Health Technology Assessment Programme



# SUPPORTING INFORMATION FOR APPLICANTS APPLYING TO THE HTA PROGRAMME

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

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#### 1. About this supporting information

This document contains information to assist applicants submitting either a **Stage 1** or **Stage 2** application form. Applications for funding are made online through the NETSCC Management Information System (NETSCC MIS). You must register or log-in to the NETSCC MIS to complete and submit your application.

Please also ensure that you have read the <u>Stage 1</u> or <u>Stage 2</u> application form guidance notes fully and referred to the NIHR HTA programme website before contacting us with any queries. We have endeavoured to cover all necessary information relating to the application form through these resources. Incorrectly completed applications may be rejected.

The following additional supporting information is available on the NIHR Website

- HTA Programme page / aims and scope
- Make a strong application
- Tips for applying
- Word version of Stage 1 application from
- Word version of Stage 2 application form

#### Other information / links:

- MRC complex intervention guidance
- ISRCTN registry

# 2. The HTA Programme - purpose and eligibility

The NIHR Health Technology Assessment programme is funded by the NIHR, with contributions from the CSO in Scotland, Health and Care Research in Wales and the HSC R&D Division, Public Health Agency in Northern Ireland. Researchers from Northern Ireland and Scotland for certain NICE related calls, as indicated in the commissioning brief, should contact NETSCC Commissioning Team <a href="https://doi.org/10.1016/j.nlm.nic.uk">https://doi.org/10.1016/j.nlm.nic.uk</a> to discuss their eligibility to apply.

If you intend to apply to the researcher led work-stream should read the remit sections of <a href="the HTA">the HTA</a> website and then <a href="identify the right programme">identify the right programme</a> page of the NIHR website to check whether your proposed research is in the remit of the HTA programme. You may also find it useful to refer to the portfolio of funded projects to see what similar projects we have funded in the <a href="mailto:past">past</a>.

If after reviewing this guidance you have any questions about the eligibility of your proposed research for HTA funding please send an email to <a href="https://https

#### Applicants are asked to:

- 1. Follow Good Clinical Practice guidelines when planning how studies, particularly RCTs, will be supervised. Further advice specific to each topic will be given by the HTA Programme at proposal Stage 2 and contracting stages.
- 2. Note that trials involving medicinal products must comply with "The Medicines for Human Use (Clinical Trials) Regulations 2004". In the case of such trials, the DH expects the employing institution of the chief investigator to be nominated as the sponsor. Other institutions may wish to take on this responsibility or agree co-sponsorship with the employing institution. The DH is prepared to accept the nomination of multiple sponsors. Applicants who are asked to submit a Stage 2 proposal will need to obtain confirmation of a sponsor(s) to complete their application. The DH reserve the right to withdraw from funding the project if they are not satisfied with the arrangements put in place to conduct the trial.

# 3. NETSCC proposal resubmission policy

Please note that an unsuccessful proposal cannot normally be resubmitted to this or any other NETS programme within one year of the original decision letter, unless applicants can demonstrate that it has changed significantly and is essentially a new proposal.

#### 4. Data Protection

We have an obligation to keep data secure and to use it appropriately. To fulfil our obligations under law and as a result of our contract with the Department of Health, we adopt various procedures to use and protect data. This will impact on how we deal with you and your joint applicants.

The Department of Health, National Institute for Health Research (DH NIHR) is the Data Controller under the Data Protection Act 1998 ('the Act'). Under the Data Protection Act, we have a legal duty to protect any information we collect from you. You should be aware that information given to us might be shared with other DH NIHR bodies for the purposes of statistical analysis and other DH NIHR research management purposes. NETSCC also reserves the right to share, in confidence, details of your application with other approved research funding organisations outside NIHR in order to coordinate research activity in the UK.

Information collected from you will not be passed to any third party outside the NIHR except specifically as detailed above without your consent except where we are under a statutory obligation or entitled to do so by law. Applicants may be assured that DH NIHR is committed to protecting privacy and to processing all personal information in a manner that meets the requirements of the Act.

# Data Security - data about you

Personal information will be held on a database in the NETSCC password-protected network that is available only to NETSCC staff. Your details and those of your co-applicants will be retained by NETSCC on behalf of the Department of Health to facilitate the running of the HTA Programme. If your application is successful at any stage of our process, your name, and the details of the sponsoring organisation, will appear on the NETSCC website <a href="www.nihr.ac.uk/hta">www.nihr.ac.uk/hta</a>. In addition, once funding has been agreed and the contract signed, your details will appear in other literature as a grant holder and will be passed to the Department of Health for inclusion in their publicly available databases of research projects.

Your name and those of your co-applicants will be added to our mailing list. This means that you will be sent updates on all the NETSCC programmes. We may also send you separate literature about the HTA Programme and related events in medical/health research. If you have any questions, or if you would prefer not to receive routine and/or general communications, please contact us at: <a href="https://htm.nc.uk">https://htm.nc.uk</a>.

#### 5. Useful Resources

#### **Research Design Service**

Applicants are recommended to seek advice from suitable methodological support services, at an appropriate stage in the development of their research idea and application. It is advisable to make contact at an early a stage as possible to allow sufficient time for discussion and a considered response.

The NIHR Research Design Service can advise on appropriate NIHR programme choice, and developing and designing high quality research grant applications (http://www.nihr.ac.uk/research-design-service/contact-us.htm).

# **Clinical Trials Unit Support**

Clinical Trials Units are regarded as an important component of many trial applications, and can advise and participate throughout the process from initial idea development through to project delivery and reporting. However, they may not be essential for all types of studies. If you feel this is the case, please justify the reasons on your application.

If you are looking for a CTU to collaborate with in your application, then the following sources can provide more help:

NIHR CTU Support Funding (<a href="http://www.nihr.ac.uk/ctu-support-funding.htm">http://www.nihr.ac.uk/ctu-support-funding.htm</a>) provides information on units receiving funding form the NIHR to collaborate on research applications to NIHR programmes and funded projects.

The UKCRC CTU Network (<a href="http://www.ukcrc-ctu.org.uk">http://www.ukcrc-ctu.org.uk</a>) provides a searchable information resource on all registered units in the UK, and lists key interest areas and contact information.

# **Clinical Trials Toolkit**

Researchers designing or undertaking clinical trials are encouraged to consult the Clinical Trials Toolkit (<a href="www.ct-toolkit.ac.uk">www.ct-toolkit.ac.uk</a>). This NIHR resource is a website designed to help researchers navigate through the complex landscape of setting up and managing clinical trials in line with regulatory requirements. Although primarily aimed at those involved in publicly funded Clinical Trials of Investigational Medicinal Products (CTIMPs), the Toolkit will also benefit researchers and R&D staff working on trials in other areas, who will find useful information and guidance of relevance to the wider trials environment.

The MHRA (<u>info@mhra.gsi.gov.uk</u>, <u>www.mhra.gov.uk</u>) can provide guidance as to whether your trial would be covered by the regulations.

#### **Outcomes**

Wherever possible, the results of HTA should provide information about the effectiveness and cost-effectiveness of care provided in its usual clinical setting and for the diverse subjects who would be eligible for the interventions under study. The endpoints of interest will in most cases include disease specific measures, health related quality of life and costs (directly and indirectly related to patient management). Wherever possible, these measurements should be made by individuals who are unaware of the treatment allocation of the subjects they are assessing. We encourage applicants to involve users of health care in the preparation of their proposal, for instance in selecting patient-oriented outcomes. Where established Core Outcomes exist they should be included amongst the list of outcomes unless there is good reason to do otherwise. Please see The COMET Initiative website at <a href="https://www.comet-initiative.org">www.comet-initiative.org</a> to identify whether Core Outcomes have been established. A period of follow up should be undertaken which is sufficient to ensure that a wider range of effects are identified other than those which are evident immediately after treatment. Where relevant, researchers should explore the effect of the intervention in relation to health inequalities. These factors should guide applicants in their choice of subjects, settings and measurements made.

#### **INVOLVE / Public Involvement**

The NIHR expects the active involvement of patients and the public in the research it supports, including research undertaken as part of an individual training award. NIHR recognise that the nature and extent of active patient and public involvement is likely to vary depending on the context of each study or award. The term involvement refers to an active partnership between patients, members of the public and researchers in the research process. This can include, for example, involvement in the choice of research topics, assisting in the design, advising on the research project or in carrying out the research.

It is important that you describe in as much detail as possible how patients and the public have been involved in the development of the application as well as plans for involvement in the proposed research. Please note that this does not refer to the recruitment of patients or members of the public as participants in the research.

Further information and resources can be found on the INVOLVE website <a href="http://www.invo.org.uk/">http://www.invo.org.uk/</a>. This includes a detailed <a href="definition">definition</a> of patient and public involvement in research, <a href="briefing notes">briefing notes for researchers</a> on how to involve patients and the public and an <a href="involvement cost calculator">involvement cost calculator</a> and budgeting guide. The NIHR <a href="Research Design Service">Research Design Service</a> provide advice on developing research applications including involving patients and the public and the <a href="James Lind Alliance">James Lind Alliance</a> has a step-by-step guide on involvement in research identification and priority setting.

#### **Ethics / Regulatory Approvals**

Guidance on the application process for ethical and other approvals can be found on the <u>HRA</u> <u>website</u>. Please note that if your study is led from England and involves the NHS in England you should apply for <u>HRA approval</u>.

If you are using patient information from an existing database, you should check whether the patients have given their consent for their data to be included in that database for research purposes, or if not whether the database is exempt under Section 251 of the NHS Act 2006. Where exemptions are not already in place, approval to use confidential patient information without consent must be requested from the HRA who make decisions with advice from the Confidentiality Advisory Group. (CAG)

To take advantage of the growing utility of routine data (such as HES, GP records etc.), we would encourage investigators, where appropriate, to ask study participants to consent to long term follow up (e.g. beyond the outcomes to be collected in the funded trial) using routinely collected data, and appropriate linkage to allow this data to be best used.

Information on the responsibilities of key research stakeholders including Sponsors, Chief Investigators and Research Teams are summarised in the <u>UK policy framework for health and social care research.</u>

#### Reasonable costs and value for money

The HTA programme accepts that some variance in costs is likely to occur between the Stage 1 and Stage 2 applications. The HTA programme will carefully scrutinise all Stage 2 application costs and any variance from the first stage. All costs need to be fully justified by the applicants to reassure that the study offers good value for money for the NHS.

It is important that consideration is given to all costs in relation to NHS support and treatment costs and the accurate values for these are included. It should be noted that applicants are expected to have contacted the appropriate Trust/s regarding the NHS support and treatment costs that may be required if their research is funded. If the costs are felt to be material, a letter of support may be provided from the Trust/s concerned as part of the Stage 2 proposal.

There are no fixed limits on the duration of projects or funding, and proposals should be tailored to fully address the research problem. Research costs are the costs of the research activity itself. These include data collection, analysis, other activities needed to answer the research questions, trial registration (if required) and the salary and indirect costs of staff employed to carry out the research.

If you are unsure of how to attribute the costs between research and NHS support and treatment costs, please refer to the following guidance on 'Attributing the costs of health & social care Research & Development (AcoRD)'

Higher Education Institutions (HEIs) should determine the Full Economic Cost (FEC) of their research using the Transparent Approach to Costing (TRAC) methodology. For HEIs, up to 80% of FEC will be paid, provided that TRAC methodology has been used. For applications where the contractor is an NHS body or provider of NHS services in England, up to 100% of direct costs will be paid.

The total costs on the Stage 1 form should include the figures at the appropriate rate, so the total should reflect HEI figures at 80% and non-HEI figures at 100%. When completing the Stage 2 form, the figure submitted should be 100%, any reductions to FEC are automatically calculated by the system prior to submission.

# 6. Feasibility and Pilot studies

We expect that when external pilot or feasibility studies are proposed by applicants, or specified in commissioning briefs, a clear route to the substantive study will be described but unless specified in the brief the substantive trial should not be included as part of the study design. A decision on the substantive study will be made at an appropriate time-point during the pilot/feasibility work. The HTA reserve the right to directly commission research or advertise for the substantive study.

Where requested, any internal or embedded pilot study should have clear and robust progression criteria.

**Feasibility Studies** are pieces of research done before a main study. They are used to estimate important parameters that are needed to design the main study. Feasibility studies for randomised controlled trials may not themselves be randomised. Crucially, feasibility studies do not evaluate the outcome of interest; that is left to the main study. If a feasibility study is a small randomised controlled trial, it need not have a primary outcome and the usual sort of power calculation is not normally undertaken. Instead the sample size should be adequate to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision.

**Pilot Studies** are a version of the main study that is run in miniature to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure recruitment, randomisation, treatment, and follow-up assessments all run smoothly. It will therefore resemble the main study in many respects. In some cases this will be the first phase of the substantive study and data from the pilot phase may contribute to the final analysis; this can be referred to as an internal pilot. Or at the end of the pilot study the data may be analysed and set aside, a so-called external pilot.

For a full definition of the terms 'feasibility study' and 'pilot study' visit the NETSCC website glossary page <a href="https://www.nihr.ac.uk/glossary">www.nihr.ac.uk/glossary</a>

In preparing for a substantive evaluation attention should be paid to appropriate guidance on how to develop interventions (such as the MRC guidance on developing and evaluating complex interventions and the IDEAL framework: <a href="www.ideal-collaboration.net/framework/">www.ideal-collaboration.net/framework/</a>).

#### 7. Diagnostics and Imaging

In evaluating diagnostic and imaging techniques, the emphasis of the HTA Programme is to assess the effect on patient management and outcomes (particularly where changes in management can be shown to have patient benefits). Improvements in diagnostic accuracy, whilst relevant, are not the primary interest of this commissioned research programme. Applicants should justify where they consider improvements in diagnostic accuracy to be relevant to these objectives. Where there is poor evidence to link diagnostic improvements to patient benefits, part of the primary research may be to assess the effects of such changes on patient outcome.

An assessment should also be made of changes in other resources (particularly other subsequent therapies) used as a result of changes in diagnostic methods.

#### 8. UK Biobank

UK Biobank is a major national health resource with the aim of improving the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses. As such, applicants are encouraged to consider whether Biobank may be able to provide suitable data for their study, rather than request funding for unnecessary new data collection. We do not want to discourage establishment of new cohorts of participants and their data where this is necessary to address the research questions under consideration, our aim is to avoid applications for funding to set up Biobank-like cohorts where the use of Biobank would prevent wasteful duplication of Biobank-like activities.

UK Biobank has recruited 500,000 people aged between 40-69 years in 2006-2010 from across the country to take part in this project. They have undergone measures, provided blood, urine and saliva samples for future analysis as well as detailed information about themselves. The health of members of this large cohort will be followed over the coming years and the participants have consented to be approached about health research. <a href="https://www.ukbiobank.ac.uk/">www.ukbiobank.ac.uk/</a>

Please note: Some of the NIHR programmes, including the HTA Programme, are unlikely to fund work which focuses on collection of physiological, biochemical or other information unless there is a clearly defined way in which this will be used for the benefit of patients (either directly or in terms of improving outcomes of other patients). For these reasons we generally do not fund bio-banks or disease registers. If you would like to include this as an element of your research proposal, please contact us.

#### 9. Systematic Reviews and Evidence Syntheses

#### Methods

Applicants should demonstrate knowledge of current research in the field and of systematic review methods and state how these would apply to the question posed. Valid and reliable methods should be proposed for identifying and selecting relevant material, assessing its quality and synthesising the results. Guidance on choice of appropriate methods is contained in NHS CRD Report Systematic Reviews: CRD's guidance for undertaking reviews in health care (third edition) (www.york.ac.uk/inst/crd/index guidance.htm).

#### Cochrane

Applicants wishing to produce and maintain a Cochrane systematic review from a HTA commissioned systematic review should make the case in their proposal. This will need to include the approval of the relevant Cochrane Review Group (<a href="www.cochrane.org">www.cochrane.org</a>). Any additional costs associated with the initial preparation of a Cochrane review should be included in your project proposal. Maintenance costs cannot be met.

#### **Updating**

It is the policy of NETSCC, HTA that all search strategies undertaken as part of evidence synthesis/secondary research projects must not be more than 12 months out of date when the draft final report is submitted. We expect that most projects will manage to bring their searches up to date prior to analysis and writing up. As research funders we are aware that exceptional circumstances can apply that would not allow this to be case but this must be the exception rather than the rule and will be assessed on a case by case basis. The expectation is that projects funded by the HTA Programme will deliver information that is both relevant and timely.

In addition, in order to inform decisions on whether and when to update the review, researchers will be expected to give some indication of how fast the evidence base is changing in the field concerned, based on the nature and volume of on-going work known at the time the review is completed. Applicants should note that they will not be expected to carry out any future updating as part of the contract to complete the review.

# Requirements for systematic reviews to be registered with PROSPERO

Applicants undertaking systematic reviews should note the commitment of NIHR to register them in the <a href="PROSPERO">PROSPERO</a> was developed by the NIHR's Centre for Reviews and Dissemination (CRD), and is the first online facility to register systematic reviews for research about health and social care from all around the world. Access is completely free and open to the public. PROSPERO registration is a condition of NIHR funding for eligible systematic reviews. Link to PROSPERO website:

http://www.crd.york.ac.uk/prospero/.

#### 10. NIHR Carbon Reduction Guidelines

Researchers applying for NIHR funding are asked to consider the carbon footprint of their research and take steps to reduce carbon emissions where appropriate. Advice on how to do this can be obtained from the NIHR Carbon Reduction Guidelines <a href="https://www.nihr.ac.uk/research-and-impact/documents/NIHR-Carbon-Reduction-Guidelines.pdf">https://www.nihr.ac.uk/research-and-impact/documents/NIHR-Carbon-Reduction-Guidelines.pdf</a>.

# 11. Transparency agenda

In line with the government's transparency agenda, any contract resulting from this tender may be published in its entirety to the general public. Further information on the transparency agenda is at:

https://www.gov.uk/government/topics/government-efficiency-transparency-and-accountability http://www.contractsfinder.businesslink.gov.uk/

#### 12. Guidance for using the electronic online Stage 1 application form

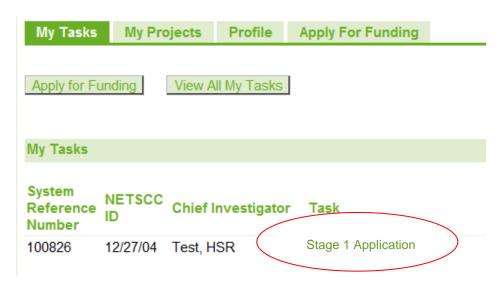
# To Access the Application form for <a>Stage 1</a> applications only

Select the call to which you wish to apply for on the <u>funding opportunity</u> page on the NETSCC website. From within the call details page press the 'Click here to apply' button to access the Stage 1 application form. This also provides call specific supplementary information e.g. the commissioning brief or specification document. This will direct you to the NETSCC MIS login page. If you already have a username (email address) and password, enter these details or, if you have not yet registered, complete the short registration process. You will then be directed to the confirmation page for the specific call. If this is the correct call, click on the Apply button and this will start the application process. Clicking Cancel will return you to your 'home page'.

Applying for a funding opportunity creates a task called **'Stage 1 Application'**. This task will be available for you to complete until **1pm on the closing date** as indicated on the research call and on your task list.

The 'Stage 1 Application' task can be accessed at any time until you either submit the application (using the Submit button in the application process which will appear once all the validation is complete) or the call closes.

See the screenshot example below:



Clicking on the Stage 1 Application link takes you to the application's main page where you can complete your application information (clicking on this link **will not submit** an incomplete application).

Additional guidance will be available on most screens as you progress through your application.

The NETSCC MIS can always be accessed directly at <a href="www.netscc-mis.nihr.ac.uk">www.netscc-mis.nihr.ac.uk</a> for you to go to your home page where all your applications and other tasks will be listed.

# To submit a Stage 1 application

In order to submit a Stage 1 application to the programme you must:

- Complete all mandatory fields as indicated with a red asterisk \*. The final review and submit page of the application provides a final check of the mandatory fields as well as providing reminders about optional entries.
- For primary research you should upload 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 (if appropriate). If the project consists of more than one work package,

consider a diagram that conveys the sequence and timing of research packages as well as how the work packages are linked. 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 (<a href="www.consort-statement.org">www.consort-statement.org</a>). Alternatively, you may find the EQUATOR Network website useful (<a href="www.equator-network.org">www.equator-network.org</a>). The .PDF file must be submitted along with your application form.

- Submit a list of references used throughout your proposal (maximum 1 sides of A4).
- Upload any other requested documents e.g. cover letter, collaborative documents, as dictated by the specification of the call.

# Giving others access to the form

- Co-applicants: Access to your application is through your user login to the NETSCC MIS. This should not be shared. The Stage 1 application does not require co-applicants to complete this form however as lead applicant you must ensure they are aware of being involved in the study team. If you want to share your form with your co-applicants, please create a PDF of the form and send it to them. Options to create a PDF are available on the Home page and the Review and Submit page.
- **Signatories:** You are not required to provide signatories for Stage 1 applications.

#### 13. Guidance for using the electronic online Stage 2 application form

# To access the application form for Stage 2 applications only

If you are applying for a <u>new call</u> e.g. an Evidence Synthesis, you can select the call to which you wish to apply for on the <u>funding opportunity</u> page on the NETSCC website. From within the call details page press the 'Click here to apply' button to access the Stage 2 application form. This also provides call specific supplementary information e.g. the commissioning brief or specification document. This will direct you to the NETSCC MIS login page. If you already have a username (email address) and password, enter these details or, if you have not yet registered, complete the short registration process. You will then be directed to the confirmation page for the specific call. If this is the correct call, click on the Apply button and this will start the application process. Clicking Cancel will return you to your 'home page'.

Applying for a funding opportunity creates a task called 'Stage 2 Application'. This task will be available for you to complete until 1pm on the closing date as indicated on the research call and on your task list.

If you have been shortlisted from a Stage 1 form:

The 'Stage 2 Application' task can be accessed at any time until you either submit the application (using the Submit button in the application process which will appear once all the validation is complete) or the call closes.

See the screenshot example below:



Clicking on the Stage 2 Application link takes you to the application's main page where you can complete your application information (clicking on this link will not submit an incomplete application).

Additional guidance will be available on most screens as you progress through your application.

The NETSCC MIS can always be accessed directly at <a href="www.netscc-mis.nihr.ac.uk">www.netscc-mis.nihr.ac.uk</a> for you to go to your home page where all your applications and other tasks will be listed.

#### To submit a Stage 2 application

In order to submit a Stage 2 application to the programme you must:

- Complete all mandatory fields. The final review and submit page of the application provides a final check of the mandatory fields as well as providing reminders about optional entries.
- Submit a Detailed Research Plan, which should:
  - Have a font size of 11 Arial
  - Not exceed 20 A4 pages
  - Have a header containing your allocated project reference number if known
  - Have a footer showing your page numbers
  - Be converted to a .PDF version before uploading it
- Submit 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 (if appropriate). If the project consists of more than one work package, consider a diagram that conveys the sequence and timing of research packages as well as how the work packages are linked. 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 (<a href="www.consort-statement.org">www.consort-statement.org</a>). Alternatively, you may find the EQUATOR Network website useful (<a href="www.equator-network.org">www.equator-network.org</a>). The .pdf file must be submitted along with your application form.
  - Submit a CTU letter of support if appropriate to the study. This is not a mandatory upload.
  - Submit a list of references used throughout your proposal (maximum 3 sides of A4).
  - Upload any other requested documents e.g. cover letter, collaborative documents as dictated by the specification of the call.

#### Giving others access to the Stage 2 form

# **Co-applicants**

Guidance for how co-applicants complete their sections can be found at: <a href="www.nihr.ac.uk/about-us/documents/NETSCC/MIS/MIS-brief-for-Co-Applicants.pdf">www.nihr.ac.uk/about-us/documents/NETSCC/MIS/MIS-brief-for-Co-Applicants.pdf</a>

#### Including co-applicants in your Stage 2 application

Access to your application is through your NETSCC MIS user login. **This should not be shared**. The Stage 2 application is designed as a collaborative submission. As the lead applicant, you can nominate co-applicants to provide their CV information and collaborate on sections of the application. You select the type of access they have to the application. As a result of the nomination, your co-applicants will be invited via email to login to the MIS, accept their role and complete their application tasks.

If your application includes co-applicants, you will not be able to complete and submit your application <u>until</u> the co-applicant has provided the information that we require from them. Once you have completed the details for each co-applicant you have to select the option 'notify' on the Research Team Instructions page. This will then prompt an email to be sent to each co-applicant with a task **Accept Stage 2 Application Participation (Co-Applicant)** for them to approve involvement with the project in question. If the applicant agrees this generates two new tasks which will appear on their homepage.

1) Collaborate on Stage 2 Application (Co-Applicant) which requires the co-applicant to update their CV details.

And the other task:

**2) Stage 2 Application**, depending on the access permissions granted by the lead applicant, allows the co-applicant to read and/or amend any details in the application. It is the responsibility of the lead applicant to ensure that the co-applicants complete all the tasks generated.

 Enter co-applicants details accurately as we will use these to contact them (the exact email address used as their MIS username is essential to ensure they receive the automatic communication as part of the application process).

Please make sure that you:

• Allow sufficient time for your co-applicants to complete both parts of their task in the online form **before** the application deadline.

# Signatories

Guidance for how signatories complete their sections can be found at: <a href="https://www.nihr.ac.uk/about-us/documents/NETSCC/MIS/MIS-brief-for-Supporting-Role-Signatories.pdf">https://www.nihr.ac.uk/about-us/documents/NETSCC/MIS/MIS-brief-for-Supporting-Role-Signatories.pdf</a>

Instead of requiring wet ink signatures (for roles such as Sponsor, Department Head, Financial Director, NHS facilities Manager etc.) on a paper copy of the application form, you will be asked to provide contact information (including a valid individual's email address) about the required signatories for the Stage 2 application so that they can complete their approvals electronically. This process replaces the need for 'wet ink' signatures with an electronic version.

For signatories this is a **two stage process** and requires those nominated to first complete an 'agree **to participate**' task prior to application submission, followed by a 'confirmation' task immediately after submission of the application.

Firstly, you the lead applicant will be able to 'Notify' the signatories which will automatically invite them via email to register/login to the MIS and accept their role.

Following submission the lead applicant will notify each signatory using the MIS, they will then acknowledge that they have seen and support your completed submitted application in time for the deadline by submitting the 'Provide full application signatures' task. They will be able to see a PDF copy of your completed application via the system.

The HTA Programme acknowledges that it may not be possible for you to obtain confirmation from your Signatories immediately after submission, however; it remains your responsibility to obtain these electronic approvals within <u>two weeks</u> of the submission deadline. You can check that your signatories have completed the approval process on your MIS task page.

Once all signatories have completed their task you should take a screen shot of the completed page and email it to the relevant funding team. For contact details see 'Assistance' below.

#### 14. Completing the form

#### **ORCID**

In line with other health research funders, NIHR have recently started implementing a new researcher identifier scheme – ORCID. ORCID provides a digital identifier that, through integration in key research workflows such as manuscript and grant submission, supports automated linkages between researchers and professional activities ensuring that work is recognised.

Applicants can now update their MIS profile with their ORCiD ID, a process that will become mandatory for all applicants in the future. This ID will only need to be entered once. To add your ORCiD ID to your MIS contact record, log in to the MIS and go to your profile. Click the link 'View ORCiD record' and follow the on-screen instructions. You will then be returned to the MIS and the profile field for your ORCiD number will automatically be populated. You will only have to do this once.

N.B. For a Stage 2 application this is a mandatory requirement.

# Saving your form

As you work through the application, you are asked to save each page. This will save all the information you have submitted so far. You can save the form at any point and leave the application prior to submission. The save button is always located at the bottom of each page of the application. Large text areas on the form also have their own save button beside them. The application task will remain on your home page until complete and submitted or the deadline for the application has passed.

# It is important to remember to 'Save' each section as you go through the form before navigating away from the page.

There is a security time out set on the MIS so that after 60 minutes of inactivity, the user will be logged out of the MIS. It is advisable therefore to save your work at regular intervals using the save button on any page. The NETSCC MIS will give you a warning that you are due to be timed out 10 minutes before it times you out. If this message is displayed, you should close the pop-up.

There is a left hand navigation menu in the application so you can select specific parts of the form to complete, however you should always ensure that you save any information entered on your page before using this left hand menu.

# Leaving the application task

You can leave your application task at any time. As long as you have saved any new information you have entered for the application, you can navigate to your home page or log out of the NETSCC MIS system.

# **Technical Support**

If you encounter any problems with the NETSCC MIS system, you should contact the programme funding support team via email. The contact details can be found on the NIHR website

# Space restrictions when entering text

You should be aware that there are character limits set for each text box within the application form. For larger text areas these are indicated with 'Limit' and 'Remaining' at the bottom of the text entry box. Please note that the system does not provide a spell checker. Carriage returns and spaces are counted as characters. The character count will be slightly less than that of a Microsoft word character count.

The form counts all blank space as a part of the content of each box, so if you are short of space it will help if you delete extra carriage returns and place any bulleted lists into paragraph format.

#### Use of non-standard characters

You are advised not to use any non-standard characters in your text; in particular, you may experience a technical difficulty that affects the use of these characters '<' '>' '>' '>' and '<'. The system will currently strip these characters out of the content of the text without warning. If you need to use these symbols, then please replace them with words (i.e. less than or greater than, or less than or equal to or greater than or equal to). You will not be able to submit the form if you have either of these symbols or any other non-alphabetical or non-numerical characters in your text. For these reasons it is advisable that you either type text directly into the form or ensure these characters are not included in any text that you copy and paste from other documents.

#### **URL links**

You may wish to include URL links to your application or refer to URL links in a body of your text. You are advised not to use any URL shortening service such as 'tiny.cc' when completing your application. This type of shortening service is associated with hacking and spamming (as it promotes the sending of links that are unclear where they are pointing).

Technical support documents including how to spell check, resize text boxes and use Mac/iPads can be found on the <a href="NIHR website">NIHR website</a>.

#### **Review and Submit Application**

Please ensure that before you submit your application, you have completed the required fields and saved a version of your form. You must submit your application form and flow diagram / references where required, by the stated deadline **before 1pm**. We are unable to grant any time extensions and the deadline will be strictly observed. You should therefore plan your application carefully. We will not enter into negotiations for extensions.

Stage 1 and Stage 2 applications must be submitted electronically.

# The HTA programme no longer requires paper copies of submissions.

Submit your application using the Submit button on the last page of the web form. Please note that the Submit button will not appear unless all necessary sections have been completed. Warning signs (①) may appear to indicate that you may have omitted some information but this sign indicates the information is not mandatory and you can submit without it.

✓	Complete	The section/form has been filled out correctly
X	Incomplete	Mandatory information has not been provided and the task cannot be submitted until this has been completed
•	Attention	This section has not been completed but is not mandatory

We strongly advise applicants at this point to check that all sections are completed and the correct documents have been uploaded into the system as they cannot be altered once submitted.

Once all sections have been completed and show as green ticks (or as a yellow advisory exclamation mark) a submit button will appear in the top left hand corner of the page and the form can be submitted to the HTA.

You will then receive an automated confirmation email from the HTA. If you do not receive an email please contact us immediately as there may be an issue with your submission.

# **Un-submitted applications**

Seven days prior to the closing date you will receive an email reminder that you have an open application (i.e. not submitted). The HTA Programme no longer supports 'rolling over' of applications to a subsequent call.

#### 15. Assistance

If, after carefully reading all the instructions, you still have difficulties completing your application, please visit the NIHR website (<a href="www.nihr.ac.uk/hta">www.nihr.ac.uk/hta</a>) which has various supporting documents available.

Any questions, queries or requests for clarification in relation to the call you are applying to should be to one of the following e-mail addresses with the reference number and title for the call for proposals as the email header.

Please be aware that while every effort will be made to respond to enquiries in a timely fashion, it is advisable to send queries in as far in advance of the call closing date as possible to ensure we can respond whilst still leaving you enough time to complete your application.

Commissioned Calls for Research (advertised briefs): <a href="https://doi.org/nihr.ac.uk">https://doi.org/nihr.ac.uk</a>

Researcher-led Calls: <a href="https://https:/