Document Title: Ethical Approval of Research Studies

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For use by:	NHS Staff Trust-Wide
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Summary of Amendments

Version Number	Modification:
6.0	Additional of information in section 4.6
	Minor administrative changes – SOP does not require re-reading.

Key Points of this Document

- This document sets out the procedures to be followed by all staff who are involved in obtaining Ethical and HRA approval for research studies to be managed by Royal Papworth Trials Unit Collaboration, or sponsored by Royal Papworth Hospital NHS Foundation Trust.
- It aims to provide clear guidance on how to obtain ethical approval so as to ensure compliance with the Trust's policies, the Research Governance Framework and other applicable legislation.

1. Purpose and Content

a. This document defines the procedure for applying for, and gaining approval from, the Health Research Authority and Research Ethics Committee to perform a clinical trial that is either managed by Royal Papworth Trials Unit Collaboration, or sponsored by Royal Papworth Hospital NHS Foundation Trust.

b. The document clarifies the requirements for obtaining ethical approval of research studies so as to conform with 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 how ethical approval for a study and the study related material should be recorded and maintained so as to comply with the Trust's wider policies.

2. Roles & Responsibilities

a. This Policy applies to all personnel who are conducting research at the Trust including: staff who are full or part-time employees of the Trust, those working at the Trust with employment contracts funded partially or wholly by third parties including those within PTUC, CUHP and those seconded to and providing consultancy to the Trust, and to students undertaking training at the Trust.

b. Staff involved in setting up, initiating and performing research studies must comply with the requirements set out in section 4.

c. The Sponsor is responsible for ensuring that the study design meets the required standards, and that the study can be conducted and reported appropriately.

d. The Principal Investigator must ensure that their research studies have all the necessary regulatory approvals in place before commencing at their site.

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. Procedure

4.1 Before Applying for Health Research Authority and Research Ethics Approval

a. Submission to the Research Governance Committee (RGPAS) for sponsorship MUST take place before submission to REC (see section 4.1.2)

b. It is recommended that the Royal Papworth Trials Unit be contacted as early as possible in the process as they will provide guidance on what level of review is required (i.e. not required, proportionate review or full review) and allocate a Clinical Project Manager to support with developing the application.

c. Further guidance on the production of the necessary documentation can be obtained from the Clinical Project Manager. Templates for consent and Participant Information Sheets can also be obtained from the Health Research Authority (HRA) http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/ or from the R&D website https://royalpapworth.nhs.uk/research-and-development/information-researchers/running-study/documents-and-templates-2?sort=description&dir=asc .

d. The Sponsor of a study being submitted to ethics must be clearly identified. The Sponsor takes primary responsibility for ensuring that the design of the study meets the appropriate standards and that suitable arrangements are in place for the conduct and reporting of the study.

e. Royal Papworth can act as sponsor for all types of research studies and clinical trials. All documentation relevant to the ethics application must be reviewed by R&D and submitted to R&D as part of the application for sponsorship (see SOP048: Applying for Royal Papworth Sponsorship).

4.1.1 Scientific Review

a. Ethics committees will expect to receive a protocol that has already undergone a proportionate scientific review. It is the responsibility of the Sponsor of the study to ensure that this review is thorough in assessing the quality of the study being proposed. A copy of any available comments or scientific reports from referees or review committees should be included in the application.

4.1.2 Sponsorship (see SOP048: Applying for Royal Papworth Sponsorship)

a. Details of the Sponsor's representative and necessary R&D contacts to be included in the ethics application form can be obtained from R&D Enquiries.

b. The application will be considered by the Research Governance Committee (RGPAS). The minimum documentation required to obtain Trust Sponsorship includes:

1. A full protocol
2. A Participant Information Sheet (PIS) where appropriate
3. An Informed Consent Form (ICF) where appropriate
4. The completed IRAS Ethics or R&D application form

c. The Research Governance Committee may approve a sponsorship application subject to certain conditions. Evidence must be provided to the committee that these have been considered or actioned prior to sponsor sign off.

4.2 Making an Application for HRA and Ethics Approval

a. The Chief Investigator (CI), or their delegate, makes the application for ethical approval of a study.

b. All applications must be made using the web based IRAS application form at http://www.myresearchproject.org.uk. The Clinical Project Manager will provide guidance on the completion of the application form and the submission process; this can also be found on the IRAS website and the HRA website at: http://www.hra.nhs.uk/research-community/the-review-process/

c. The application form must be signed electronically by the Chief Investigator (CI) and the Sponsor's representative; for Royal Papworth this is the Clinical Director of R&D, or their delegated representative of the Trust. Any subsequent changes to the application form will invalidate the signatures.

d. An applicant must follow the instructions provided in IRAS about submitting an application. Review bodies have specific submission procedures, including contacting

Central Booking Service for REC submission - See details at: http://www.hra.nhs.uk/research-community/applying-for-approvals

4.3 Ethics Committee Review

a. Information on the review process is provided on the HRA website: https://www.hra.nhs.uk/approvals-amendments/

b. It is strongly recommended that the CI attend the REC meeting to answer any queries raised by the committee.

4.4 Response from the Ethics Committee

a. The CI is notified of the REC's decision in writing.

b. If the REC gives the submission a favourable opinion, the research study can be submitted for Trust Approval (see SOP034: Trust Approval and Research Governance).

c. Alternatively, the REC may issue a provisional opinion, which means that certain requirements have to be met before they will approve a study. Satisfactory responses to the queries will be required before a favourable opinion is obtained.

d. If an unfavourable opinion is given applications can be resubmitted as a new application to the same REC, providing the reasons given for the unfavourable opinion have been addressed.

4.5 Proportionate Review

a. Studies which present minimal risk or burden for participants are eligible for proportionate review. The Clinical Project Manager will give guidance on whether proportionate review is appropriate for your study. For further advice see http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-proportionate-review-service/

b. To submit a proportionate review application in England, Once your application is ready to submit, including having all IRAS electronic authorisations in place, call the Central Booking Service (CBS) (CBS operators via: 0207 104 8000 between 9am and 4.30pm on weekdays).

c. Researchers are not required to attend proportionate review sub-committee meetings and the sub-committee will review a valid application within 14 days of receipt.

4.6 Following Ethical Review

a. Copies of all communications with the REC, including covering letters and emails, should be sent to the Clinical Project Manager. Copies of the letters from REC should also be stored in the Trial Master File.

b. It is the responsibility of the CI (or their delegated representative) to ensure that:

1. The REC approval letter has been checked to ensure that the correct versions of documents have been referenced
2. all conditions for ethical approval have been appropriately actioned prior to study green light
3. all PIs working on the study have a copy of the REC response letter and this should be stored in the Investigator/Site file.

c. R&D approval is required for each site before the study can begin and will not be given until a favourable ethics opinion and HRA approval has been received in writing.

5. 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

Approved by: *Management/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

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Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

Review date:	May 2022

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

..... 15th October 2019

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

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