Document Title: Trust Confirmation of Capacity and Capability and Sponsor Green Light Notification to Conduct Research Studies

Document Number: R&D SOP034

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Summary Amendments

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| Version Number: | Modification: |
| 1.d, 4, 4.2, 4.3, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6, 4.3.7, 4.4.4, 6 | Updates and further clarifications of the process for gaining Trust Confirmation |
| Appendix 1 | Removed and replaced with reference to GD018 |
| Version 10.0 | SOP updated throughout |
| Version 11 | Sponsor Green Light Process added & requirement for CTIMP/Device trial staff to be SOP compliant. |

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| Key related documents: | Trust Research Policy  SOP037 Amendments to Research Studies  SOP035 Using the Research Governance Database  SOP048 Applying for Papworth Sponsorship  SOP009 Set-up & Project Management of Research Studies  SOP003 Informed Consent for Research Studies  SOP013 TMF Creation & Maintenance  SOP015 Site Recruitment & Initiation  SOP024 Contract Negotiation & Review  SOP025 Assessment & Registration of Trust Risk Rating for Research Studies  FRM098 RPH Sponsor Green Light Checklist  FRM013 Risk Assessment Tool  FRM024 Risk Assessment Form of RPH Sponsored CTIMP  TPL037 Sponsor Green Light |

Key Points of this Document

* This document sets out the procedures to be followed by all Staff members who are involved in the initiation, set-up and running of research.
* It provides guidance on how to gain Trust Confirmation of Capacity and Capability and receive notification of Sponsor Green Light (where applicable) to conduct research studies within Royal Papworth Hospital NHS Foundation Trust and is applicable to all research studies, whether sponsored by Royal Papworth Hospital or externally.
* Research studies must not start without Health Research Authority (HRA) approval, formal email confirmation of the Trust’s Confirmation of Capacity and Capability to perform the research, **and** receipt of Sponsor site activation (Sponsor Green Light).

# Purpose and Content

* + - * 1. This document defines the Trust’s research procedures for investigators requiring Trust Confirmation of Capacity and Capability (TCCC) to conduct research studies **for local delivery** at Royal Papworth Hospital.

1. The document clarifies the requirements for obtaining TCCC in accordance with the national regulations and as described in Good Clinical Practice (GCP: ‘a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected’).
   * + - 1. The document provides guidance on the Trust’s processes for verifying that all aspects of a study comply with national legislation and guidance so that Trust Capacity and Capability can be confirmed.
         2. The Trust is required to meet various national performance targets for research studies. This document defines the relevant metrics for measurement of performance applicable to this process (see NIHR reports and performance page for more details: https://www.nihr.ac.uk/about-us/who-we-are/reports-and-performance).
         3. It is not within the scope of this document to cover the process and requirements for issuing/gaining Sponsor Green Light or for gaining regulatory approvals. Details on the requirements for gaining regulatory approvals are available from the relevant regulatory authorities and the Health Research Authority (HRA) (see [HRA Approval - Health Research Authority](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/)). Details on gaining notification of Sponsor Green Light are available on FRM098 RPH Sponsor Green Light Check List document.

# Roles, Responsibilities & Definitions

* + - * 1. This Policy applies to all personnel that are conducting research at the Trust, irrespective of study Sponsor.
        2. The **Research Governance Project Approval System (RGPAS)** is the process used for formally assessing local impact of a study, before TCCC can be issued. Where appropriate, the RGPAS Committee will provide local approval for setup processes to begin. The **RGPAS Committee** will alsoreview applications for RPH Sponsorship. Terms of Reference for RGPAS are available from the R&D Governance Team upon request.
        3. Following a study’s review at RGPAS, the decision to issue TCCC is undertaken by the R&D Governance Team on behalf of the Trust upon review of all information provided and fulfilment of all RGPAS actions.
        4. Chief and Principal Investigators are responsible for ensuring that a study has the relevant approvals and authorisations in place, including regulatory approvals, TCCC, and Sponsor Green Light, before undertaking any research activities.
        5. The Sponsor (whether Royal Papworth Hospital or external) or their delegated representative is responsible for the submission of all required information to the R&D Governance Team both during the TCCC process and following any amendments to the study (for amendments, see SOP037). It is the Sponsor’s (or their delegate’s) responsibility to maintain a version control document to ensure only those documents approved by HRA and included in site TCCC are used by those sites.
        6. Filing of the TCCC email, as well as any subsequent amendments, and the fully executed Site Agreement, as well as any subsequent amendments to contract, within the Trial Master File (paper TMF or electronic TMF (eTMF)), is the responsibility of the Research Governance Team.
        7. The Trust’s Research Governance Database (EDGE) will be kept up to date in accordance with SOP035 (‘Using the Research Governance Database’), with the support of the R&D Governance Team. The PI or delegate must keep their Project Site data (red level) entry up to date and accurate, ensure the minimum dataset is complete, maintain recruitment records and, if applicable, upload all relevant invoices. For responsibility of the Project-level data (green level), see SOP035.

# Policy

* + - * 1. This SOP is mandatory and, as per the Trust’s Information Governance and Records Management framework, non-compliance with may result in disciplinary procedures.

# Process for issuing TCCC

## Initiation of the TCCC review process

* + - * 1. Study teams should contact the R&D Governance Team ([papworth.randdenquiries@nhs.net](mailto:papworth.randdenquiries@nhs.net)) as early as possible (i.e., prior to Site selection), in order to identify and address any potential issues prior to Site set-up and application for TCCC.
        2. For studies that require Sponsorship or co-Sponsorship by Royal Papworth Hospital SOP048 ‘Royal Papworth Sponsorship of Research Studies’ should also be followed.
        3. This SOP should be read in conjunction with *SOP009 ‘Project Management of Research Studies’, SOP003 Informed consent for research studies, SOP013 Trial master file creation and maintenance* and *SOP015 Site Recruitment and Initiation* (particularly section 4.2). The PIs / study team will find these SOPS helpful in understanding what documentation is required to achieve TCCC in conjunction with the R&D Governance Team.
        4. A study should be submitted for RGPAS review once the study’s feasibility has been assessed by the R&D Governance Team (in conjunction with the relevant Team Leader and supporting departments, where applicable). The study is registered and given a P0 number, PIC number, or CRF number (in the case of studies involving the Clinical Research Facility in the Heart and Lung Research Institute), and then loaded onto EDGE.
        5. The feasibility review for RGPAS includes, but is not limited to:
  1. Confidentiality Disclosure Agreements (CDAs) and / Expression of Interest forms (EOIs) completed and returned to the Sponsor/CRO (where applicable).
  2. Confirmation HRA approval is in place.

### Identification of a suitable PI, if one is not already in place. Suitability of an Investigator is assessed and confirmed through review of capacity and submission of an up-to-date CV (signed and dated within 3 years), GCP certificate (within 3 years) and full compliance with assigned SOPs. In instances where further assurance is needed i.e. the researcher is inexperienced, the Clinical Director of the relevant area may be contacted to review and authorise.

### Review of draft budget and draft Site Agreement (contract) (where applicable).

### Requirement for agreements outside of the Site Agreement e.g. sub-contracting (where applicable).

### R&D team capacity (where applicable).

### Capacity of relevant clinical services and support departments impacted by the study, including local labs and the Clinical Research Facility (CRF). For studies being led or involving the CRF, please contact [papworth.hlri.crf1@nhs.net](mailto:papworth.hlri.crf1@nhs.net) as there will be additional CRF specific processes to be followed.

### Availability of required equipment.

### Assessment of patient cohort.

### Assessment of site’s ability to recruit to time and target.

* 1. Risk Assessment (FRM013/FRM024).
  2. The need, if any, for a local IRMER (MPE/CRE review) to be conducted.
  3. Pharmacy’s review of relevant documents (CTIMPs) and storage capacity.
     + - 1. RGPAS review:  
            The PI or delegated member of the Research Team will attend the RGPAS committee meeting in accordance with the RGPAS Terms of Reference, and the following items will be discussed:
  4. Confirm the overall project feasibility and recruitment target
  5. Review the risk assessment, and agree on risks and mitigations;
  6. Identify any issues or obstacles that would prevent the study from proceeding at the Trust and agree any corrective actions;
  7. Agree required local checks, including, but not limited to, Directorate Authorisations, Pharmacy, local IRMER, Pathology registration, Information Governance requirements such as National Opt Out scheme (MESH) checks etc. All Clinical Directorates impacted by the proposed research are required to assess the impact of the proposed research on their area and give authorisation for the research to take place. Directorate Authorisations are given on the basis of the information supplied by R&D. This information must clearly detail all relevant research activities imposed on the departments within the directorate.
  8. Review the monitoring plan and assign Trust monitoring if deemed required.
  9. Financial viability of the study and the need, if any, to apportion costs to other services.
     + - 1. Outcomes of RGPAS committee meeting will be minuted and the RGPAS committee will recommend either:

Proceeding to study set-up, in principle, pending full Capacity and Capability review and satisfactory completion of required conditions, authorisations, and governance checks, or

Will not proceed to study set-up at this time. In this case, feedback and advice is provided to the research team to clarify the concerns for them to resubmit once all issues have been addressed, where applicable. Where the study returns for review, documented evidence of these issues having been addressed must be submitted.

* + - * 1. Following RGPAS, the Local Information Pack (LIP) will be requested to be submitted to the R&D Governance Team, via the R&D Enquires inbox ([papworth.randdenquiries@nhs.net](mailto:papworth.randdenquiries@nhs.net)).
        2. The LIP should not be received before the RGPAS decision confirming approval to proceed to study set up. If the LIP is received before then, the Sponsor will be informed that the LIP cannot be formally accepted until RGPAS approval to proceed to set up.
        3. The receipt of the LIP by the R&D Governance Team will start the clock for the government metric on initiating research: <https://www.nihr.ac.uk/documents/performance-in-initiating-and-delivering-guidelines/19932>

## Requirements for all studies for issuing TCCC

* + - * 1. The R&D Governance Team will support the Research Delivery Team to identify and fulfil the necessary local checks required for issuing TCCC for the study. The requirements will vary depending on the study, but all studies will require as a minimum:

Confirmation of HRA approval (This will include a list of all approved documents and confirmation all other relevant regulatory approvals i.e. REC, MHRA are in place).

Full suite of documents (Local Information Pack) as listed in the HRA approval letter and version control document as well as any amendments submitted prior to TCCC.

Acceptance by the R&D Governance team of the Trusts approval to take part in the study (RGPAS approval).

Actions from RGPAS are completed.

Budgets are agreed.

Contracts are signed as per SOP024 Contract Negotiation and Reviews, including contractual agreements for use of external services to facilitate the study.

All required Directorate Authorisations, (IRMER) CRE / MPE and Pharmacy reviews are approved.

Honorary Contracts / Letters of Access, plus other local governance requirements, are completed where applicable.

Risk assessment agreed and completed (See SOP025: Assessment and Registration of Trust Risk Rating for Research Studies).

Receipt of up-to-date CV and GCP certificates of PI and/or CI (if local) and any sub-investigators.

Confirmation of registration of the study on the Trust Asset Register (see DN613: Information Security - Information Asset Security and Control Procedure).

Completed EDGE workflow checklists.

Patient Pathways and key requirements for study (i.e., booking of scans, prescribing of drugs, registration of local blood tests with Pathology, etc.) have been organised with Clinical Teams/Services.

Confirmation of PI and/or CI (if local) SOP compliance as recorded in IQM.

Receipt of Pharmacy Risk Assessment (CTIMPs).

Scientific Advisory Board (SAB) submissions have been achieved and approved for studies involving the Clinical Research Facility (CRF) at the Heart and Lung Research Institute / any other CRF.

## Issuing of TCCC

* + - * 1. Once all the above requirements for TCCC have been completed, the Site Agreement has been fully executed, and the EDGE workflow checklist completed, the Principal Investigator is notified by the R&D Governance Team, on behalf of the Clinical Director of R&D, of TCCC by email. This email will be copied to the Sponsor’s representative, the Clinical Director of R&D, the Senior and Operational Managers of R&D, the relevant local Clinical Delivery Team Leader and Study Team, and, where appropriate, Pharmacy (CTIMPs) and any other relevant support departments.
        2. For all studies, the TCCC email will include a sentence informing the PI and Study Team of their obligation to ensure continuing compliance with all relevant SOPs. TCCC will not be issued until confirmation of completion of SOPs by all Study Team members has been confirmed.
        3. The Sponsor Team will confirm that the Site may be activated by replying to TCCC with Notification of Sponsor Green Light, alongside any Site File instructions that may be applicable at that time.
        4. Where Royal Papworth Hospital NHS FT is the study sponsor the notification of Sponsor Green Light will be received once FRM098 RPH Sponsor Green Light Check List is complete. Notification of sponsor green light shall be communicated via email and where appropriate, template TPL037 Sponsor Green Light may be used.

# Participant Identification Centres (PICs)

* + - * 1. If a request has come for Royal Papworth Hospital to act as a PIC site, the following approvals process will occur:
        2. PIC studies will be presented to an RGPAS committee meeting to outline any impact upon the relevant Direct Care Team or Research Delivery Team and outline any funding arrangements.
        3. Documents required for review:

HRA approval letter

All HRA/REC approved documentation relevant to PIC sites

* + - * 1. TCCC will be issued on completion of the following factors:

Clinical and directorate agreement to support the PIC activity

Agreement the funding and/or recruitment mapping is appropriate

Full execution of the appropriate PIC Agreement.

* + - * 1. Once the above is completed and RGPAS has agreed to proceed to setup stage, then TCCC will be granted.

# Non HRA Projects (e.g., Service Evaluation/Improvement or Audit)

* + - * 1. All applications for a project to be deemed a Service Evaluation/Improvement, Audit, or other project not requiring HRA approval should be submitted to the R&D Governance Team for review, along with the documents listed below. For information on what constitutes Research in the NHS as opposed to Service Evaluation/Improvement, Audit, or Health Surveillance, see the HRA ‘Defining Research’ table here <https://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2022.pdf>, or contact the R&D Governance Team.
        2. Documentation required for review:

Brief Protocol of project. A template can be found on the R&D website. The Protocol should be clear on the purpose of the work and how the results are planned to be used.

Completed HRA ‘Is my Project Research?’ Tool. This Tool can be found here: <https://www.hra-decisiontools.org.uk/research/redirect.html> .

Completed REC ‘Do I need NHS REC review?’ Tool. This Tool can be found here: [Do I need NHS Ethics approval? (hra-decisiontools.org.uk)](https://www.hra-decisiontools.org.uk/ethics/).

* + - * 1. Service evaluations will be circulated for review within the R&D Governance/Senior Management.
        2. A Non-HRA Confirmation letter will be issued by the R&D Governance Team confirming that the proposal is deemed ‘not Research in the NHS’. Applicants will be directed to the Trust’s Clinical Audit Dept who will advise the applicant on next steps. Where a decision is split, the proposal will be discussed at the next RGPAS committee meeting until a final decision is made.

# Refusal or withdrawal of TCCC

* + - * 1. The Trust is not obligated to issue TCCC for studies, even if HRA approval has been given e.g. if the risk to the Trust is unacceptable, or compromises recruitment to ongoing studies.
        2. TCCC is issued on the basis of the information provided to R&D at time of confirmation. Royal Papworth Hospital NHS Foundation Trust reserves the right to withdraw TCCC should they be made aware of issues which may negatively affect study patients; the trust; the study itself or staff.
        3. If TCCC is suspended, the study will be suspended, a full investigation will be undertaken and then a decision made to stop the study or continue. Investigators may only proceed once confirmation in writing from R&D has been received.
        4. If TCCC is withdrawn, appropriate plans must be documented and agreed with the appropriate regulatory authorities to ensure the safety of the patients.

# Risk Management / Liability / Monitoring & Audit

* + - * 1. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.
        2. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust’s auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).
        3. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.
        4. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Studies for guidance on the governance process in detail along with a supporting process map.





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| Approved by:  Managment/Clinical Directorate Group | | | Research and Development Directorate | | | | | |
| Approval date:  (this version) | | | [Current active version approved date] | | | | | |
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| This document supports:  Standards and legislation | | | Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments.  UK Policy Framework for Health and Social Care Research (2023) | | | | | |
| Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach. | | | | | | | | |
| Groups | Disability | Race | | Gender | Age | Sexual orientation | Religious & belief | Other |
| Yes/No | NO | NO | | NO | NO | NO | NO | NO |
| Positive/Negative |  |  | |  |  |  |  |  |
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