



***National Institute for
Health Research***

Guidance Notes

NIHR Clinical Trials Fellowships

Round 7, June 2018

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Introduction

On behalf of the National Institute for Health Research (NIHR), the NIHR Trainees Coordinating Centre (TCC) is launching the seventh round of NIHR Clinical Trials Fellowships.

The NIHR through its various national research programmes (www.nihr.ac.uk), commissions new research of direct relevance to the NHS. Many of these studies involve clinical trials. The conduct and execution of well-designed trials requires partnership with clinicians, other trialists and methodologists and ideally builds on the experience, expertise and infrastructure provided by Clinical Trials Units (CTUs).

Clinical Trials Fellowships (CTFs) are designed to support existing NIHR trainees with an interest in, and experience of, working with clinical trials as part of their current training award who would benefit from further training within the setting of a CTU (in receipt of NIHR CTU Support Funding). The training programme should expose the trainee to all aspects/stages of trials and should not limit individuals to one study.

These guidance notes are intended to help individuals and CTUs who are eligible to apply for a **NIHR CTF** complete an application.

Application Process

Please note all applications for this round must be made using TCCi, which can be accessed via <https://tcci.nihr.ac.uk>. These guidance notes must be read in full in order to complete this process.

Eligibility

NIHR CTFs are open to existing NIHR trainees in partnership with CTUs in receipt of [NIHR CTU Support Funding](#). Applications should be submitted jointly by the CTU and the applicant.

NIHR trainees must:

- Hold one of the following awards at the time of application:
 - NIHR Doctoral Research Fellowship (DRF)
 - NIHR Postdoctoral Fellowship (PDF)
 - NIHR Career Development Fellowship (CDF)
 - NIHR Clinical Lectureship (CL) (part of NIHR's Integrated Academic Training Programme, including NIHR recognised locally-funded CLs)
 - NIHR Clinician Scientist Award
 - HEE/NIHR Integrated Clinical Academic Programme Clinical Doctoral Research Fellowship (ICA CDRF)
 - HEE/NIHR Integrated Clinical Academic Programme Clinical Lectureship (ICA CL)
 - NIHR Clinical Academic Training Clinical Doctoral Research Fellowship (CAT CDRF)
 - NIHR Clinical Academic Training Clinical Lectureship (CAT CL)
 - NIHR Healthcare Scientist Doctoral Research Fellowship (HCS DRF)
 - NIHR Healthcare Scientist Postdoctoral Research Fellowship (HCS PDF)

- NIHR School for Primary Care Research (SPCR) doctoral studentships
 - NIHR School for Primary Care Research (SPCR) launching fellowships (post doctoral)
 - Be involved in a clinical trial as part of their training award; and
 - Have continued support from their employing organisation for the duration of the fellowship (this may or may not be the same as the institution that hosts the CTU).
- Applicants undergoing medical or dental specialty training must also have permission from their Postgraduate Dean for time out of their training programme. A signed letter of support from the Postgraduate Dean will be required prior to contracting, showing that the Postgraduate Dean confirms that the period and form of research are acceptable and compatible with training towards obtaining a CCT in the applicant's chosen specialty.

CTUs must:

- Be based in England; and
- Be in receipt of NIHR CTU Support Funding, with at least one year of their current contract in force at the deadline for submission of an application.

The CTUs participating in this round are listed at Annex A and on our website at <https://www.nihr.ac.uk/ctf>

Individual CTUs may be involved with up to two separate applications per round, supporting different trainees.

Scope

NIHR CTFs provide 6 months dedicated time (or 8 months part-time at 75% Whole Time Equivalent (WTE) or 10 months part-time at 60% WTE) for the trainee to undertake activities that expose them to a range of clinical trials and studies.

NIHR is looking for innovative proposals that expose trainees to all aspects and stages of clinical trials and studies and should not limit the individual to a single project where they would only see one stage in depth. Training programmes should provide trainees with 'hands on' experience that considers the issues involved in the design, conduct, analysis, and interpretation of all trials (including public health based research).

NIHR expects trainees to demonstrate clearly how they would draw on their existing NIHR-funded research and how this additional training would support their future career either as a clinical trials collaborator or principal investigator.

Funding

Each NIHR CTF will attract full cost of employment (including National Insurance, Superannuation and London Weighting where appropriate) for the trainee for the 6 month period plus costs to support their clinical trial training activities (capped at £5,000 for each award). Up to 80% of "Full Economic Costs" (FEC) will also be paid to Higher Education Institutions.

Fellows will need to start the fellowship between 1 January 2019 and 1 March 2020, subject to the CTU having continuing NIHR CTU Support Funding in place for the duration of the fellowship.

Management

Successful NIHR CTFs will be required to submit a progress report at the end of the fellowship to NIHR TCC. The host organisation is also required to submit a financial reconciliation following completion of the award.

Application Procedure

- All CTUs in receipt of NIHR CTU Support Funding will be contacted and invited to participate in the round.
- Details of participating CTUs will also be available on the NIHR website.
- Potential candidates will be invited to apply for an NIHR CTF in partnership with a participating CTU.
- All applicants must have contacted the CTU where they are interested in working by **Wednesday 11th July 2018**, stating their name, contact details, current NIHR award, projected end date, summary of their trials exposure to date, and reasons for applying.
- Completed applications must be submitted to NIHR TCC by 13:00 on **Thursday 23rd August 2018**.
- Applications will be reviewed and scored by an expert panel, which makes recommendations to the Department of Health and Social Care.
- The outcome will be announced during Autumn 2018.

Participants and Signatories

You are required to supply the names and email addresses (if not already registered on the TCCi application system) of the individuals who will be undertaking 'participant' roles as part of your application. Everyone named in this section will be acting as a 'participant' to your application and will need to agree to be part of this application. Participants are required to review the declaration for the role before confirming participation as part of the one-click 'confirm' process.

By confirming participation, participants are acknowledging their involvement and input into this application and agree to be involved in it *before* it is submitted. You must ensure all participants are happy for your application to be submitted before submitting it on the online system. Details of the individuals who will be required to approve your application after submission (signatories) should be entered in the 'Participants & Signatories' section.

It is recommended that you contact your participants and signatories as early as possible to ensure they understand any action they must take and will be available to sign off when you submit.

Please note that it is often the case that one or more of the participants named in this section are also named as signatories. If this is the case, they will need to be included in this section for both roles.

Participants

The participants must confirm their participation on your application and complete any relevant section of the application form before you will be able to press the submit button

Details for the following individuals are required:

- CTU Representative
- Research Support
- Research Contract Officer

After the Research Support participant has confirmed their participation in the application, they must complete the required statement in the 'Training & Development and Research Support' section. This statement can be completed independently whilst you (the applicant) work on the rest of the application.

Signatories

The signatories will be responsible for “signing off” your application as well as completing any relevant section of the application form. They will be invited to confirm participation on your application as soon as their contact details have been entered.

Details of the individuals who will approve your application after submission are required:

- Host Organisation – Head of Department
- Administrative Authority or Finance Officer

The Finance Officer will be able to complete the Detailed Budget section in conjunction with the Applicant.

Please note: when the form is complete and all validation errors have been addressed, the Lead Applicant may submit their application. Clicking the submit button does not send the application to NIHR TCC for consideration; it alerts the authorised signatories (Finance Officer, Head of Department) that the form is ready for final approval. Only when all signatories have approved the application is it then complete and is submitted to NIHR TCC. Please allow plenty of time before the closing date for this process to take place.

Assessment Criteria

Applications for NIHR CTFs will be assessed against the following criteria:

- The potential of the trainee to undertake high-quality clinical trials in their future career
- The impact the fellowship will have on the trainee’s career development and trajectory
- The extent to which the Fellowship will provide a high-quality and stimulating research training experience in all aspects of clinical trials of relevance to the NIHR
- The provision of academic supervision and support
- The extent to which the Fellowship will support professional and personal development

Application Outcome

Applicants will be informed of the outcome of their application by email when all required processes are complete. No indication will be given of outcome before that. Feedback will be sent to all applicants after the funding decisions have been made.

Closing date

Applications must be made using TCCi – <https://tcci.nihr.ac.uk> and submitted by
13:00 on Thursday 23 August 2018

Further guidance for submitting the application on the online application system is available from page 7 onwards.

Completing the Application Form

1. Application Summary Information

Host Organisation

Please give details of the organisation who will be the contractor if the Fellowship is funded. This must be the applicant's proposed Employing Host Organisation (substantive employer), which will administer the NIHR CTF.

Please note:

- The contractor is expected to respond to annual financial reconciliation exercises, provide the final financial reconciliation statement for the Fellowship and to respond to ad hoc requests for financial information during the lifetime of the project.
- In the same way, the contractor is expected to respond to any queries relating to Intellectual Property, commercialisation and benefit realisation.

If the name of your host organisation does not appear in the pre-populated list please email TCCawards@nihr.ac.uk

Proposed Start Date

Note this should be from the 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 Fellowship. Start dates range from 1 January 2019 to 1st March 2020.

WTE of Award

Awards can only be undertaken with the WTE* options given.

Please select whether you wish to hold the fellowship on a full-time basis over 6 months (100% WTE) or part-time over 8 months (75% WTE) or 10 months (60% WTE).

It is not possible to undertake a Fellowship on any other basis other than 100%, 75% or 60% WTE.

* *Whole Time Equivalent (WTE) = percentage of full-time hours per week.*

2. Applicant CV

Please note, some of the responses to these questions are automatically pulled through from information entered in the 'Manage My Details' page.

Degrees and Professional Qualifications

Please provide the full details of any completed higher degree(s) and, where relevant, the full details of any higher degree(s) you are currently undertaking.

Present and previous positions

When entering details of your current and previous positions please indicate at what percentage (WTE) in each post you were undertaking research. For example, if you were a Clinical Lecturer and undertook research for 2.5 days a week and clinical work for 2.5 days per week; please enter 50% for that position. If

you have worked part time at 60%, and undertook research for half of that time, please enter 30% for that position.

This information is used to assess applications to schemes for which there are specific eligibility criteria around the amount of research and/or clinical experience an applicant has.

Research grants held

Details of all grants obtained in the last five years should be provided, including personal research training awards or fellowships, plus any additional previous grants relevant to this application. Please indicate clearly any co-applicants and provide brief details of the nature and full extent of your involvement (e.g. project design, project management, day to day running, data collection, data analysis, writing papers for publication, etc.).

Publication Record

Please **only** include the details of articles which are in press and have been accepted as final by the publisher. Only publications relevant to your application should be included.

Do not include abstracts, conference proceedings or articles in preparation. If relevant, details of these may be included in the '*Applicant Research Background*' section.

Depending on professional background and expertise, applicants are not necessarily expected to have an extensive list of publications at the pre-doctoral application level.

Relevant Prizes, Awards and other Academic Distinctions

Please provide details of any awards or distinctions that would be relevant to your application including details of what the award was for.

ORCID

The NIHR is an ORCID member and encourages all researchers to obtain this persistent digital identifier that distinguishes them from every other researcher. Lead applicants must include an ORCID ID in their application. Without it, your application will not be validated and you will not be able to submit. For more information and to register please see <http://orcid.org/>.

Gender

This question is included with the application form (in addition to being asked as part of equal opportunities monitoring) to ensure we are meeting NIHR's commitment to gender equality in relation to academic career progression. The response to this question will not be displayed to the review panel.

3. Applicant Research Background

Professional background

Select the one option that best describes your professional background. This will determine any options that appear below for your profession, if applicable.

Please describe your research career to date

Please use this question to describe your research experience and career to date and how this makes you suitable for this award. You should include research you have led or made a significant contribution to (making clear what your role was), the research methods you have experience of, and the impact and outputs of the research you have been involved in. You should also detail any other relevant experience

such as supervisory, management, teaching, public engagement and involvement, or leadership experience; or any other skills and experience which highlights your suitability for the Fellowship you are applying for and which demonstrates your potential as a future health research leader.

Please detail your progress to date in your existing fellowship or lectureship in relation to your clinical trial. Please outline the relevant stages of a clinical trial for which you have experience and highlight the areas where further training would be appropriate.

Please indicate how this training will build on your existing experience.

Please outline your future research and career intentions, including what ways this award will add value to your career.

(1,000 word limit)

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

Select 'Yes' or 'No' to indicate whether this or a similar application has previously been submitted to this or any other funding body. This must include any previous submissions for an NIHR research training award. Please detail the title of any previous submission(s), the funding body and scheme, the outcome and the date this is due if a decision is pending. If the application was unsuccessful please indicate why and detail how this application differs from previous submission(s) and how any feedback received has been used to inform this application.

Current and previous NIHR awards

In order to help track the progression of NIHR trainees please indicate whether you have previously held another NIHR research training award.

4. Training and Development and Research Support

Proposed training and development programme

This section should provide the NIHR CTF Review panel with information about the academic content, purpose and management of your NIHR CTF.

Please state the name of the CTU where the NIHR CTF will be based. **You should discuss this section with your CTU representative before you complete the form.**

Please provide a clear outline of the training programme. The training should provide 'hands on' experience for all stages of clinical trials and build on the expertise of the unit. This may include involvement in the development of trial protocols, conduct, analysis and interpretation of ongoing trials in the unit. A timetable and milestones for the proposed training programme should be included. It is important that the training and development programme is tailored to your specific needs and fully justified. Training may include, but is not limited to; formal courses, training in specialist skills and research methodologies, workshops, placements with other research groups or centres, leadership skills and conference attendance.

Research costs cannot be funded through this award, however, and the primary supervisor for any subsequent award is responsible for ensuring a NIHR CTF awardee secures all necessary regulatory approvals before undertaking any research included in the NIHR CTF training and development programme.

(1,000 word limit)

Clinical Trials Unit Representative

The individual named here must also be added in the 'Participants and Signatories' section of the

application form and is required to agree participation, thus confirming that they have read the application and the Applicant Guidance Notes and agree to abide by the conditions under which an award may be granted.

Research Support

The individual named here must also be added in the 'Participants and Signatories' section of the application form. They are required to agree participation, thus confirming that they have read the application and the Applicant Guidance Notes and are willing to provide research support and act as your mentor for research and career development and agree to abide by the conditions under which an award may be granted.

Collaborations

You should include details of other members of the CTU who will be involved in the training and development programme, their role in the CTU and how their expertise will be used to support the trainee

Detail any collaborations you intend to establish to support your training and development programme. This may involve short visiting placements or secondments in new (to the applicant) research environments, e.g. other clinical trials units or NIHR Biomedical Research Units/Centres.

(600 word limit)

Host Organisations support statement

The Research Support participant is required to complete this section. The statement should detail how the organisation is going to support the applicant to successfully complete their training and development programme. This statement should be tailored specifically to the applicant, their training needs, and include how the organisations intend to support the applicant to develop their clinical academic career in the long-term.

This section can only be accessed by the Research Support participant once they have agreed participation and cannot be accessed, but can be viewed, by you as the applicant.

Detailed Budget

Guidance for the completion of the finance section is available in the next part of the Applicant Guidance Notes.

5. Participants and Signatories

A number of participants and signatories are required to be added to your application and, where applicable, to complete sections of it. Details of the required individuals are provided on pages 5-6 of these Applicants Guidance notes and in the online application form along with details of how they should be added. The flow diagram in Annex B goes through the actions required of participants, signatories and the applicant.

6. Acknowledge, review and submit

Conflict checks

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

Agreement to terms and conditions

Please click the check box to confirm you agree to the Terms and Conditions of submission as detailed on the application form.

Finance Guidance

The finance section should provide a breakdown of the costs associated with undertaking the Fellowship and provide justification for the resources requested.

This section must be completed by the Applicant in conjunction with the Research Support Office or Finance Office at the employing host organisation (the organisation that authorised the application and which, in the event of an award being made, will employ the Applicant).

Applicants must make a copy of these Applicant Guidance Notes available to the Finance Officer in question.

The funding requested in the finance section will form the basis of the Fellowship should the application be successful.

All costs provided should be 'value for money' and will be assessed by the NIHR and members of the NIHR CTF Review Panel. The NIHR reserves the right to reject any costs that it considers unreasonable or not fully justified.

The NIHR CTF award funds:

- Full cost of employment (including the employer's contribution to National Insurance, Superannuation and London Weighting where appropriate) for the trainee for the duration of the award (6 months dedicated time, or 8 months part-time at 75% WTE or 10 months part-time at 60% WTE)
- Up to 80% of "Full Economic Costs" (FEC) will also be paid to Higher Education Institutions.
- Plus costs for their training and development programme to support their clinical trial training activities (**capped at £5,000 for each award**).

The fellowship **does not** include, or pay for, any research activities.

NIHR Personal awards are not project or programme grants; therefore, extensions to the duration of awards to allow for completion of research and/or training and development are not permitted. This does not affect suspensions of awards to allow for periods of maternity, paternity, adoption or sickness leave.

GENERAL INFORMATION to support the Completion of the finance section

- Costs must be provided at current prices. An adjustment for inflation will be made annually thereafter at rates set by the Department of Health and Social Care. Whilst allowances for incremental increases should be included on the form, nationally or locally agreed pay increases should be excluded.
- Further itemisation of costs and methods of calculation may be requested to support the application at a later date.
- Payments will be made to the contracted organisation only and the contracted organisation will be responsible for passing on any money due to their partner organisation(s).
- Appropriate sub-contracts must be put in place for any element of the Fellowship which is to be paid to another organisation.
- All applications are expected to have appropriate NHS, HEI, commercial and other partner organisation input into the finance section of the application form.

Detailed Budget

INFORMATION ON DIFFERENT TYPES OF ORGANISATIONS

Higher Education Institutions (HEIs)

- 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.**

NHS bodies and other providers of NHS services in England

- 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.
- If you are a commercial organisation/consultancy, please fill in direct costs and commercial indirect costs. Indirect costs should be charged in proportion to the amount of research staff effort requested on the funding application form. Up to 100% of costs will be paid.

Other Partner Organisations

- If you are an other partner organisation (e.g. charity or NGO), please fill in direct costs and other partner organisations indirect costs. Indirect costs should be charged in proportion to the amount of research staff effort requested on the funding application form. Up to 100% of costs will be paid.

Direct Costs

Details of Post and Salary

This section presents an overview of salary costs for the applicant.

Please state the proposed salary point and scale at the **start of the Fellowship** (“starting point on scale”). These should be detailed at 1.0 WTE.

Please note immediate promotion to a higher grade as a result of securing a fellowship will not be funded. Please **do not** include any Clinical Excellence or Discretion/Merit awards or discretionary points. NIHR agrees to fund consultant salaries at a full-time rate equivalent to 10 Programmed Activities per week

These are costs that are specific to the Fellowship, which will be charged as the amount actually spent and can be supported by an audit record. They should comprise:

I) Salary costs

This section specifies the annual costs of the applicant. You should now allocate the individual staff member costs to each year of the Fellowship, allowing for increments. Use current rates of pay, and build in any known annual increments (again at current rates). You will not be able to claim for pay awards retrospectively, once a Fellowship is underway.

Please note the salary figures need to be calculated using the current annual costs, %WTE and number of months.

It is important to double check that the %WTE, total months and yearly costs information are consistent with the information presented in ‘Details of Posts and Salaries’ (‘Details of Posts and Salaries’ should show the full current staff costs independent of %WTE etc, whereas the yearly costs in ‘Salary Costs’ depend on %WTE etc).

II) Training and Development

These are costs relating to the applicant's training and development programme. All costs in this section will be funded at up to 100% for HEI, NHS and Commercial/Other Partner organisations.

Please itemise and describe fully the costs associated with the fellow's clinical trials training and development programme. (up to £5,000). Please provide estimates if exact costs are not available at the time of application. Any travel and subsistence associated with training and development should be included here.

Indirect Costs/Overheads

HEI Indirect Costs

Total HEI indirect costs must be fully justified. HEIs are permitted to claim estate and other indirect costs. These costs are calculated on the basis of TRAC methodology. Proposals from other types of institutions/organisations should leave this section blank.

HEI indirect costs are based on the number of full-time equivalent research staff working on the research and the indirect/estates charges set by an institution.

The applicant(s) should consult their HEI Finance Departments for the appropriate figures to include in the estate charges and other indirect cost sections.

Commercial/Other Partner Organisation Indirect Costs

Commercial/Other Partner Organisations can claim indirect costs which are the costs of resources used by the research that are shared by other activities. Please seek advice from your finance department about the appropriate cost for this section.

Total Commercial/Other Partner Organisation indirect costs must be fully justified.

I) Indirect Costs

Indirect costs will be charged in proportion to the amount of research staff effort requested on the award. Commercial/Other Partner Organisations should calculate them, using their own cost rates.

They comprise:

- General office and basic laboratory consumables
- Premises costs
- Library services/learning resources
- Typing/secretarial
- Finance, personnel, public relations and departmental services
- Usage costs of major research facilities
- Central and distributed computing
- Charge out rates for shared equipment
- Cost of capital employed

SUMMARY OF COSTS

- NIHR programmes currently fund HEIs at a maximum of 80% of full economic cost, NHS bodies and other providers of NHS services in England 100% and commercial/other partner organisations at 100%.
- Please note that whilst these percentages will be used to calculate the maximum grant payable, the programme reserves the right to award a grant for less than this maximum where it is considered appropriate.

Additional Supporting Information

Plagiarism

The NIHR expects all content within applications for funding to be original material of the applicant's own work, with the exception of sections that other participants are required to complete. Whilst we anticipate and expect that applicants will get help and advice from various sources when putting together an application, including on occasion input from those previously awarded funding, care must be taken to ensure this does not lead to plagiarism of either published work or other previous applications. If an allegation of plagiarism is raised against an application, this will be investigated in accordance with the NIHR's policy on plagiarism, a copy of which is available on request from tcc@nihr.ac.uk.

NIHR Privacy Notice

Our purpose for collecting information is to communicate with you about your application and have the necessary information to evaluate you for a grant. The data we collect here is collected in the public interest. Information provided here may be subject to Freedom of Information requests.

The Trainees Coordinating Centre (TCC) is part of the Department for Health and Social Care (DHSC), National Institute for Health Research (NIHR). The contracting agent for TCC is the Leeds Teaching Hospital Trust (LTHT). The DHSC is the Data Controller and LTHT is the Data Processor under the General Data Protection Regulation (GDPR) EC 2016/679. DHSC NIHR respects the privacy of individuals who share their data and processes it in a manner that meets the requirements of GDPR. The DHSC Data Protection Officer can be contacted by email at: data_protection@dh.gsi.gov.uk

The [NIHR privacy policy](#) includes further information including ways we may use your data, our contact details and details on your individual rights regarding how your data is used. Your data may be shared across the NIHR, including with other coordinating centres, to allow the application to be managed and for statistical analysis, and with external grant reviewers as part of the process for managing the allocation of a grant. Information collected from you will not be shared outside the EEA without your consent.

International Standard Randomised Controlled Trial Number (ISRCTN)

All primary research studies need to be assigned an ISRCTN. You can view the ISRCTN website at: www.isrctn.org/. Please note that the remit of this database has been widened to include all primary research projects, even those that are not randomised controlled trials. There is no registration fee for NIHR funded trials.

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 <https://www.nihr.ac.uk/research-and-impact/documents/NIHR-Carbon-Reduction-Guidelines.pdf>.

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/publications/procurement-and-contracting-transparency-requirements-guidance>.

NIHR INVOLVE

INVOLVE is funded by the National Institute for Health Research, to support active public involvement in NHS, public health and social care research.

As a national advisory group, its role is to bring together expertise, insight and experience in the field of public involvement in research, with the aim of advancing it as an essential part of the process by which research is identified, prioritised, designed, conducted and disseminated.

INVOLVE can support prospective applicants and existing awardees to incorporate effective patient and public involvement into their work. Support includes; help with calculating appropriate costs for involving patients and the public, help with developing potential strategies for involvement, case studies of involvement activities including the impact they have had, and help with writing plain English summaries. Full details of the support INVOLVE can provide and contact information is available via the INVOLVE website: www.invo.org.uk.

Ethics / Regulatory Approvals

Guidance on the application process for ethical and other approvals can be found on the [HRA website](#). Please note that if your study is led from England and involves the NHS in England you should apply for [HRA approval](#).

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 \(CAG\)](#).

NOTE: NIHR is interested in taking advantage of the growing utility of routine data (such as HES, GP records etc.), and would like 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.

Contractual Arrangements

Financial support under an NIHR Fellowship is subject to a contract between the NIHR and the employing host organisation.

Once funding for a Fellowship has been discussed and agreed, the NIHR will confirm the financial arrangements with the employing host organisation. The NIHR will provide the employing host organisation with a contract setting out the details of these arrangements. The employing host organisation will be expected to issue the Fellow with an employment contract commensurate with their experience and seniority.

Government procurement transparency regulations require publication of details of all contracts made with the Department of Health and Social Care on the Department of Health and Social Care Website. Confidential information including research proposals (Plain English Summaries will be published), detailed finance information, bank details, and departmental staff names (other than the award holder's name) will be removed from the published versions.

Freedom of Information Act

The NIHR manages the NIHR CTF Programme on behalf of the National Institute for Health Research (NIHR) and Health Education England. As such, the findings of researchers funded by the programme are incorporated in to the Department of Health and Social Care Freedom of Information Publication Scheme: <https://www.gov.uk/government/organisations/department-of-health/about/publication-scheme>

Equal Opportunities and Diversity

The NIHR and DHSC have a duty as a public body to promote equality of opportunity. All applicants will be contacted shortly after the closure date by NIHR Equality Monitoring.

Monitoring ensures that all applications to NIHR Programmes are treated equally in terms of gender, ethnicity and/or disability.

The information you share with the monitoring system:

- will be stored separately from your application
- only be used for the purpose of monitoring equal opportunities
- be kept securely and in confidence

Guidance and Advice

Please read these Applicant Guidance Notes carefully. If you require any further information, advice or guidance please contact:

NIHR Trainees Coordinating Centre, Tel: 0113 346 6260, Email: TCCawards@nihr.ac.uk

Annex A List of Clinical Trial Units - Round 7

A full list of the following CTUs participating in Round 7, with contact details are on our website <https://www.nihr.ac.uk/ctf>

Birmingham Clinical Trials Unit, University of Birmingham

Bristol Clinical Trials and Evaluation Unit, University of Bristol and Bristol Royal Infirmary

Bristol Randomised Trials Collaboration, University of Bristol

Cambridge Clinical Trials Unit

Cancer Research UK Liverpool Cancer Trials Unit

Comprehensive Clinical Trials Unit, University College London

Intensive Care National Audit and Research Centre (ICNARC)

Keele Clinical Trials Unit, Keele University

Kings Clinical Trial Unit, King's College London

Leeds Institute of Clinical Trials Research, University of Leeds,

Leicester Clinical Trials Unit, University of Leicester

Liverpool Clinical Trials Research Centre

Nottingham Clinical Trials Unit, University of Nottingham

Oxford Clinical Trials Research Unit, The Botnar Research Centre

Peninsula Clinical Trials Unit, Plymouth University

Pragmatic Clinical Trials Unit, Barts and The London School of Medicine and Dentistry

PRIMENT Clinical Trials Unit, University College London

Sheffield Clinical Trials Research Unit, The University of Sheffield

Southampton Clinical Trials Unit, University of Southampton

Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick

York Trials Unit, University of York

Annex B Application Submission Flow Diagram

