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Researchers and their teams may print off this document for training and reference purposes but are responsible for regularly checking the JRCO website for more recent versions.

### NIHR studies

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1. PURPOSE

This Standard Operating Procedure (SOP) details what National Institute for Health Research is and how to apply to have your study adopted onto the NIHR portfolio.

2. INTRODUCTION

The goal of the National Institute for Health Research (NIHR) is to create a health research system in which the NHS supports outstanding individuals, working in world class facilities, conducting leading edge research focused on the needs of patients and the public. The NIHR is directed by Professor Dame Sally C. Davies, Chief Medical Officer and Director General of Research & Development at the Department of Health.

The NIHR now brings together government support for research in the NHS in England, through the NIHR Clinical Research Network Coordinating Centre (CRNCC). The NIHR CRN Portfolio is a database of clinical research studies being undertaken in the NHS that are supported by the NIHR Clinical Research Network (CRN) in England.

Details of clinical research studies which meet specific eligibility criteria (see Appendix 1) are recorded in a database known as the UK Clinical Research Network Portfolio, which comprises the NIHR CRN Portfolio in England and the corresponding Portfolios of Northern Ireland, Scotland and Wales. The Network has a list of funding partners (see Appendix 2).

NIHR uses a system called CSP (Coordinated System for Gaining NHS Permission) in order to upload your study documents onto their central document repository. The uploading of the documents is performed by the local Clinical Research Network although this is normally devolved to the local R&D offices.

From 18th July 2011 a new version of CSP called RDMIS has been adopted. Part of the new system requires that the local R&D office perform the Quality Assurance checks.

3. PROCEDURE

3.1 Accessing CSP

CSP is accessible within the Integrated Research Application System (IRAS). [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk). You must tick England in the project filter question 3 and Yes to question 5a and Yes to 5b if the study is supported by the BRC. **If your study does not have funding secured, the Networks will not accept your study for adoption.**

Once you have ticked the questions mentioned above, a CSP Application Form will appear in the menu of your IRAS application form. This should be completed and submitted through IRAS by the Chief Investigator (CI) or delegated member of the study team. You will receive an acknowledgment email from the system.
If your study is potentially eligible, the CI will then be emailed and asked to complete and submit the R&D form along with the associated documents to CSP through IRAS.

Once this has been validated, another email will be sent to the CI, asking for the study related documents.

These should be submitted through IRAS to the Comprehensive Research Network (CRN) of which the NHS organisation is a member. The local Network for studies happening at Imperial or their associated NHS Trusts is North West (NW) London.

If your study needs to be considered for the NIHR Clinical Research Network Portfolio in order to receive service support funding or research infrastructure support through the Comprehensive Clinical Research Network, the Network will email you to confirm whether your study is eligible which could take up to 30 working days after the Network receive your R&D Form and the associated documents including the funding letter.

3.2 Global versus Local Checks

Governance checks are a standard set of checks done by NIHR CSP to ensure that studies meet the requirements of the Research Governance Framework and other applicable standards/regulations. There are 2 types of checks performed within CSP; Global and local.

**Global** – the global checks are completed by the lead R&D office. The lead R&D office will be the site that was named in A68 of the IRAS form. This question also determines which will be responsible for the global checks. Global checks would include for example, uploading and checking documentation such as the protocol and insurance. Global checks are performed by only one institution.

**Local** – the local checks are completed by the R&D offices of every organisation the study is being conducted at. A site might be responsible for performing both global and local checks. Local checks would include for example, uploading the participant information on the local Trust headed paper and the signed and dated CVs of every member of the research team listed in the SSI form. If a site is only responsible for local checks, it must wait for the lead site to complete the global checks before it is able to sign off the study.

3.3 Feasibility Process

Imperial's JRCO feasibility process was introduced in May 2014 with the aim to combine and replace aspects of the current review by the Joint Research Compliance Office (JRCO). Support at this early stage in the process will give the study the best possible chance to be completed successfully within budget, on time and generating high quality data.

The feasibility study will be coordinated by the CI/PI/study team and the final decision rests with the relevant ICHT Clinical Division research manager to assess whether the study is deemed feasible, it is advisable to consider a range of criteria, with the help of other teams around the College and Trust, including evaluations of patient recruitment targets, inclusion/exclusion criteria, equipment and resources, facilities and locations.
Before submitting the study in CSP the study will need to be submitted to the clinical divisional manager allocated to its speciality.

Contact details are as follows:

**Heidi Saunders**  
Divisional Research Manager - Investigative Sciences and Clinical Support & Cardiovascular  
Heidi.saunders@imperial.nhs.uk

**Donna Mclean**  
Divisional Research Manager - Surgery and Cancer  
Donna.McLean@imperial.nhs.uk

**Ella Johnson**  
Divisional Research Manager - Medicine  
ella.johnson3@imperial.nhs.uk

**Marcela Carvajal**  
Research Feasibility Officer – Medicine & Cardiovascular  
Marcela.Carvajal@imperial.nhs.uk

**Debra Matich**  
Divisional Research Manager – Women’s and Children’s  
Debra.Matich@imperial.nhs.uk

### 3.4 Documents to be sent to the Network and to the JRCO if happening at ICHT sites

All documents must be uploaded using the IRAS checklist to be considered a valid research application. (VRA)

The following documents are required in order to process your study through CSP.

If a site within ICHT is going to conduct the study. Please note that we only accept one investigator for Imperial College Healthcare NHS Trust. So if the Chief Investigator is based at Imperial College Healthcare NHS Trust, they must also be named as the Principal Investigator. Other researchers can be named as co-investigators.

**Mandatory**

1. Submit **signed** IRAS NHS R&D form/IRAS REC form via IRAS to CSP. …
2. Submit **signed** IRAS Site Specific Information (SSI) form for Imperial College Healthcare site preferably in pdf format via IRAS to CSP. ..
3. Final REC approved Protocol (Including any superseded versions approved by REC in any amendments) 4. Final REC approved Participant information sheet and consent forms on Trust headed paper (Including any superseded versions approved by REC in any amendments

5. Study specific documentation approved by the REC (e.g. patient diary cards)
6. REC favourable opinion letter

7. REC Favourable Opinion letter for any substantial amendments included the NOSA form and the ANNEX Forms for CTIMPS (If applicable)

8. Signed and dated copy of the principal Investigator CV.

9. CV’s for the research team listed in the SSI – Signed and dated.

If applicable

1. Certificate of ARSAC

2. MHRA CTA approval

3. Confirmation of authorisation from MHRA for any substantial amendments

4. Confirmation of REC favourable opinion for any substantial amendments

5. Any other approvals documentation that is relevant to the study (NIGB approval, GTAC LOA & Research Passports etc.)

6. Confirmation from support departments that their involvement is agreed (emails are acceptable proof)

Final R&D sign-off is also dependent on the following documents/approvals being in place internally, if applicable:

1. Clinical trial site agreement signed off by Pre-award Imperial AHSC JRCO and sponsor organisation (if applicable) A fully signed contracts need to be in place before trust approval can be issued.

2. Approval by Research Imaging committee, including IRMER approval (if applicable) - You must contact Liam Greenshields Liam.greenshields@imperial.nhs.uk at the earliest possible opportunity, if you have a project that utilises Imperial College Trust imaging equipment/facilities. Such project requires review by the Imaging research Committee and they only meet once a month.

The JRCO aims to approve studies happening at ICHT sites within 15 days of receipt of a valid research application and submission of the signed SSI form and confirmation that the study has been adopted into the NIHR portfolio.

3. Imperial College Healthcare NHS Trust Has a Safety Committee which must approve research projects occurring at this site before submission to GTAC. Contact Sharon Wood – Director of Safety Services Tel: 08714 610 122 Email: s.wood@salveo.co.uk
4. New Interventions Committee approval for new device studies being conducted at the Trust
(Contact: Dr Onn Min Kon; onn.kon@imperial.nhs.uk)

3.5 Ineligible Studies

If your study is deemed to be ineligible for inclusion onto the Portfolio it cannot proceed through
NIHR CSP. This does not affect whether your study can go ahead or not. In order to
progress your application through for Trust approval, you will need to change your answer to
Q5a on the Project Filter questions to No. This will then remove the CSP application form from
your IRAS folder for your study and you will then be able to create and submit your SSI form.
Please see JRCO SOP 031 if your study is deemed ineligible.

When everything is in place a trust approval letter will be issued for the study and the project
can commence. A copy of the trust approval letter should be placed in the site file and the
CI/PI/Study team will have 30 days from the date of approval to recruit its first participant.

3.6 Participant Identification Centres (PICs)

Participant Identification Centres (PICs) are organisations which refer potential participants to a
research team at another organisation, but do not conduct trial related activity themselves. If
consent or screening will take place, then the site would not be classed as a PIC and you will
need to complete a SSI form in IRAS.

You must ensure that all PICs are listed in part C of the R&D form and send the JRCO details of
what activity will take place at ICHT and a copy of the protocol. Once a PIC is listed in the R&D
form, the local CRN will be able to notify the R&D office responsible for that site in order for the
site to carry out PIC checks. The checks are similar to the global and local checks and you will
receive confirmation from the NHS Trust that you may use the site as a PIC.

3.7 Amendments

All the Amendments for CSP studies must be uploaded and processed via CSP.
You will need to complete a substantial amendment form for ethics, which can be
generated from the IRAS application (see Appendix 2 or
https://www.myresearchproject.org.uk/help/Contents/BlankPdfForms/NoticeOfAmendmentForm.pdf)

For studies submitted using the old NRES application form, you may use the
Notice of Substantial Amendment Form (see Appendix 3 or access

Alternatively you can create a basic dataset in IRAS based on the information in
your original application in the old NRES application form. You can use this basic
dataset to generate a Notice of Substantial Amendment

The substantial amendment form should be submitted to the NHS Research
Ethics Committee which gave a favourable opinion to the research (the REC),
along with any updated documents, such as consent forms or protocols. A copy
must also be sent to the JRCO if Imperial College AHSC is the research
4. MONTHLY REPORTING

If your study is accepted by NIHR for adoption onto the Portfolio, you will have to submit monthly reports on the number of participants you have recruited to the study. For more information on how to do this, please contact the R&D Office or the study coordinator at the Trust at which your study is being conducted. If the site is within Imperial College Healthcare NHS Trust recruitment Data Contact needs to be nominated:

**Recruitment Data Contact (RDC)**

Recruitment data for your study must be uploaded on a monthly basis using a Microsoft Excel Template to the UKCRN Portfolio Database. The monthly reporting of accurate recruitment data, or indication that there has been no recruitment, is a condition of inclusion of your study in the NIHR CRN Portfolio. Please can you nominate a suitable person to be assigned the role of Recruitment Data Contact (RDC) for your study. This person will be responsible for uploading recruitment data for your study on a monthly basis. Ideally the person you nominate should be familiar with Microsoft Excel. Please provide the contact details for this person to the NIHR Portfolio team.

Recruitment data is measured against key performance indicators which are used to demonstrate the success of the Clinical Research Network (CRN) and will feed into the process of allocating future funding for NHS infrastructure for research across the Clinical Research Networks. This ensures that infrastructure resources are directed to where they are required for the most patient benefit.

Frequently Asked Questions about recruitment data can be accessed via -

5. REFERENCES

www.nihr.ac.uk


http://www.crn.nihr.ac.uk/can-help/funders-academics/gaining-nhs-permissions/

http://www.cuh.org.uk/sites/default/files/research/RD_GD003_NHS_permission_processed_through_NIHR_CSP.pdf

http://www.researchdirectorate.org.uk/Documents/News/IRAS%20and%C2%B0CSP%C2%B0leaflet%20JAN13.pdf

https://www.myresearchproject.org.uk/help/hlpupdates.aspx

http://www.ct-toolkit.ac.uk/routemap/r-and-d-submission

http://www.crn.nihr.ac.uk/can-help/funders-academics/nihr-crn-portfolio/

http://www.crn.nihr.ac.uk/can-help/funders-academics/gaining-nhs-permissions/the-csp-flowchart/

6. APPENDIXES

Appendix One: Eligibility Criteria for NIHR Clinical Research Network Support

Introduction

1.1 The purpose of this paper is to set out the criteria governing the eligibility of studies for NIHR Clinical Research Network (NIHR CRN) support. It therefore relates only to England.

1.2 Details of the aims and purpose of the NIHR Clinical Research Network can be found at: http://www.nihr.ac.uk/files/pdfs/Briefing%20documents/4.1%20Clinical%20Research%20Network.pdf The NIHR Clinical Research Network is the English component of the UK Clinical Research Network (UKCRN).

1.3 The main role of the NIHR CRN is to support later phase clinical trials and other well-designed studies. The NIHR supports Experimental Medicine studies primarily through Clinical Research Facilities, Experimental Cancer Medicine Centres, and Biomedical Research Centres and Units. However, those Experimental Medicine studies funded by the NIHR or its Partners but conducted in the NHS outside these centres will have the necessary NHS Support provided by the NIHR CRN.

1.4 The NHS is responsible for meeting the Treatment Costs of research via the normal arrangements for commissioning patient care1.

2 Definition of ‘research study’

2.1 Research can be defined as the attempt to derive generalisable (i.e. of value to others in a similar situation) new knowledge by addressing clearly defined questions with systematic and rigorous methods2. This excludes: audit; needs assessments; quality improvement and other local service evaluations. It also excludes routine banking of biological samples or data except where this activity is integral to a self-contained research project designed to test a clear hypothesis. NHS Research Ethics Committee approval and NHS permission are prerequisites for research to be supported via the NIHR CRN.

2.2 The Study Sponsor (as defined by the Research Governance Framework for Health and Social Care) has the formal responsibility for confirming that a study is research.

2.3 The definition of a research study as set out above applies to all studies for which NIHR Clinical Research Network support is sought regardless of the research funder.
3. Eligibility for NIHR CRN support

3.1 All studies must already have full research funding (i.e. funding to meet all research costs as defined in HSG (97)32) before they can be considered for NIHR CRN support.

3.2 The source of research funding is the principal determinant of eligibility for NIHR CRN support.

Automatically eligible studies

3.3 Studies that are automatically eligible for consideration for NIHR CRN support are studies that are funded by the NIHR, other areas of central Government, and NIHR non-commercial Partners.

3.4 NIHR non-commercial Partners are those organisations that:
   i) Award research funds as a result of open competition across England with high quality peer review (definitions are set out in Appendix I); and
   ii) Fund research that is of clear value to the NHS; and
   iii) Take appropriate account of the priorities, needs and realities of the NHS in making decisions about the research that they fund.

3.5 NIHR non-commercial Partner status is confirmed via a self-declaration process. NIHR non-commercial Partners are required to sign a self-declaration that they meet the criteria set out in 3.4, and to confirm the funding streams that are applicable. Non-commercial funding organisations that self-declare as NIHR non-commercial Partners may be audited to ensure that they meet the criteria. The list of NIHR non-commercial Partners, which is regularly updated, is available on the NIHR CRN Co-ordinating Centre website [http://www.crncc.nihr.ac.uk/](http://www.crncc.nihr.ac.uk/)

3.6 Individual studies funded as part of programme or centre grants, or as part of research training awards, will be required to have undergone protocol peer review before they can be considered for NIHR CRN support (see Appendix I for the definition of high quality peer review). The study Sponsor should provide confirmation of appropriate peer review.

3.7 A non-commercial study supported by multiple funders is automatically eligible for NIHR CRN support if one of the funders is the NIHR, other areas of central Government of an NIHR non-commercial Partner.

3.8 Studies where the funder providing the research costs is different from the funder managing the funding competition, including the peer review process, will have their eligibility determined by the funder responsible for managing the funding competition.

Potentially eligible studies
3.9 ‘Potentially eligible’ studies require formal consideration via the Adoption Process. The NIHR CRN manages the Adoption Process for both commercial and non-commercial studies on behalf of the Department of Health.

3.10 Five types of studies require adoption:
• Commercial contract research (industry-funded, industry-sponsored studies)
• Investigator-initiated, commercial-collaborative studies (Industry-funded, non-industry sponsored studies)
• Non-commercial studies funded by overseas governments
• Non-commercial studies funded by overseas charities
• Certain other high quality studies (see 3.15)

3.11 **Commercial contract research.** One of the aims of the NIHR CRN is to facilitate studies of benefit to patients that are sponsored by industry. A specific adoption process was developed by the UKCRC Industry Road Map Group to enable these studies to access NIHR CRN support. Studies that are eligible for NIHR CRN support require full cost recovery from industry i.e. recovery of the cost of activities that are additional to treatment outside the context of the study including NHS Support Costs.

3.12 **Investigator-initiated, commercial collaborative studies** are studies that are initiated by non-commercial investigators (e.g. University or NHS staff) with the majority of the research funding being provided by a commercial organisation (e.g. a pharmaceutical, biotechnology or devices company) specifically to support that study. Contracts for such studies should include provision for the investigator to take responsibility for analysis, interpretation and publication of findings. This investigator-initiated commercial collaborative research includes pilot studies and nested exploratory studies. It is recognised that commercial organisations do not usually award this funding by means of a structured competition. Nevertheless, to be eligible for NIHR CRN support (and for the NHS to meet the Treatment Costs, including Excess Treatment Costs, of the study), the potential field of researchers who could be awarded the funding must not have been restricted to specific Universities or NHS Trusts within England. Funders of investigator-initiated, commercial collaborative studies are required to provide the NIHR CRN Co-ordinating Centre with written confirmation that the funding opportunity was open to all qualified researchers in England. It is also essential that all investigator-initiated commercial collaborative studies must have been subjected to high quality peer review before they can be considered for NIHR CRN support. Peer review should be commensurate with the size and complexity of the study. The study Sponsor should provide confirmation of appropriate peer review.

3.13 **Non-commercial studies funded by overseas governments** will be considered for NIHR CRN support via the Adoption Process.

3.14 **Non-commercial studies funded by overseas charities** will be considered for NIHR CRN support via the Adoption Process.
3.15 **Certain other high quality studies** funded by any source of funding not mentioned above, but which appear to meet the criteria set out in 3.4 will be considered for NIHR CRN support via the Adoption Process.

4 **Assessing need for NIHR CRN support**

4.1 It is the responsibility of the relevant Local Research Network (Comprehensive, Topic Specific or Primary Care) to consider a study’s requirement for NIHR CRN support at each site. This process will be co-ordinated by the Lead Network\(^4\) on behalf of the Chief Investigator. This assessment will be made only for studies that have been accepted as eligible for NIHR CRN support by the NIHR CRN Co-ordinating Centre (as set out in sections 2 and 3). For multi-centre studies the NIHR CRN support required may vary across Local Research Networks and sites.

4.2 Timely reporting of recruitment data to the NIHR CRN Co-ordinating Centre by the Chief Investigator or their team, and acknowledgement of Network support in relevant publications, are conditions of accessing NIHR CRN support.

5 **Prioritisation of NIHR CRN support**

5.1 The resources needed in the NHS to support research, both NHS Support and availability of suitable/appropriate patients, are finite. To enable the Government to meet its commitment to provide the necessary NHS Support for its own and its Partners' research, whilst also allowing other important research to be undertaken within the Network, there is a need to prioritise eligible studies. When resources are stretched it is important that NIHR CRN effort on studies with the highest priority is not diminished. Studies with a lower priority can still receive NIHR CRN support but patient recruitment may take a little longer.

**High priority studies**

5.2 Studies that have a high priority for NIHR CRN support are those studies that are:

a) Funded by the NIHR, other areas of central Government or an NIHR non-commercial Partner or
b) Adopted commercial contract research

The Government is committed to providing the necessary NHS Support for its non-commercial Partners' research therefore there should be no need for there to be any prioritisation of NIHR Partner studies on the basis of the costs of support.

**Medium priority studies**

5.3 Studies that have a medium priority for NIHR CRN support are those studies that are:

a) Funded by overseas governments; or
b) Investigator-initiated commercial collaborative studies

**Low priority studies**

5.4 Studies that have a low priority for NIHR CRN support are those studies that are:

a) Funded by overseas charities; or
b) Funded by any source of funding not mentioned above, but which meet the criteria set out in 3.4

**Department of Health**
**[February 2011]**

**Definitions of the criteria for ‘NIHR non-commercial Partner’**

1. NIHR non-commercial Partners are those organisations that:
   i) Award research funds as a result of open competition across England with high quality peer review; and
   ii) Fund research that is of clear value to the NHS; and
   iii) Take appropriate account of the priorities, needs and realities of the NHS in making decisions about the research that they fund.

**Open competition**

2. Open competition ensures that the best range of researchers is able to apply for the funding. Open competition is defined by:
   a) The competition being open to all appropriately qualified individuals, and
   b) Knowledge of the competition being available to all appropriately qualified individuals, and
   c) The research funder being completely independent of the recipient organisation.

**High quality peer review**

3. Peer review must be independent, expert, and proportionate:
   a) **Independent**: At least two individual experts should have reviewed the study. The definition of independent used here is that the reviewers must be external to the investigators’ host institution and not involved in the study in any way. Reviewers do not need to be anonymous.
   b) **Expert**: Reviewers should have knowledge of the relevant discipline to consider the clinical and/or service based aspects of the protocol, and/or have the expertise to assess the methodological and statistical aspects of the study.
   c) **Proportionate**: Peer review should be commensurate with the size and complexity of the study. Large multicentre studies should have higher level (more reviewers with broader expertise and often independent review committee or board), and potentially international peer review. Small single-centre studies and investigator-initiated commercial collaborative studies still require expert and independent peer review but this might be arranged through the institutions R&D office (as required by the NHS Research Governance Framework for England and Wales). If the R&D office is unable to undertake the review, the NIHR CRN Co-ordinating
Centre will arrange a review via the NIHR Health Technology Assessment Programme or the NIHR Research Design Service, dependant on the size of the study.

**Clear value to the NHS**

4. This requirement is specified in the ‘Statement of partnership on non-commercial R&D in the NHS in England’ (Annex B of ‘Responsibilities for meeting the Patient care Costs associated with Research and Development in the NHS’, HSG (97)32). As part of the self-declaration as an NIHR non-commercial Partner, funding organisations are required to confirm that the research they fund is of clear value to the NHS.
Appendix Two: NIHR Non-commercial Partner List

1 Introduction
1.1 The Eligibility Criteria for NIHR Clinical Research Network Support (February 2011) effective from 1 April 2011, sets out the criteria governing the eligibility of studies for National Institute for Health Research (NIHR) Clinical Research Network (CRN) support. It therefore relates only to England. Studies that are automatically eligible for consideration for NIHR CRN support are studies that are funded by the NIHR, other areas of central Government, and NIHR non-commercial Partners.

1.2 The purpose of this document is to provide a list of non-commercial funding organisations that meet the NIHR Partner criteria below. This reference guide is intended to enable researchers and other users to easily identify NIHR non-commercial Partners and is updated every two weeks by the NIHR CRN.

2 NIHR Partner Criteria

2.1 As set out in the Eligibility Criteria for NIHR Clinical Research Network Support (February 2011) effective from 1 April 2011, NIHR non-commercial Partners are those organisations that:

- Award research funds as a result of open competition across England with high quality peer review; and
- Fund research that is of clear value to the NHS; and
- Take appropriate account of the priorities, needs and realities of the NHS in making decisions about the research that they fund.

2.2 NIHR non-commercial Partner status is now confirmed via a self-declaration process. Non-commercial organisations are required to sign a self-declaration that they meet the NIHR non-commercial Partner criteria and to confirm the funding streams that are applicable. Further information on self-declaration as an NIHR Partner is available on the CRN website.

2.3 It is important to note that:

NIHR non-commercial Partners that operate multiple funding streams must self-declare against the NIHR Partner criteria with respect to all of the existing funding streams they administer. NIHR non-commercial Partners that operate a mixture of funding streams, some of which are eligible and some of which are not, are marked by an asterisk (*) in the table provided in section 3. You are advised to contact a member of the Portfolio Team at the NIHR CRN (via portfolio.helpdesk@nihr.ac.uk) for further information on the eligibility of these NIHR non-commercial Partners ‘funding streams.

All studies supported by an NIHR non-commercial Partner are still required to meet all other NIHR Clinical Research Network Eligibility Criteria before being considered automatically eligible for consideration for NIHR CRN support.

The research funders denoted by (‡) in the table provided in appendix 3 have “self-declared” that they meet the NIHR non-commercial Partner criteria as stated in the Department of Health policy document Eligibility Criteria for NIHR Clinical Research Network Support (February 2011). The NIHR Clinical Research Network has included
these organisations in good faith. NIHR non-commercial Partners may be audited by the NIHR CRN to ensure that they meet the required criteria.
## Appendix 3  Current list of NIHR non-commercial Partners

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<td>Academy of Medical Sciences</td>
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<tr>
<td>Action for ME ‡</td>
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<tr>
<td>Action Medical Research</td>
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<tr>
<td>Action on Hearing Loss (formerly Royal National Institute for Deaf People (RNID))</td>
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<tr>
<td>Alcohol Research UK ‡</td>
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<tr>
<td>Alzheimer's Research UK</td>
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<tr>
<td>Alzheimer's Society</td>
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<tr>
<td>Arthritis Research UK (formerly ARC Arthritis Research Campaign)</td>
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<tr>
<td>Arts and Humanities Research Council (AHRC)</td>
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<tr>
<td>Association for International Cancer Research (AICR)</td>
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<tr>
<td>Asthma UK</td>
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<tr>
<td>Ataxia UK</td>
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<tr>
<td>Autistica (formerly Autism Speaks UK)</td>
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<tr>
<td>Baily Thomas Charitable Fund</td>
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<tr>
<td>Bardhan Research and Education Trust of Rotherham (BRET)*</td>
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<tr>
<td>Big Lottery Fund*</td>
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<tr>
<td>Biotechnology and Biological Sciences Research Council (BBSRC)</td>
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<tr>
<td>Bliss - The National Charity for the Newborn</td>
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<tr>
<td>Bone Cancer Research Trust</td>
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<tr>
<td>Bowel Disease Research Foundation (BDRF)</td>
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<tr>
<td>Breakthrough Breast Cancer</td>
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<tr>
<td>Breast Cancer Campaign</td>
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<tr>
<td>British Academy (For the Promootion of Historical Philosophical and Philological Studies), The</td>
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<tr>
<td>British Academy of Childhood Disability (BACD)</td>
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<tr>
<td>British Cardiac Research Trust (BCRT) ‡</td>
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<tr>
<td>British Dietetic Association (BDA)</td>
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<tr>
<td>British Elbow and Shoulder Society (BESS) ‡</td>
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<tr>
<td>British Geriatrics Society*</td>
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<tr>
<td>British Heart Foundation (BHF) ‡</td>
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<td>British Hip Society</td>
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<tr>
<td>British HIV Association (BHIVA)</td>
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<tr>
<td>British Infection Association (BIA)*</td>
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<td>British Liver Trust</td>
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<tr>
<td>British Lung Foundation</td>
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<tr>
<td>British Maternal and Foetal Medicinal Society (BMFMS) ‡</td>
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<tr>
<td>British Medical Association (BMA)*</td>
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<td>British Occupational Health Research Foundation (BOHRF)</td>
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<td>British Orthodontic Society Foundation (BOSF)*</td>
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<td>British Orthopaedic Association (BOA)</td>
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<td>British Renal Society (BRS)</td>
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<tr>
<td>British Scoliosis Research Foundation (BSRF)*</td>
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<tr>
<td>British Sjögren's Syndrome Association</td>
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<tr>
<td>British Skin Foundation</td>
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<tr>
<td>British Society for Antimicrobial Chemotherapy (BSAC)*</td>
</tr>
<tr>
<td>British Society for Rheumatology (BSR)*</td>
</tr>
</tbody>
</table>
The research funders on this list denoted by (‡) have “self-declared” that they meet the NIHR non-commercial Partner criteria as stated in the Department of Health policy document Eligibility Criteria for NIHR Clinical Research Network Support (February 2011). The NIHR Clinical Research Network has included these organisations in good faith. NIHR non-commercial Partners may be audited by the NIHR CRN to ensure that they meet the required criteria.

British Society of Interventional Radiology (BSIR)
British Thyroid Foundation
BUPA Foundation

Cancer Research UK ‡
Castang Foundation
Chartered Society of Physiotherapy (CSP) / Physiotherapy Research Foundation
Children With Cancer UK
Children's Liver Disease Foundation
Cicely Saunders International
Circulation Foundation ‡
CLIC Sargent Cancer Care for Children
Coeliac UK
College of Emergency Medicine, The
College of Optometrists, The
Colt Foundation, The *
Core (The Digestive Disorders Foundation)
Crohn's in Childhood Research Association (CICRA)
Cure Parkinson's Trust
Cystic Fibrosis Trust

Daphne Jackson Trust, The ‡
Deafness Research UK (Hearing Research Trust)
Diabetes Research & Wellness Foundation (DRWF)
Diabetes UK
Dimbleby Cancer Care
DISCS (Diagnostic Investigation of Spinal Conditions and Sciatica)
Dr Hadwen Trust for Humane Research
Dunhill Medical Trust
Dystrophic Epidermolysis Bullosa Research Association (DebRA)*

Economic and Social Research Council (ESRC)
Engineering and Physical Sciences Research Council (EPSRC)
Epilepsy Action (British Epilepsy Association)
Epilepsy Research UK

Fight for Sight
Foundation for the Study of Infant Deaths (FSID)*

Great Ormond Street Hospital Children’s Charity ‡
Guarantors of Brain
Guide Dogs for the Blind Association
Guillain-Barre Syndrome Support Group UK ‡

Healing Foundation, The ‡
The research funders on this list denoted by (‡) have “self-declared” that they meet the NIHR non-commercial Partner criteria as stated in the Department of Health policy document Eligibility Criteria for NIHR Clinical Research Network Support (February 2011). The NIHR Clinical Research Network has included these organisations in good faith. NIHR non-commercial Partners may be audited by the NIHR CRN to ensure that they meet the required criteria.

Health Foundation
Health and Safety Executive
Healthcare Infection Society
Health Protection Agency
Heart Research UK
Henry Smith Charity
Howard Foundation, The
Huntingdon’s Disease Association

I
INSPIRE Foundation, The
Insulin Dependent Diabetes Trust (IDDT) ‡
Intensive Care Society
International Glaucoma Association ‡
ITP Support Association

J
J P Moulton Charitable Foundation ‡
June Hancock Mesothelioma Research Fund
Juvenile Diabetes Research Foundation Limited (JDRF)

K
Kay Kendall Leukaemia Fund, The
Kidney Research UK (KRUUK)
Kids Kidney Research
King’s Fund, The

L
Leukaemia & Lymphoma Research ‡
Leverhulme Trust* ‡
Lowe Syndrome Trust, The
Lupus UK

M
Macmillan Cancer Support ‡
Macular Disease Society, The
Marie Curie Cancer Care
McPin Foundation, The
ME Research UK
Medical Research Council (MRC)
Meningitis Research Foundation
Meningitis UK
Motor Neurone Disease Association (MNDA)
Multiple Sclerosis Society (of Great Britain & Northern Ireland) ‡
Multiple Sclerosis Trust
Muscular Dystrophy Campaign
Myasthenia Gravis Association
Myeloma UK
N
National Association for Colitis and Crohn's Disease (NACC)
National Back Pain Association (BackCare)
National Eye Research Centre (NERC)*
National HIV Nurses Association
National Institute of Academic Anaesthesia (NIAA)*
National Obesity Forum
National Osteoporosis Society
National Policing Improvement Agency
Natural Environment Research Council (NERC)
Neuroblastoma Society, The
Newlife Foundation for Disabled Children
NHS Blood and Transplant (NHSBT)
NHS Connecting for Health*
NHS National Institute for Health and Clinical Excellence (NICE)
Novo Nordisk UK Research Foundation
Nuffield Foundation*

O
Obstetric Anaesthetists' Association (OAA)
Oral and Dental Research Trust, The ‡
Orthopaedic Research UK
Otorhinolaryngological Research Society (ORS)
Ovarian Cancer Action

P
Paget's Association (National Association for the Relief of Paget's Disease)
Pain Relief Foundation, The ‡
Pancreatic Cancer Research Fund
Pancreatic Cancer UK
Parkinson's UK
Pelican Cancer Foundation, The
Pharmacy Practice Research Trust (PPRT)
Primary Immunodeficiency Association
Prostate Action
Prostate Cancer Charity
Psoriasis and Psoriatic Arthritis Alliance, The (PAPAA)
Psoriasis Association, The
PSP Association, The ‡
Pulmonary Hypertension Association UK ‡

R
Raynaud's and Scleroderma Association*
Remedi
Research Autism
Research into Ageing (Age UK) ‡
Resuscitation Council (UK)
Roald Dahl's Marvellous Children's Charity ‡
Rosetrees Trust (The Teresa Rosenbaum Golden Charitable Trust) ‡
Royal College of General Practitioners
Royal College of Ophthalmologists
Royal College of Pathologists
Royal College of Physicians
Royal College of Physicians and Surgeons of Glasgow
Royal College of Radiologists
Royal College of Surgeons of Edinburgh
Royal College of Surgeons of England*
Royal Society for the Prevention of Accidents, The ‡
Roy Castle Lung Cancer Foundation, The ‡
RP Fighting Blindness (British Retinitis Pigmentosa Society)
S
Samantha Dickson Brain Tumour Trust
Shirley Glassstone Hughes Trust Fund, The ‡
Sir Jules Thorn Charitable Trust
Society and College of Radiographers (SCoR)
Society for Mucopolysaccharide Diseases, The a‡
SPARKS Charity
Spinal Research (International Spinal Research Trust)
Stroke Association, The ‡
Stuart Strange Vasculitis Trust (The UK Vasculitis Trust) ‡
Sue Harris Bone Marrow Trust, The
T
Target Ovarian Cancer ‡
Technology Strategy Board
Tommy’s
Tuberous Sclerosis Association
U
UK and Eire Glaucoma Society (UKEGS)
UK Clinical Pharmacy Association (UKCPA) ‡
UK Occupational Therapy Research Foundation (UKOTRF)
UK Respiratory Research Foundation (UKRRF)
UK Spinal Cord Injury Research Network (UKSCIRN) ‡
W
Waterloo Foundation, The ‡
Wellbeing of Women
WellChild Trust, The
Wellcome Trust ‡
World Cancer Research Fund
Appendix Three: Amendments submission to CSP illustrated guide

To submit an amendment to CSP electronically:

You will need to create pdf and xml files of the amendment. In the IRAS submission tab for the amendment, select Proceed to Submission. Save the pdf file created. Then go to the submission history at the bottom of the tab to save the xml file.

Upload the amendment to the R&D Form Checklist tab, making sure you upload using the paperclip icon to the correct category. You may need to scroll to the right of the screen to see the paperclip.
You must upload pdf and xml versions of the amendment at the same time.

Go to the E-Submission tab for the R&D Form and scroll down to see the documents added to the checklist. Click to submit the new/additional documents:

```
<table>
<thead>
<tr>
<th>Document Title</th>
<th>Document Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notice of Substantial Amendment</td>
<td>amendment notice</td>
</tr>
<tr>
<td>Notice of Substantial Amendment XML file</td>
<td>amendment notice</td>
</tr>
</tbody>
</table>

Please click the "Submit new/additional documents" button below to send these documents to the reviewer and add these documents to your R&D application:

**IMPORTANT** - The following document(s) have been added and/or amended in checklist since you submitted your application:

```
[Submit new/additional documents button]
```
You will see the submission recorded in the Submission History at the bottom of the R&D Form E-Submission tab:

![Submission History](image)

If this is the second or subsequent amendment, you will need to duplicate a row within the amendment section so that the document is recognised as an amendment. Do NOT use the Add New Row button at the bottom of the checklist as this will not categorise the document as an amendment.

**To add second or subsequent amendment:**

In the R&D Form Checklist tab, copy the row to add another amendment.
You will now need to replace the document for the duplicated row.
Click on the paperclip and upload the new amendment

You must upload pdf and xml versions of the amendment at the same time
Continue with the submission as described above.

You will see a message in IRAS in due course to confirm whether the amendment was invalid, or just involved new sites or was accepted:

Once REC/MHRA approval has been obtained and confirmed by CSP, you will see a message in IRAS confirming this:
Note that this does not confirm that all sites will implement the amendment, as this is a study-wide confirmation. Some sites may object.

Appendix 4 – Amendment Guidance and Process
New process for handling amendments to NIHR CSP studies

The CSP amendments process was implemented in 2011. It is recommended to run in parallel to regulatory review and introduced the principle of a 35 day default approval of amendments for NHS Trusts. In recognition of the large number of amendments that have no impact on NHS Trusts, the process has been updated introducing a new concept of ‘notifiable’ and ‘non-notifiable’ amendments. The new process will benefit both researchers and NHS Trusts by reducing over-processing and minimising unnecessary delays to the implementation of non-notifiable amendments.

Key principles

- Applies to both substantial and non-substantial amendments as categorised by the Sponsor.
- Studies must have gained approval through CSP.
- The 35 day period starts on receipt of a full amendment submission (i.e. amendment form, letter and revised documents).
- Where required, regulatory approval must be in place before an amendment can be implemented. The only exception to this rule is an urgent safety measure.

### Notifiable

- An amendment that impacts on participating NHS Trusts therefore needs to be considered and may need change control actions.

### Non-notifiable

- An amendment that does not have an impact on NHS Trusts.

For notifiable amendments, Trusts have a maximum of 35 days to raise an objection otherwise the amendment can be implemented at the end of the 35 day period. However Trusts are encouraged to implement earlier where possible.

What must I do?

- Amendments should be submitted to CSP electronically through IRAS for England-led studies. We strongly recommend that this happens in parallel to the applications to other regulators.
- Where the study is led by another Devolved Administration, the amendment should be sent to a Lead Nation contact who will liaise with England. Currently, the 35 day timeline for implementing amendments only applies to sites in England.
- The Sponsor/CI is responsible for providing details of the amendment, including copies of revised documents, to all participating Investigators and study teams.

What happens once I submit my application?

The Lead Local Clinical Research Network (LCRN) will confirm:

- whether the submission is complete
- whether the amendment is notifiable or non-notifiable
- the date of implementation to the Sponsor/CI.

Details of the amendment will be available to the participating R&D offices through CSP, where necessary for impact review and contract revision as required (agreement of which should not delay implementation).

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As defined by REC, examples of substantial and non-substantial amendments can be found on the NRES website.

May, 2014