Standard Operating Procedure

# CONFIRMATION OF CAPACITY AND CAPABILITY TO DELIVER RESEARCH AT UHBRISTOL

**SETTING** Trustwide

**AUDIENCE** All staff who wish to undertake research at UHBristol

**ISSUE** The implementation of a new national system for approving NHS research and a subsequent local change in trust processes.

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## Standard Operating Procedure (SOP)

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| Approved by: | Trust Research Group | | |
| Frequency of review: | Annual | | |

| Review date | Version number | Version Date | Effective Date | Reason for change | Author/Responsible person | Authorised by |
|---|---|---|---|---|---|---|
| - | 1.0 | 17.10.16 | 31.10.16 | n/a | Jess Bisset | Diana Benton |
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### 1. Purpose

The purpose of this SOP is to describe the processes undertaken by UHBristol R&I department to review and confirm capacity and capability to deliver research at the Trust.

### 2. In Scope

Research undergoing HRA approval involving UHBristol premises, staff or patients.

**Out of scope**

Research that does not involve UHBristol premises, staff or patients and does not require HRA approval. Research tissue banks and research databases. Any other non-research projects e.g. audit, service evaluation, service improvement.

## 3. Definitions/Abbreviations

| | |
|---|---|
| C&C | Capacity and Capability |
| CI | Chief Investigator |
| HRA | Health Research Authority |
| REC | Research Ethics Committee |
| R&I | Research & Innovation |
| SoA | Statement of Activities |
| SoE | Schedule of Events |

## 4. Background

*-Health Research Authority website 2016:*

'HRA approval is a new process within England which replaces the requirement of researchers to obtain NHS permission from each NHS Trust where they plan to deliver their research. Instead, sponsors or delegated others, will apply for HRA approval which encompasses required regulatory reviews, currently excluding MHRA approval which will still need to be sought separately, and other applicable reviews by HRA staff which will replace current R&D approval checks. NHS Trusts in England will no longer issue NHS permission, but instead provide confirmation of capacity and capability for a proposed research study'.

*http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/*

This SOP describes the processes within the UHBristol Research & Innovation (R&I) department to review and confirm capacity and capability (C&C) of the trust to deliver a proposed research study. The process is separated into the following scenarios:

i.) studies which are notified to R&I as not requiring C&C review

ii.) studies notified to R&I where UHBristol is a potential participating site (Host) requiring C&C review

iii.) studies sponsored by UHBristol requesting C&C review from participating sites (including UHBristol as a site).

## 5. Procedure

5.1 Studies which are notified to R&I as not requiring C&C review

a) The HRA will email ResearchApprovals@UHBristol.nhs.uk any research which has been assessed as not requiring C&C review by local NHS organisations and where UHBristol has been listed as a participating site on the IRAS form.

b) Within this email the HRA will confirm whether the research can be implemented immediately at site or whether a 35 day review for 'no objection' is required.

c) The R&I projects officer who monitors the ResearchApprovals inbox will therefore either;

i) Immediately file the email by creating an electronic sub folder on the R drive in the folder entitled 'HRA – studies where capability and capacity not required' using the IRAS number to label the folder, and notify the local team (where required) for information

or

ii) Send the email to one of the Research Management Facilitators (RMF) who will review within the 35 day timescale whether there is any objection to the research taking place at UHBristol. The review by the RMF will involve assessing the documentation provided by the HRA in the email to establish whether any resource needs or funding is identified. Where applicable the RMF will liaise with the local team/service where the research will take place and discuss whether there are any objections.

d) Where a review of 'no objection' takes place the RMF will communicate by email the outcome to the CI, Sponsor and relevant local team. There is no template for this communication and it will be dealt with on a study by study basis.

e) In the same way as c (i) above the RMF will then create an electronic sub folder on the R drive using the study IRAS number to label the folder, and will store all of the applicable documentation and correspondence.

e) In some instances research may be emailed to the ResearchApprovals inbox directly from researchers or sponsors rather than by the HRA. The Projects Officer will review these and where the HRA letter indicates that sites do not need to confirm capacity and capability will pass to an RMF to review as detailed in c (ii) above.

5.2 Studies notified to R&I where UHBristol is a potential participating site (Host) requiring C&C review

a). On receipt of any communication to the R&I department at UHBristol regarding a new proposed research study, the recipient will ensure this is sent to the ResearchApprovals@UHBristol.nhs.uk generic inbox for assessment by the projects officer who will review the HRA assessment letter (if available) to determine whether C&C review is required. If no C&C is required the projects officer will follow the process described in 5.1

b). Once received into the ResearchApprovals inbox and the study is identified as requiring C&C review the projects officer will, as a minimum, request the latest version of the protocol and will contact the applicable local research team to enquire whether they are aware of the proposed research study.

c). On receipt of confirmation from the research team that appropriate feasibility has been conducted in line with the guidance from the HRA: http://www.hra.nhs.uk/resources/hra-approval-guidance-for-sponsorschief-investigators-working-collaboratively-with-nhs-organisations-in-england/ *and* there is a documented joint decision between the local research team and sponsor to proceed with set up, the projects officer will add the study to EDGE completing the required fields as described in the EDGE fields standalone template and will create an electronic folder on the R drive under 'Active Studies' using the template in the folder, saving all correspondence and documentation received to date. The projects officer will then allocate the study to an RMF. Where no local team is identified or the UHBristol personnel sits outside of a dedicated research team (see Appendix A) the projects officer will make enquiries with the applicable clinical team about feasibility of set up before it is allocated to an RMF. As a minimum the clinical team should confirm that they wish to undertake the study and have suitable capacity to do so. The order in which studies are allocated for review from the ResearchApprovals inbox will follow UHBristol research priorities (see Appendix B).

d). Once allocated, the RMF will liaise with the local team/personnel and sponsor/lead site to undertake C&C review by completing the following workflows on EDGE:

(i) R&D – RMF Set Up Workflow

(ii) R&D – Capacity & Capability Review Workflow

These workflows act as standalone templates in the R&I Quality Management System and are maintained by the Information Officer. The workflows consist of a set of numbered questions that the RMF has to work through (like a checklist). Each question has a 'show procedure' button which provides further information on what review is required by the RMF. Comments during the review must be documented in the comments box with the date the comment was made. As each question is completed the RMF must mark it as completed with the date. These workflows can be viewed at any time by UH Bristol personnel allocated to that study record on EDGE. This allows transparency in the capacity and capability review process.

Versions of the workflows will be documented on an 'EDGE workflow log' which will be maintained by the Information Officer in the Quality Management System folder on the J drive. Any requested updates to the workflows will need to be authorised by a member of the R&I senior management team before they are implemented.

e) Support Department Authorisations

Where any support department involvement is required authorisation will need to be obtained in accordance with the EDGE workflow. Latest versions of the pro-formas used to obtain authorisation and applicable guidance (which are standalone templates) can be found on the R&I website and in the QMS on the J drive. The RMF *must* liaise with the PoC as early as possible to determine what support they require in obtaining the authorisation. For some personnel they may request that the RMF does this on their behalf, for others they may request that they help chase authorisation if a response is not received in a timely manner. The RMF must escalate any issues with authorisation (i.e. no response after 3 weeks) from the support departments to the Team Leader where the delay is affecting ability to meet the 70 day benchmark.

5.2.1 Triggering the NIHR 70 day benchmark metric

The NIHR 70 day metric to promote 'faster easier clinical research' as described here http://www.nihr.ac.uk/policy-and-standards/hra-approvals-and-nihr-metrics.htm will now be triggered from the point that a complete HRA pack is submitted to ResearchApprovals@UHBristol.nhs.uk, the applicable research team and the Clinical Research Network: West of England (for Portfolio studies only). As described in 5.2 c there must be a documented joint decision between the local research team and sponsor to proceed with set up *prior* to the pack being submitted. Only if there is will the submission of the pack as described above trigger the 70 day metric. The complete pack is described on the HRA website: http://www.hra.nhs.uk/resources/nhs-site-set-up-in-england/

However, C&C review must be initiated by the RMF at the *earliest stage possible* (i.e. receipt of protocol/any information about the study). The RMF should not wait for submission of the complete pack before starting the C&C review. As the RMF works through the applicable workflows on EDGE for C&C review they will request any missing documents are submitted to ResearchApprovals@UHBristol.nhs.uk , the research team and research network in line with the process described above. Where a complete pack (as described on the HRA website) has not been received at once, receipt of the last document to complete the pack will act as the trigger point for the 70 day metric. The RMF will record this on EDGE in the HRA entity as 'Date Site Selected' in accordance with NIHR guidance.

5.2.2 Confirmation of C&C at UHBristol

a) Once the workflows have been completed by the RMF on EDGE, and depending on whether all reviews are satisfactory (i.e. there is the capacity and capability to deliver the proposed research), the RMF will:

- For non-commercial studies, complete the green and white sections of the 'Statement of Activities' (SoA) as applicable

- Write and send an email confirming C&C using the standalone template 'email to confirm C&C' to sponsor, Point of Contact (PoC) at lead research team, local PI, local PoC and applicable support departments attaching the SoA (for non-commercial studies) and partially or fully executed model non-commercial agreement where applicable.
- Ensure all applicable fields on EDGE have been updated using the standalone template 'EDGE fields' as a guide
- For commercial studies, provide a scanned copy of the fully executed contract along with an email confirming C&C using the standalone template 'email to confirm C&C' to sponsor, local PI, local PoC and applicable support departments. The RMF will also arrange for original wet ink contracts to be returned to sponsor

b) Where there is insufficient capacity or capability to deliver the study at UHBristol the RMF will email the sponsor, PoC at lead research team, local PI (if identified), local PoC and applicable support departments to notify them of the reasons why C&C cannot be confirmed. There is no template for this email as it will be on a study by study basis.

c) Once C&C confirmation has been issued the RMF will keep the study listed as an 'RMF active study' on EDGE in order to chase:

- when the study has been opened by the sponsor (in order to update the details page in EDGE)
- the 70 day benchmark
- any other outstanding documents (i.e. Letter of Access)

d) After the study is opened and the 70 days has passed (regardless of whether a patient has been recruited or not) the RMF will remove it as an 'RMF active study'. The Information Officer will then take over responsibility for data maintenance of that study on EDGE.

### 5.3 Studies sponsored by UHBristol requesting C&C review from participating sites (including UHBristol site)

Full details of the UHBristol sponsorship process can be found in the 002 R&I Sponsorship SOP. The processes described here detail how C&C confirmation will be sought from all sites, including UHBristol site where UHBristol is the sponsor.

#### 5.3.1 UHBristol site

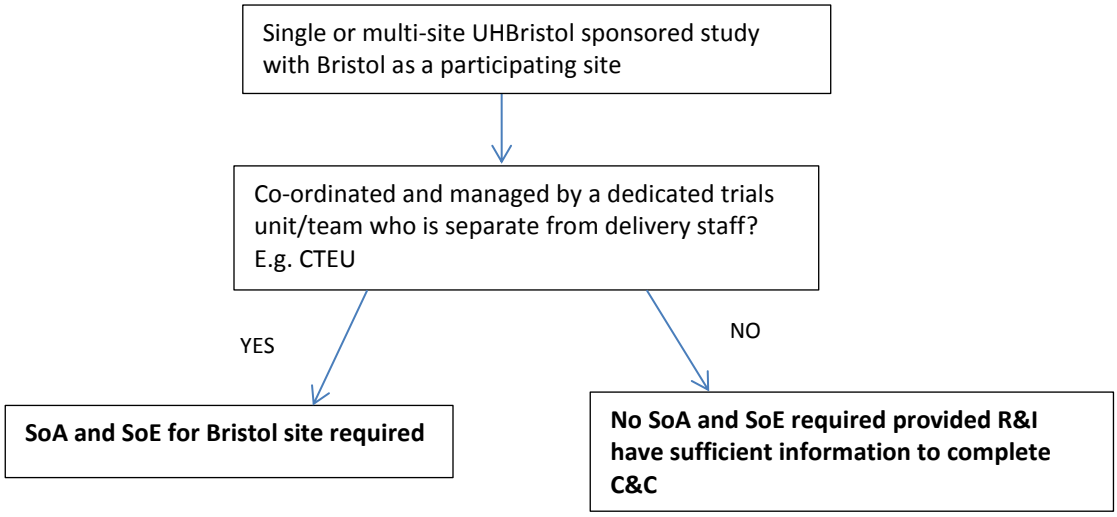
a) The RMF in conjunction with the Research Projects Manager (RPM) as applicable, will complete the following workflows on EDGE for UH Bristol sponsored studies:

(i) R&D – RMF Set up workflow
(ii) R&D – Sponsorship workflow (post HRA)*
(iii) R&D – Capacity and Capability Review

*this workflow is entitled post HRA to indicate its use after the HRA process was implemented. It replaces a previous sponsorship workflow

**The C&C review for UHBristol site can begin at any point during the sponsorship process to enable an efficient review.**

b) The following flow chart will be used to determine whether a Statement of Activities (SoA) and Schedule of Events (SoE) is required for the Bristol site:




c) The allocated RMF will work through the EDGE workflows in the same process as described in 5.2. When all of the applicable workflows have been completed the RMF will issue a sponsor green light email for the Bristol site which will include confirmation of C&C. The following standalone templates will be used:

- 'Greenlight for sponsored CTIMP studies at UHB'
- 'Greenlight for sponsored non CTIMP studies at UHB'

This email will be sent to the CI, main PoC in study team and any other applicable personnel.

5.3.2 Participating sites (excluding UHBristol)

a) In accordance with HRA guidance it is encouraged that, before the IRAS form is finalised, any initial discussions with potential participating sites take place in order to determine whether they have the potential capacity and capability to participate. As sponsor, this discussion with participating sites is delegated to the Chief Investigator (CI). This will be communicated by the RMF or RPM (as applicable) to the CI as early as possible in the sponsorship process. It is expected at a minimum that the CI or a delegated member of their team will provide the sites with the final version of the protocol in order for sites to conduct proper feasibility.

b) Once sites have been confirmed, these sites can be added to part C of the IRAS form by the CI.

c) The HRA process then dictates that an SoA and SoE should be completed for **each type of research site:** http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/statement-activities-hra-approval/ The allocated RMF will assist the CI by reviewing the completed SoA and SoE for each site type prior to submission for HRA approval. d) It will be formally documented in the sponsorship letter that the task of obtaining C&C confirmation from participating sites is delegated to the CI. The CI may delegate this to a member of their team and this delegation must be fully documented.

e) The RMF will advise whether the SoA can be used in place of a site agreement. Generally, this is accepted for non CTIMPs but exceptions do apply. Where the RMF is unsure they will raise it at the weekly operations meeting for a senior manager to confirm

f) The CI or delegated team member will arrange capacity and capability review by submitting the pack to the site in line with HRA guidance. Further information about how to work with participating sites to gain C&C confirmation can be found on the HRA website: http://www.hra.nhs.uk/resources/hra-approval-guidance-for-sponsorschief-investigators-working-collaboratively-with-nhs-organisations-in-england/#sthash.qWN82MjA.dpuf

g) When the participating sites have provided confirmation of C&C the RMF will liaise with the CI and main PoC at Bristol to confirm the process for providing green light to recruit to sites. For CTIMPs this will always be the responsibility of the RMF or RPM. A copy of the confirmation of C&C and a completed SIV checklist must be submitted by the main PoC at Bristol to the RMF/RPM before green light can be issued. Where a UH Bristol support department is involved in external site delivery (e.g. pharmacy supply of IMP) a copy of the green light for each site will be sent to the relevant PoC in the support department. For non-CTIMPs, depending on the complexity of the study, the process of issuing green light may be delegated to the CI. For very low-risk non-CTIMP studies green light at other sites may not be required. Where the RMF is unsure they will raise it at the weekly operations meeting for the Team Leader or a senior manager to confirm.

## 6. Dissemination and training in the SOP

### a. Dissemination of this SOP

i. **New SOPs and new versions of existing SOPs:** The Research Operations Manager will be responsible for ensuring authorised SOPs are uploaded to the DMS in line with Trust policy and on the R&I website as described in the SOP "Authorship, review, revision and approval of research procedural documents produced by Research & Innovation". Internal Trust Staff are expected use the DMS to access latest versions of SOPs and to check the website regularly for updates, as communicated in the Training SOP.

Notice of new or amended procedural documents that have undergone a major amendment will be given via the following routes:

- Inclusion in the R&I e-bulletin (monthly);
- Direct email to Research Leads, Research Unit Managers and Band 7 staff for onward cascade
- Direct email to Chief Investigators of CTIMPs sponsored by UHBristol;
- Direct email to the Head of Research Governance at the University of Bristol (as relevant).

### b. Training in this SOP

i. All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

ii. The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of the SOP and its amendments.

## 7. Appendices – Appendix A UHBristol research teams/units
## Appendix B UHBristol research priorities

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**RELATED DOCUMENTS** 002 R&I Sponsorship SOP

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|---|---|
| **AUTHORISING BODY** | Trust Research Group |
| **SAFETY** | N/A |
| **QUERIES** | Contact Jess Bisset, Research Operations Manager 0117 342 0233 or email research@uhbristol.nhs.uk |

## Appendix A – Research teams at UH Bristol

| D&T | Medicine | Surgery Head & Neck | Specialised Services – Cardiac | Specialised Services – Oncology | Women & Children |
|---|---|---|---|---|---|
| Pharmacy Trials Unit - lead Sandra Williams | Medical Research Team– lead Kate Green | Surgical Research Team – lead Rebecca Houlihan<br>ITU Research Team– lead Katie Sweet<br>Clinical Research Unit (Eye Hospital) – lead Eleanor Hiscott | Clinical Trials Evaluation Unit – lead Manuela Antognozzi<br>Cardiology Team – lead Ruth Bowles | Bristol Haematology and Oncology Centre Clinical Trials Unit – lead Heather Carroll | Women & Children's Research Unit – lead Natalie Fineman |

Appendix B

## Research Priorities at UH Bristol

Our ambition of delivering world class research when combined with the increasing financial pressures on research delivery across the Health Care System continues to drive the need to explicitly identify which areas and types of research will be prioritised for resources at UHBristol. Resource for this purpose can be defined as time, access and money.
The following funders receive the highest priority grading:

1. NIHR and partner grants awarded through the Trust
2. NIHR and partner funded trials that are eligible for the NIHR portfolio
3. Above and Beyond, NIHR Research Capability Funding, and David Telling pump-priming awards and NIHR Biomedical Research Units/Centre (BRU/C) funded projects
4. Fully funded commercially sponsored trials

Of note, within our BRU/C funded projects this may also include commercial grant activity.

Where possible, other types of research activity will also be supported by the R&I research management team, however, this will only be possible once the needs and priorities identified above have been met. Examples include:

- student research projects
- commercial or non-commercial studies and/or grant activity that is not eligible for the NIHR portfolio