Document Title: Research Studies: Trust Confirmation of Capacity and Capability to Conduct Research Studies

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Summary Amendments

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

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 to conduct research studies within Royal Papworth Hospital NHS Foundation Trust.

- Research studies must not start without **both** Health Research Authority (HRA) approval **and** formal email confirmation of the Trust's Capacity and Capability to perform the research.

1 Purpose and Content

a. This document defines the Trust's research SOP for investigators requiring Trust Confirmation of Capacity and Capability (TCCC) to conduct research studies at Royal Papworth Hospital.

b. 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').

c. 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.

d. 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. The following link also provides further information https://www.nihr.ac.uk/about-us/our-contribution-to-research/research-performance/clinical-research-network-performance.htm (read section 12).

e. It is not within the scope of this document to cover the process and requirements for gaining regulatory approvals which should be available from those regulatory authorities and the Health Research Authority (HRA).

2 Roles, Responsibilities & Definitions

a. This Policy applies to all personnel that are conducting research at the Trust.

b. The **Research Governance Project Approval System (RGPAS)** is the process for issuing TCCC for all studies to commence within the Trust. The **RGPAS committee** review applications for sponsorship and proposals to host research studies at Royal Papworth. Terms of reference for the meeting are available from R&D on request.

c. The decision to issue TCCC is undertaken on behalf of the Trust by the Clinical Director of R&D or their designee on review of all information provided.

d. Local Chief and Principal Investigators are responsible for ensuring that a study has the relevant approvals in place before it can be performed at Royal Papworth Hospital.

e. The Sponsor or their delegated representative is responsible for the submission of all required information to the Research Governance Team both during the TCCC process and following any amendments to the study (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.

f. Governance Team: Filing of all the TCCC-related correspondence and documentation within the Trial Master File (paper TMF or electronic TMF (eTMF)), is the responsibility of the research Governance Team.

g. The Trust's research project database (EDGE) will be kept up to date with the support of the Governance team. Research teams must keep their project entry up to date and accurate, and ensure the minimum dataset is complete (SOP035).

3 Policy

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

4 Process for issuing TCCC

4.1 Initiation of the TCCC review process

a. Study teams should contact R&D as early on in the process as possible i.e. prior to site selection or at study design, in order to identify and address any potential issues prior to site set-up and application for TCCC.

b. For studies that require sponsorship or co-sponsorship by Royal Papworth Hospital SOP048 Royal Papworth Sponsorship of Research Studies' should also be followed.

c. This SOP should be read in conjunction with *SOP009 Project Management of Research Studies* and *SOP015 Site Recruitment and Initiation* (particularly section 4.2) for Royal Papworth Trials Unit Collaboration, Royal Papworth Hospital NHS Foundation Trust sponsored or hosted studies. The PIs / study team will find these two SOPS helpful in understanding what documentation is required to achieve TCCC in conjunction with the Research Governance team.

d. A study should be submitted for RGPAS review once the study's feasibility has been assessed by the Governance team and Team Leader. The study is registered and given a P0 number, loaded onto EDGE.

e. **This review includes, but is not limited to:**

1. Review of draft budget and draft contract
2. Confidentiality Disclosure Agreements and / Expression of Interest forms) completed and returned to the Sponsor / CRO
3. Confirmation HRA approval is in place

4. Requirement for a material transfer agreement (if not included in the study contract)
5. Review of study agreements - Identifying a PI, if one is not already in place
6. PI capacity and suitability. Suitability of an Investigator is assessed and confirmed through submission of an up to date CV (signed and dated within 3 years). 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.
7. R&D team capacity,
8. clinic capacity
9. availability of required equipment.
10. Assessment of patient cohort
11. likeliness to recruit is completed

f. **RGPAS review**:

The PI or delegated member of the Research Team will attend the RGPAS committee meeting and the following items will be discussed.

1. Confirm the overall project feasibility;
2. Agree the risk assessment;
3. Identify any issues or obstacles that would prevent the study from proceeding at the Trust and agree any corrective actions;
4. Confirm which local checks are required to confirm Trust Capacity and Capability, including Directorate Authorisations, Pharmacy, MPE and CRE review, Pathology registration, 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.

5. Review the monitoring plan and assign Trust monitoring if deemed required.

6. Outcomes of RGPAS committee meeting review of TCCC will be minuted and the RGPAS committee will recommend either:

    1. Trust Confirmation agreed, in principle, pending full Capacity and Capability review and satisfactory completion of required conditions, authorisations, and governance checks, or

    2. Trust Confirmation cannot be agreed 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.

g. Following RGPAS, the Local information Pack and HRA approval / initial assessment letter will be requested to be submitted to the Research Governance team, via the R&D Enquires inbox (papworth.randdenquiries@nhs.net).

h. The Local Information Pack should not be received before the RGPAS meeting in which it is agreed to proceed with the study. If the pack is received before then, it will be rejected.

i. The receipt of the Local Information Pack by the Research 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.

4.2 Requirements for all studies for issuing TCCC

a. The Research Governance Team will support the Research 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:

1. 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)

2. Full suite of documents (Local Information Pack) as listed in the HRA approval letter and version control document

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

4. Actions from RGPAS are completed

5. Budgets are agreed

6. Contracts are signed as per SOP024 Contract Negotiation and Reviews

7. All required Directorate Authorisations, CRE / MPE and Pharmacy reviews approved

8. Honorary Contracts / Letters of Access, plus other local governance requirements, are completed where applicable.
9. Risk assessment agreed and completed (See SOP025: Assessment and Registration of Trust Risk Rating for Research Studies)

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

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

12. Completed EDGE workflow checklists

13. 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;

4.3 R&D Governance Team 'Amber Light' Checklist

a. Once budgets and contracts are agreed in principle and Directorate Authorisations are obtained, the R&D Governance Team will issue 'Amber Light' approval. This means that R&D is nearing completion of the TCCC process and authorises the Site Initiation Visit (SIV) to be conducted. For the SIV to take place, the following actions should be complete:

1. The actions prior to RGPAS committee presentation have been completed.
2. RGPAS approval to study set-up has been received
3. Actions outlined as part of the RGPAS committee discussion have been completed
4. DAs responses have been received
5. Risk assessment is completed
6. Pathology registration is completed
7. Draft budgets and draft contracts are in an amicable state and nearing completion
8. Research Team has started its operational review including confirmation the patient pathway is still in place and clinic space has been determined.
9. Research staff training is planned / has been completed.

4.4 Issuing of TCCC

a. 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 Research 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 Chief Investigator, the Clinical Director of R&D and, where appropriate, to Pharmacy (CTIMPs) as well as the relevant Clinical Project Manager (CPM) and study staff.

b. For Royal Papworth sponsored CTIMPs and Device studies (i.e. those studies that would be subject to MHRA inspections) the study registration email notification will include a sentence informing the PI and study team of their obligation to ensure they have read all relevant SOPs. TCCC will not be issued until confirmation of reading SOPs by all study team members has been secured.

c. The sponsor team will confirm that the site may open by replying to TCCC with notification of Sponsor Green Light, alongside any Site File instructions that may be applicable at that time.

5 Participant Identification Centres (PICs)

a. If a request has come for Royal Papworth Hospital to act as a PIC site the following approvals process will occur:

b. Documents required for review:

1. HRA approval letter

2. All HRA/REC approved documentation relevant to PIC sites

c. TCCC will be issued on completion of the following factors:

1. Clinical and directorate agreement to support the PIC activity

2. Agreement the funding and/or recruitment mapping is appropriate

3. Completion of agreement, if applicable.

d. The TCCC decision will be tabled and documented at the next RGPAS.

6 Service Evaluations

a. All applications for a project to be deemed a service evaluation (project not deemed to be research / requiring HRA approval) should be submitted to the Research Governance Team. To help decide whether a project may be eligible, go to: http://www.hra-decisiontools.org.uk/research/index.html or contact the Research Governance Team.

b. Documentation required for review:

1. Brief protocol of project. A template can be found on the R&D website.

c. Service evaluations will be circulated for review within the R&D senior team. A response should be expected within two weeks.

d. A Service Evaluation approval letter will be issued where two CPMs confirm the proposal is deemed a Service Evaluation as opposed to research. Where a decision is split, the proposal will be discussed at the next RGPAS committee meeting until a final decision is made.

7 Refusal or withdrawal of TCCC

a. 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.

b. 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.

c. 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.

d. If TCCC is withdrawn, appropriate plans must be documented and agreed with the appropriate regulatory authorities to ensure the safety of the patients.

8 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. 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).

c. 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.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

See Guidance Document 018 Trust Confirmation of Capacity and Capability to Conduct Research Studies for guidance on the governance process in detail along with a supporting process map.

R&D Papworth Governance Process

R&D Non-Papworth Commercial Governar

Approved by: *Managment/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	[Current active version approved date]
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
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 (2018)
Key related documents:	Trust Research Policy

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							

Review date:	November 2023

I certify the contents of this SOP has been reviewed and ratified

..... 30th November 2020

Signed by Dr Ian Smith, Clinical Director of R&D — Date

SOP release date: 9th December 2020