including patient and public members.

Information and resources to assist you can be found on the INVOLVE website (a detailed definition of patient and public involvement in research, briefing notes for researchers on how to involve patients and the public and an involvement cost calculator and budgeting guide).

In this section it is important that you identify all stakeholders who are relevant to your research proposal. For each stakeholder group you need to be clear about how they benefit from your proposed research and, where appropriate, how they have been involved in the development of the application, as well as the plans for their involvement in the proposed research.

1. What is the problem being addressed?

Provide a clear explanation of the health problem to be addressed, the impact on patients and/ or public as well as health and care services, and how this research would fill a demonstrable evidence gap.

Provide a brief explanation of:

- a. the unmet health need to be addressed
- b. the size of the incident or prevalent population
- c. your proposed innovation
- d. a justification of your choice of study design
- e. details of any mechanistic components.

For studies of diagnostic or prognostic tests, please modify these headings as appropriate.

2. Why is this research important in terms of improving the health and/or wellbeing of the public and/or to patients and health and care services?

It is essential that you clearly identify the health and care need your research meets or contributes to. Please outline the anticipated value or contribution the study will provide.

Explain the case for this research, and how it will meet the needs of the public/patients.

3. Review of existing evidence - How does the existing literature support this proposal?

Explain why this research is needed now, both in terms of time and relevance. We will only fund primary research where the proposed research is informed by a review of the existing evidence.

- a. Explain why this research is needed now. Please put your research into the context of current practice, other recent or ongoing research or time-limited opportunities.
- b. Provide information to show that you have reviewed all the directly relevant published literature.

- c. Give details of other trials or research currently underway, both nationally and internationally, which are relevant to the proposed study.
- d. Describe the evidence that provides proof of concept in man for your research. Please ensure you include references on proof of concept in your bibliography. If you need more information about what proof of concept is required, please see: <http://www.nets.nihr.ac.uk/programmes/eme/remit>
- e. Explain how your research fits into the EME remit and the call to which you are applying. For information about the EME remit please see: <http://www.nets.nihr.ac.uk/programmes/eme/remit>

4. What is the research question / aims and objectives?

Please summarise the research question / key aims and objectives.

Please provide:

- a. the aim (broad question) of your proposed research.
- b. for clinical trials, a single sentence describing the primary outcome measure.
- c. a numbered list of the clinical objectives (specific components).
- d. a numbered list of the mechanistic objectives where appropriate. Mechanistic components to studies are strongly encouraged. These must test a clear hypothesis and contain an indication of how the tests/measurements will confirm or refute this hypothesis. For examples of EME funded studies with mechanistic components, please see: <http://www.nets.nihr.ac.uk/programmes/eme/remit>
- e. the deliverables from the project, linked to the numbered list of objectives.

5. Project Plan

Provide an scientific summary of the project plan of investigation plus any additional points required to support statements made in the previous sections, and include any key references required to justify the points made (e.g. in the use of particular outcome measures or methods of analysis).

This gives you an opportunity to explain and elaborate on the information in questions 1-4. Please do not repeat information already given.

- a. Describe your study using an appropriate format for the design. An indication of time line and work sequence for staged projects is also needed. The EME Programme strongly encourages innovative study designs involving stratification, the use of routinely collected digital data or novel methodologies. Please ensure these elements are fully described and it is clear how the use of these approaches could help to speed up the translation of promising interventions and/or have the potential to increase the impact of the research.

If your research is a clinical trial, please base your summary on a PICO format, i.e. the study Population, planned Intervention, Comparison/control and Outcome measures. Most CTUs, RDS or R&D offices also have suitable templates, which can be used as a basis for your response.

If your research is not a clinical trial (for example, a validation of a diagnostic test) provide a carefully structured project plan. At a minimum it should explain the source and availability of specimens/patients, the tests/interventions you plan to use, the controls or “gold standard” comparators, the statistical tests you plan to use and the expected differences that can be detected.

In addition to the above, you must include the following key information required by the EME Board:

- b. For randomised clinical trials a sample size with an associated power calculation. Information must be provided so the Board can replicate the calculation and understand the assumptions made.

- c. A recruitment plan including the approximate number of patients that would be likely to be available.
- d. A realistic indication of timelines for regulatory steps, team recruitment, patient recruitment, study completion, data analysis and write-up as well as the anticipated pathways to impact. This must be in text format, not a diagram. **Link to NIHR Dissemination guidance:** [How to disseminate your research: Getting your message heard - and used.](#)
- e. A description of the team that is proposed to deliver this research. The EME Programme expects to see a multidisciplinary team, which includes all relevant expertise to enable delivery of the proposed research, and promotes team science <http://www.acmedsci.ac.uk/policy/policy-projects/team-science/>. If your application includes a mechanistic study, your study team must demonstrate the appropriate skills to support such a study.
- f. If the study involves a drug or other intervention clearly justify why this drug/intervention has been chosen over alternatives, and provide a justification for the dosing regimen/treatment schedule.
- g. A justification of how the project offers value for money.

6. Intellectual property and commercialisation

The definition of Intellectual Property (IP) includes copyright (such as new software, checklists, scales, protocols, questionnaires, toolkits, guidelines or similar) and research tools (such as data analysis techniques, assays, cell lines, biomarkers, materials or equipment and devices) patents, trademarks and designs.

- a. Please provide details of any existing or potential future intellectual property and ownership, including patents or patent applications that are relevant to the project.
- b. If commercial partners are involved in the study, a detailed description of the contributions and expectations from all parties must be included.
- c. If the study involves a drug or other intervention clearly justify why this drug/intervention has been chosen over alternatives

7. Uploads

ATTACHMENT 1: FLOW DIAGRAM

Finally, please create a flow diagram (single-side of A4), as a separate PDF file, for submission with your application form. This should illustrate the study design and the flow of participants. Applicants should also describe complex interventions and controls as accurately and fully as possible within their diagram. If proposing an RCT, we advise you refer to the CONSORT statement and website for guidance, (<http://www.consort-statement.org>). Alternatively, you may find the EQUATOR Network website useful (www.equator-network.org). The PDF file should be submitted along with your application form.

ATTACHMENT 2: REFERENCES

One single-side A4 page, listing references used throughout your proposal is also a mandatory upload. Please use either the Vancouver or Harvard referencing conventions.

ATTACHMENT 3: PAPERS IN PRESS

You may include relevant in-press publication that provides proof of concept. Please provide detail of when this was submitted and to which journal.

8. Acknowledge, review and submit

Conflict checks

Please declare any conflicts or potential conflicts of interest that you or your co-applicants may have in undertaking this research, including any relevant, non-personal & commercial interest that could be perceived as a conflict of interest.

Agreement to terms and conditions

I have read and understood the terms on which I have been nominated as Chief Investigator for this proposal along with the associated documentation and accept this role.

(Note that terms and conditions statement to include expectation/responsibility for applicant keep host institution/interested parties informed).

Checklist of information to include when submitting a NIHR stage 1 research application

Applicants should click the check boxes to indicate that they have included the necessary information prior to submitting their application.

- A good quality Plain English Summary
www.involve.nihr.ac.uk/makeitclear
- A clear explanation of the problem being addressed
- A clear demonstration of the need and importance of the research
- A review of existing literature (primary research)
- A clear research question / aim(s) and objectives
- A clear project plan summarising the study design and methods
- A clear description of team member roles and contribution
- Appropriate and relevant involvement of patients and the public www.involve.nihr.ac.uk
- A clear, appropriate and relevant plan for dissemination
- A flow diagram illustrating the study design / flow of participants (document upload)
- One single-side A4 page of references using either the Vancouver or Harvard referencing conventions (document upload)