

Document Title: Document Title: Submitting Clinical Research Studies for Review at a Trial Feasibility Committee (TFC)

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This document supports: <i>Standards and legislation</i>	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments.

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	UK policy framework for health and social care research 2017
Date equality analysis completed.	30/11/2017
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Version Control

Version	Date	Author	Status	Comment
1	31/03/2015	Farhan Naim	Final	New Document
1.1	03/10/2017	Lucy Parker	Final	SOP Review Date Time Extension
2.0	29/03/2018	Rachel Fay	Final	Transfer to new SOP template. Inclusion to TFC waiver process, cross-site studies and research taking place at Barnet, Chase Farm and satellite locations within the trust. Update to roles and responsibilities of the R&D office portfolio manager, lead research nurse and TFC Theme director. Incorporating Health Research Authority (HRA) approval processes. Post-trial access to IMP review
2.1	10/09/2019	Neil Hubbard	Final	Change of statement of activity to Organisational document.

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1. INTRODUCTION

The Trust operates a Trial Feasibility Committee (TFC) system to ensure clinical research studies opening at the trust can be delivered safely, to time and to target (the metrics by which the trust's clinical research activity is measured by the National Institute of Health Research, NIHR). The TFCs also operate to ensure that the trust has the resources and sufficient capacity to deliver the study protocol in its entirety. This resource includes the use of NIHR funded research nurse/data manager time, the use of NHS R&D funded research nurse/data manager time, the involvement of NHS service support departments (pharmacy, imaging, pathology, lung function etc.), the use of NHS in-patient bed stays and where applicable the use of research space e.g. within the Institute of Infection and Immunity, and the capability and capacity of the medical staff leading and supporting the research.

Such assessment of feasibility is essential for the trust to ensure NIHR targets on recruitment to time and target are met. For this reason the TFC must be conducted prior to formal 'Confirmation of Capacity and Capability' being given that state RFL are ready to commence and deliver a particular study.

2. OBJECTIVE

The TFC system has been established to ensure there is a streamlined process to conducting feasibility assessment in one sitting bringing together investigators, service support departments and R&D personnel on a monthly basis.

3. DEFINITIONS

CI - Chief Investigator (CI) is the authorised health care professional who takes primary responsibility for the conduct of the trial. There is only one Chief Investigator per Member State.

GCP - Good Clinical Practice (GCP) is an international ethical and scientific quality 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.

NIHR – National Institute for Health Research

PI - Principal Investigator (PI) is the person who takes responsibility for the initiation and conduct of the study at site. There is one Principal Investigator at each site participating in a research study. For a single site study the Chief investigator may also take on the role of Principal investigator

RFL - Royal Free London Hospital NHS Foundation Trust

R&D - Research & Development

UCLPHS – UCL Partners Harmonised System

4. SCOPE

The TFC approval may act as 'date site selected' for all studies, including studies being processed by the UCLP harmonised system (UCLPHS). This includes, commercial, non-commercial, hosted and RFL sponsored studies. In all cases, TFC approval will be mandatory. The TFC process replaces the CRN 'AAC checks'

(accept, arrange, confirm), which serve a similar function within UCLPHS. For this reason, the CRN's AAC checks are not required at for RFL.

TFC review is distinct from peer review and sponsorship process. Please refer SOP055 Peer Review and SOP 29 Applying for Royal Free sponsorship

5. EQUALITY STATEMENT

The Royal Free London NHS Foundation Trust is committed to creating a positive culture of respect for all individuals, including job applicants, employees, patients, their families and carers as well as community partners. The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability (including HIV status), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. It is also intended to use the Human Rights Act 1998 to treat fairly and value equality of opportunity regardless of socio-economic status, domestic circumstances, employment status, political affiliation or trade union membership, and to promote positive practice and value the diversity of all individuals and communities.

This document forms part of the trust's commitment. You are responsible for ensuring that the trust's policies, procedures and obligation in respect of promoting equality and diversity are adhered to in relation to both staff and service delivery.

The equality analysis for this SOP is attached at Appendix 4.

6. DUTIES

The Trust is committed to the delivery of world class care and expertise to both staff and patients, and our values of positively welcoming, actively respectful, visibly reassuring and clearly communicating are fundamental to the delivery of this. This policy has been developed with our values in mind, and is intended to be implemented within the spirit of these values.

This SOP applies to all personnel that are conducting research at the Trust including: staff that are full or part-time employees of the Trust, those working at the Trust with employment contracts funded partially or wholly by third parties, those working at the trust under honorary contract or under the remit of a valid research passport, those seconded to and providing consultancy to the Trust, and to students undertaking training at the Trust.

A summary of the roles listed in the procedure and the responsibilities of each role holder for the procedures detailed in the SOP006 Roles and responsibilities for the conduct of research studies.

7. DETAILS OF THE PROCEDURE

All research should be discussed with R&D Portfolio Manager, TFC Chair and Lead nurse to assess the impact in concept with exceptions possible. Studies that do impact on RFL resources require a TFC submission and presentation to the TFC committee for review and approval. Studies that have limited impact on resource require a TFC submission and upon review may be granted a 'TFC waiver' by the TFC chair and lead research nurse for the theme – see TFC waivers section (page 11).

When

The TFCs meet on a monthly basis, there is no upper limit for the number of studies reviewed, but in practice it will not normally be possible to review more than 6 studies. Whilst the dates for each committee meeting vary, the timelines for making a submission are shared. A complete submission with the required document set (see below) must be submitted 7-working days prior to the date of the meeting. Late submissions will be deferred to the next available slot at a future meeting but may be allowed at the Chair's discretion. Investigators are encouraged to submit their studies as soon as they become aware of their participation.

In the event that more than 6 studies are submitted for review or if studies are submitted late, the TFC chair can exercise their discretion to allow further studies to be reviewed in consultation with the theme lead nurse. Priority on the TFC agenda will be given to: NIHR portfolio, commercial studies with an imminent site activation date planned or where the clinical needs are pressing i.e. the patients are waiting for enrollment onto an investigational medicinal product (IMP).

The CRN or R&D cannot issue the confirmation of capacity to open Royal Free to the sponsor until a TFC approval or waiver is given in writing.

TFC approval is the date the RFL site is 'selected', as per the HRA and NIHR guidance. Once TFC approval is given Royal Free will endeavor to comply with the NIHR research performance metrics with the aim to confirm capacity within 40-days and recruit the first patient within 70-days of TFC approval/site selection. Should the PI declare that they are not in a position to recruit a patient within 70-days of TFC approval, the Chair may issue a TFC 'Approved in principle,' informing all parties of the intended start date. Sponsors may be asked by the TFC to resubmit the HRA package and/or TFC application when resources become available, including PI and staff availability.

It will not normally be possible to submit studies for TFC review prior to the submission to Health Research Authority and without a final approved IRAS form. However, TFC Chairs will exercise their discretion to review studies not yet submitted to HRA. For example:

Commercial trial where the CI is employed by RFL:

In these instances it may be appropriate to bring the study prior to receiving HRA approval. However, for the trial feasibility review to be accurate the TFC chair may ask for assurance that the protocol and IRAS form have been submitted for TFC be a final revision.

RFL sponsored: It is not the purpose of the TFC to perform peer review of RFL sponsored studies prior to REC/HRA approval or submission to a grant (see SOP055 Peer Review). However, it is advisable that CIs consult the theme lead nurses and support departments prior to submission to HRA to get an informal indication whether it is possible to deliver the proposed study at RFL (single site studies). Please see SOP026 Site Selection and initiation for RF Sponsored studies

Who

Four TFCs have been set up across the trust (Appendix 2), each assessing studies within the trust wide clinical research themes. The grouping of the research themes is based on the national NIHR divisions. The TFCs meet monthly and consist of a core membership as listed below;

- Chair (Appendix 2)- Research Theme Director
- Deputy Chair
- R&D Director/Deputy
- Research Theme Lead Nurse
- Research Theme Portfolio Managers
- R&D office staff
- Representatives of service support departments (pharmacy, imaging, pathology, lung function, medical electronics, cardiology)
- Consultant investigators of relevant specialties

Role of the TFC Chair and Deputy Chair

Should the TFC chair be absent a deputy chair is assigned to each committee or alternatively the R&D Director will cover the role. If TFC Chair is the PI presenting a study to be reviewed by the committee the Deputy Chair or R&D Director will act as chair to avoid a conflict of interest. In these circumstances, this will be documented in the meeting minutes or via email and only the deputy or R&D Director can approve the TFC outcome. The TFC Chair's decision is final (see page 10 for appeals process).

Role of the R&D office Portfolio Manager

The portfolio manager is responsible for coordinating and supporting the TFC meeting, servicing the meeting including taking the minutes and booking rooms, circulating the paperwork, checking that the application is complete and providing guidance to investigators or research teams. The portfolio manager and the research theme lead nurse are not responsible for completing the TFC application form but may contribute to the feasibility review of the study.

How

When notified by the sponsor, investigators or research teams of a forthcoming study, the portfolio managers will contact them to provide guidance on submitting to the next TFC meeting. To make a submission the PI is responsible for sending to R&D the following document set will be required by the TFC meeting deadline:

- Final signed IRAS form (copy from the sponsor)
- Current approved protocol (copy from the sponsor)
- Signed TFC application form, appropriate to the study i.e. ATMP/CTMP TFC form; Non-CTIMP TFC form or TFC waiver form (completed by PI or delegate – not the Portfolio Manager. A template document available on R&D webpage or by emailing portfolio manager/R&D)

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- Signed Delegation of Duties Agreement (DDA - RFLRDDOC0036) completed by PI or delegate – template document available on R&D webpage or by emailing portfolio manager/R&D)
- Signed PIS (this is important for pharmacy to assess the information being provided to patients in respect of post-trial arrangements)
- Where a study is a ATMP using Genetically Modified Organisms (GMO), include a copy of the UCL_UCLH_RFH Clinical GM Risk Assessment Form and outcome, if received (see SOP 064 - Set-up of hosted trials using Investigational Medicinal Products (MPs) which are considered to be Genetically Modified Organisms)

On receipt of these documents the TFC Portfolio Manager will check that they are complete and then will allocate the study to the next available slot at the TFC meeting. Studies will be allocated on a first-come-first-served basis; it is advisable to submit studies for TFC review as soon as the IRAS form and protocol are available. The documents will then be saved on the TFC shared drive for committee members to review and comment on as well as on the EDGE database for the CRN to review.

It is mandatory for the PI, or a suitably informed member of their research team i.e. sub-PI or trial manager to attend the meeting in person, or to arrange to dial into the meeting. This is in part to assure the TFC that the PI and research team have the oversight and time to commit to the PI role.

At the TFC meeting, the investigator will be required to attend or dial in and present the study briefly, any issues which may have been highlighted by the committee members will be raised and a resolution will be sought from the investigator. On occasion, the PI may send an informed delegate to present the study i.e. a sub-investigator who is briefed on the study support requirements and protocol.

The committee will review the following HRA criteria to confirm feasibility:

- a) **Assessing** whether or not the RFL as an NHS organisation has the capacity and capability to participate in the study by:
- Establishing the approval of all departments involved
 - Checking that all research delivery (research nurse, data manager, clinical trial practitioner) and/or staff and resources are available to deliver the study successfully to time and target and in accordance with the protocol, sponsor SOPs and GCP
 - Calculate a feasible participant recruitment target
 - Establishing the suitability of the PI through education and experience and providing additional guidance/support.
 - Reviewing the PI's research portfolio and capacity to maintain oversight, including the current number of open trials
 - Assessing that there is adequate nursing support and data management support to deliver
 - Reviewing the PI previous performance in delivery research to time and target (RTT)
 - Other considerations may be taken into account when reviewing applications to open new studies. These may include but are not limited

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to: known GCP and R&D SOP compliance issues, inadequate sponsor oversight i.e. lack of monitoring regulated trials. These may be brought to the chairs attention by members of the TFC or other parties. Such matter will be dealt with discretion and in accordance with trust policies and values.

- Establishing the post-trial IMP access arrangements for CTIMPs
- Identifying any Excess Treatment Costs

b. Arranging: Establishing what practical arrangements are required to deliver the study. NB this stage may be very brief where the activities at the local organisation are minimal.

- Plan and put in place any required staff training as appropriate in line with HRA guidance and sponsor requirements (NB not necessarily a GCP course)
- Put in place all arrangements to deliver the study across the required patient pathway
- Where applicable outsourced services (e.g. lab tests, scans, etc.) and identify where service level agreements (SLA) are required.
- Incorporate feedback and intelligence from support departments as to the capacity to deliver the protocol at RFL
- TFC form will indicate where arrangements for research passports or letters of access for staff who do not have honorary or substantive contracts with RFL are required

It is not the purpose of the committee to provide scientific, peer or ethical review of studies.

There will be four possible outcomes for a study post TFC review which the Chair will seek consensus from the committee for;

Approved. Study may proceed to obtain Confirmation of Capacity via North Thames CRN (commercial and portfolio adopted studies) or via R&D (non-portfolio studies and single site RFL sponsored studies).

Investigators must not start research activities until they receive the confirmation of capacity email with either a signed organizational document or contract.

TFC approval is not trust approval to start the study

Approved in principle but further information is required by the committee or action needs to be taken before full approval is issued. For example, the study is feasible but the PI or sponsor is not in a position to start the study within 40-days of the TFC meeting. In these instances the study may be 'approved in principle.' The costings and contracting will continue and the portfolio manager will liaise with the sponsor/CRN to discuss a more suitable site selection date. A second example is where the TFC request that the PI closes and archives a study/studies that are open but not performing/recruiting to time and target before opening a new study.

Not approved due to lack of resource, but may be considered by the committee again when resource becomes available and evidence is provided to the R&D and

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TFC. Portfolio managers will provide guidance on applying for funding (commercial and non-commercial grants) and future NIHR adoption.

Declined. Appeals will be considered and should be made via the R&D director and the R&D Escalation process (SOP 61 Escalation).

Occasionally there may be a need to expedite the Confirmation of Capacity for a particular study where the timing of the TFC review adds extra delay. On such occasions the investigator should liaise directly with the relevant Research Theme Director to request approval outside of the meeting, with the exception of CTIMPs, ATMPs and medical device studies. It is not guaranteed that this request will be successful; considerations will be made on a case by case basis and will require input from the applicable service support departments and theme lead research nurse. Such exceptional circumstances will be documented in writing by the Portfolio Manager's (PMs) in lieu of committee minutes.

Trial Feasibility Committee Waivers

PIs of studies with no or limited impact on RFL resources (no material impact on service support departments [Pharmacy, imaging, medical photography, etc.], or contractual requirements will still be asked to complete the TFC form but the sub-committee will review the application off-line via email. This process is known as a 'TFC waiver' and the study is not discussed formally at the TFC meeting but will be documented in the minutes under that month's 'waivers'. Correspondence relating to the TFC review and final decision will be saved by the PM for future records.

TFC Sub-committee will include: TFC Chair, Lead Nurse and the Portfolio Manager (PM) as a minimum. It is the Portfolio Managers responsibility to assess whether a study is appropriate for consideration of a TFC waiver.

Studies which can be considered a review via a TFC waiver process are:

Studies that meet the GAFREC exemption (research that the HRA has deemed not requiring NHS REC approval). Studies include those that are limited to:

- Research involving previously collected, non-identifiable information
- Research involving previously collected, non-identifiable tissue samples
- Research involving acellular material
- Research involving NHS staff i.e. NHS staff interviews and questionnaires
- Healthcare market research
- Research involving the premises or facilities of care organisations

See HRA website for guidance on GAFREC exempt studies

Studies that meet these IRAS categories and that do not have a resource implications may be considered for TFC waiver, at the Chair's discretion:

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- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with data (specific project only)
- Research database/s

Patient Identifying Centres (PIC) studies may have no impact on RFL resources but R&D must be assured that the local collaborator is in agreement and it does not compete for participant recruitment with other planned or current research. PIC waiver request will be sent via e-mail to the Theme Leads with the Lead Research Nurse with the following documents:

- with a copy of the protocol
- IRAS form,
- Along with written evidence i.e. email that the RFL local collaborator has agreed to take on the role.

PIC studies will be sent the TFC PIC waiver questions as per (see RFLWPD0006) and will not be required to complete the TFC form.

The TFC waiver process may also be used to add location *within the RFL trust*. See section 'Adding a new location at the RFL to a non-CTIMP after it has opened' (page 12).

TFC waiver process

1. PI or delegate completes the concise TFC form.
2. The TFC form asks the PI/researcher to confirm if they require any support for running the study, for example to extract anonymous data from RFL computer systems, maintaining the site file (SOP 019 investigator site file) and archiving (SOP 044 Archiving) .
3. Once the TFC form have been return to the portfolio manager and checked for completeness they will be submit the for the TFC subcommittee via e-mail along with the Protocol/IRAS form to the Theme Lead and the Lead Research Nurse for consideration outside of the TFC meeting
5. In such situations, the TFC Chairs will ensure that the Lead Nurses and other relevant research delivery staff are informed and consulted prior to the approval being granted.
6. If the Theme Lead and the Lead Research Nurse are happy for a TFC waiver to be issued and confirm this via e-mail then the portfolio manager will notify the CRN (if commercial or NIHR adopted) and will proceed with the confirmation of capacity process (SOP 051 Confirmation of capacity for non-harmonised studies; SOP052 confirmation of capacity for harmonised studies).

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7. However if the TFC subcommittee determine that the study does indeed need further review and consideration then the portfolio manager will add this to the subsequent TFC meeting as well notifying the PI/researcher of this

8. In instances when the Theme Lead is not available/or on leave and urgent authorisation is needed, then the above requests will be re-directed to the deputy theme leads/or R&D directors

9. Portfolio manager will ensure that all documentation and correspondence regarding TFC waivers are saved on the R&D databases (LPMS) for future reference.

Studies ineligible from TFC waivers:

The following studies where RFL will be a research site (not a PIC) must be presented by the PI or delegate at a TFC and are not eligible for a TFC waiver:

- Clinical trial of an investigational medicinal product
- advanced therapy medicinal product (ATMP)
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Any study that require support from RFL departments or research nursing teams to conduct the study in accordance with the protocol and GCP.

Barnet Hospital, Chase Farm Hospital and the Royal Free Hospital & satellite sites including Cheshunt Community Hospital, Edgware Community Hospital and Finchley Memorial Hospital.

All studies that take place with RFL that meet the criteria for full TFC review should be subcommittee to the committee. All CTIMPs and ATMPs must go to full TFC review regardless of location. Portfolio Manager may arrange for teleconferencing facilities for PIs and delivery staff to dial into the TFC meetings, or the chair may agree to review via email. It may be necessary for the Barnet research delivery team i.e. data manager, nurses to dial into the TFC meeting, or send in writing their comments regarding resources in addition to the TFC submission.

Cross-site feasibility TFC

R&D encourages PIs and sponsors to open their studies across all locations within the RFL 'research site': Barnet Hospital, Chase Farm Hospital and the Royal Free Hospital as well as at our satellite sites including Cheshunt Community Hospital, Edgware Community Hospital and Finchley Memorial Hospital.

In accordance with the UK policy framework for health and social care research there should only be one principal investigator who takes responsibility for the conduct of the research at all locations within the RFL site, as we are one legal entity. Opening a study at multiple locations will be a consideration of the TFC application and

committee review, with consideration given to PI oversight, patient pathway, maintenance of essential documents and data collection.

Adding a new location within RFL to a non-CTIMP after it has opened.

R&D encourages equity of access to research for patients at all of RFL locations. If confirmation of capacity / NHS permission has already been issued, these requests are considered an internal non-substantial amendment. Such requests will be reviewed via the TFC waiver process to ensure the capacity of opening the study safely at the new location at the trust.

What if someone else wants to be PI at the new location within RFL?

There should be one PI at RFL with few exceptions. As a rule, the new location should have a co-investigator who the PI delegates' responsibilities i.e. informed consent. Should the current PI feel that it is not feasible for them to maintain PI oversight at the new location R&D may consider opening at the location with a new PI. However, the current PI must be content with the arrangements. (See PI oversight for cross-site studies page 13). The R&D portfolio manager will follow the TFC waiver process in these circumstances with these additional checks:

- That they have the current PI's approval in writing to open at the new location
- The new PI must sign the Delegation of Duties Agreement (DDA - RFLRDDOC0036). This is to ensure the PI roles and responsibilities for all locations are clarified.
- A concise TFC form for the new location

These documents recorded and present to the TFC subcommittee for review.

Adding a new location within RFL to a CTIMP after it has opened

Should a CTIMP already be open at Barnet, for example, but the sponsor or PI wants to open at Royal Free hospital, R&D need to ensure there is a robust feasibility review and that the support departments, including pharmacy, at the new locations have the capacity to open.

Trials that fall under the categories listed below must be re-submitted to the TFC meeting in these circumstances.

- o Clinical trial of an investigational medicinal product
- o advanced therapy medicinal product (ATMP)
- o Clinical investigation or other study of a medical device
- o Combined trial of an investigational medicinal product and an investigational medical device

Portfolio managers should inform pharmacy and all support departments and treat the trial as setting up a 'new CTIMP.' Once approved by TFC, follow SOP051 (Confirmation of capacity and capability for non-Harmonised Studies) and update the new location on the R&D database.

PI must not open the study at the new location until they receive 'confirmation of capacity email' from R&D. TFC approval is not trust approval to start the study at the new location.

PI oversight for cross-site studies.

There should only be one principal investigator who takes responsibility for the conduct of the research at all locations within the RFL site. However, where a study is open at two or more and it is deemed not feasible for one PI to have oversight of patients' safety, data integrity and GCP compliance at both locations, there may be a PI at both locations with agreement with the R&D office and TFC Chairs.

Delegation of responsibilities to the PI in such 'cross-site studies' at RFL are clarified by both PIs signing Delegation of Duties Agreement (DDA - RFLRDDOC0036) so that the responsibilities for each location are clearly identified and agreed to.

As RFL is one legal entity there will only be one contract with the Sponsor (if one is required).

The Portfolio Manager will update the R&D database with all locations, identifying each PI and cross-site documentation and correspondence. This is to ensure that the PIs and delivery teams at both locations are notified of all R&D communications during the life-cycle of the study, including amendments, close down and archiving.

See SOP 006: Roles and Responsibilities for the Conduct of Research Studies and Clinical Trials including CTIMPs

8. POLICY

This SOP is mandatory and non-compliance with it may result in disciplinary procedures.

9. RISK MANAGEMENT/ LIABILITY/MONITORING & AUDIT

- The SOP Working Group will ensure that this SOP and any future changes to this document are adequately disseminated.
- 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).
- In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the R&D Manager/Deputy R&D Director 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.
- The Research and Development Directorate is responsible for the ratification of this procedure.

10. FORMS/TEMPLATES TO BE USED

TFC Application Form (CTIMP, Non-CTIMP or waiver)

TFC Outcome Form

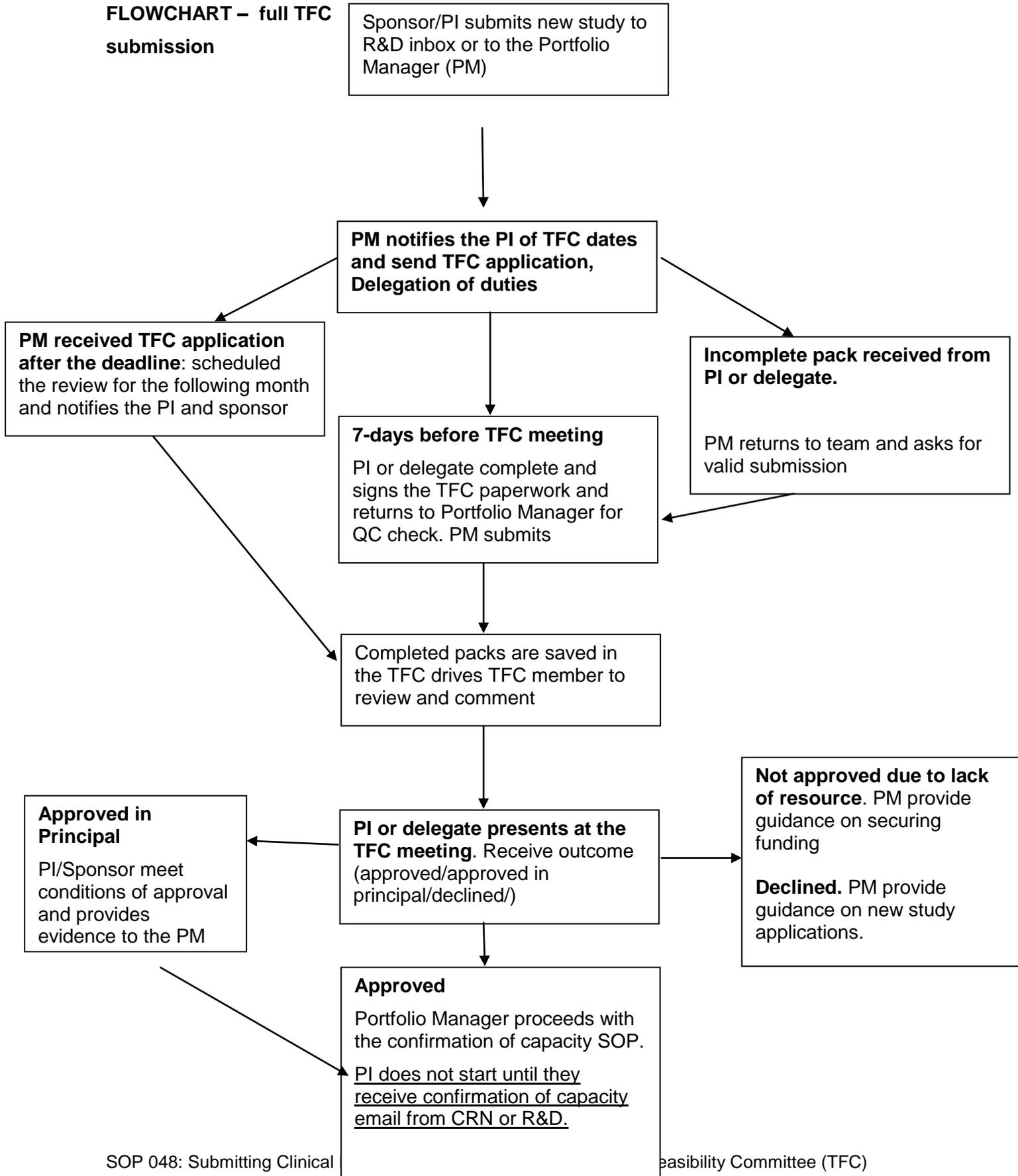
RFLWPD0006 – TFC application process, including template emails & template minutes (R&D office staff only)

DDA - RFLRDDOC0036 – Delegation of Duties

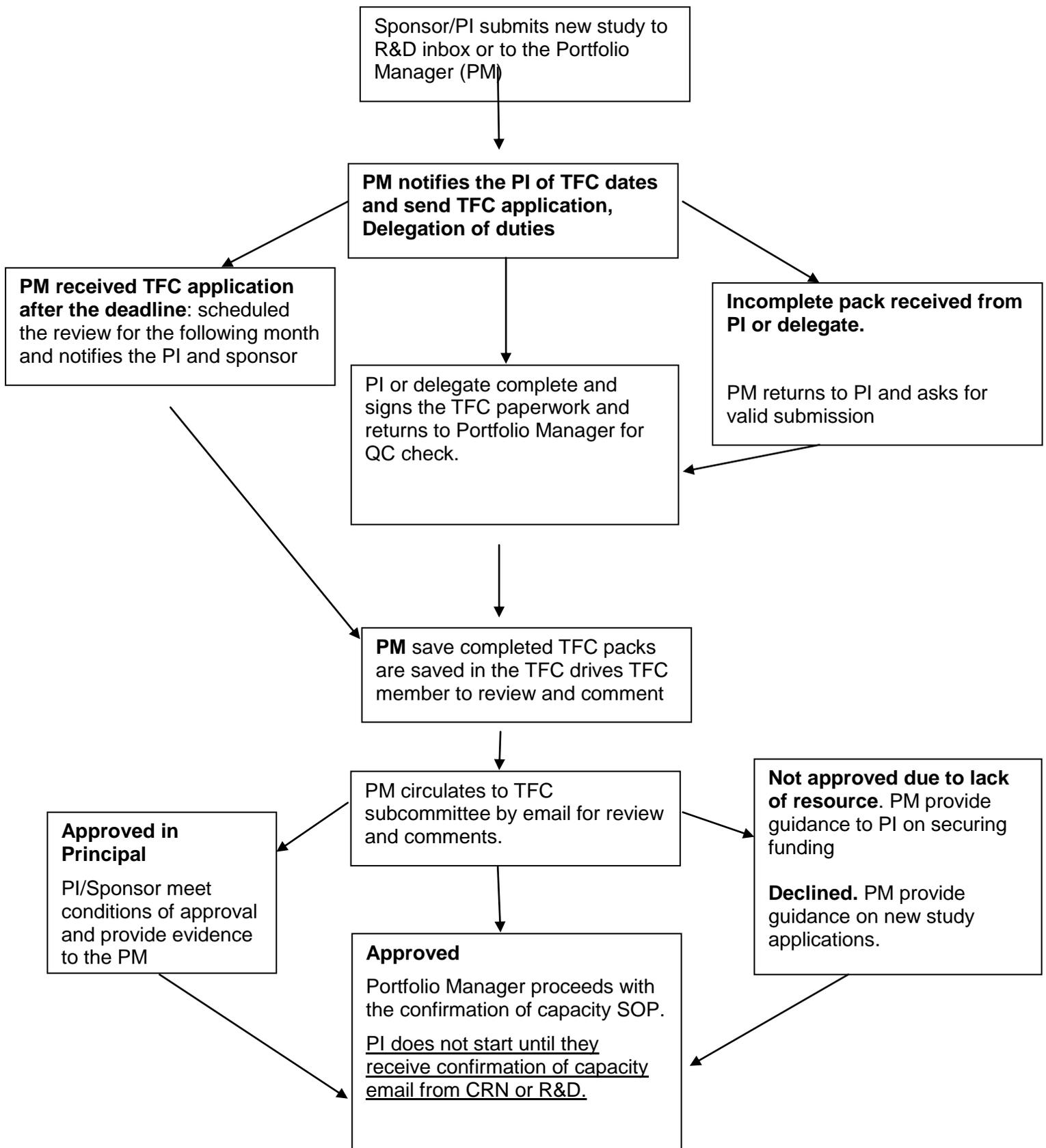
11. FLOWCHARTS

See next page

FLOWCHART – full TFC submission



FLOWCHART – TFC Waiver



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APPENDIX 2

Royal Free London NHS Foundation Trust Equality Analysis guide and Tool

An equality analysis is a review of a policy, practice, function, business case, project or service change which establishes whether there is a negative effect or impact on particular social groups. This In turn enables the organisation to demonstrate it does not discriminate and, where possible, it promotes equality to meet the needs of the diverse patients and communities we serve.

This check list is a way to help you think carefully about the likely impact on equality groups and take action to improve services. This is also an opportunity to evidence positive practices in our services and demonstrate strategic integrity to ensure that our services and employment practices are fair, accessible and appropriate for all patients, visitors and carers, as well as our talented and diverse workforce.

Name of the policy / function / service development being assessed	Applying for NIHR Adoption
Briefly describe its aims and objectives:	This SOP describes the procedures to be followed by all RF staff if a study is potentially eligible for NIHR portfolio adoption
Directorate and Lead:	Rachel Fay, R&D Manager
Evidence sources: DH, legislation. JSNA, audits, patient and staff feedback	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care (2017)
Is the Trust Equality Statement present?	Yes X No if no do not proceed with Equality Analysis (EA)

If you are conducting an EA on a procedural document please identify evidence sources and references, who has been involved in the development of the document, process or strategy, and identify positive or negative impacts. It is the discussion regarding the equality impact of the document that is important.

Equality Analysis Checklist

Go through each protected characteristic below and consider whether the policy, practice, function, business case, project or service change could have any impact on groups from the identified protected characteristic, involve service users where possible and get their opinion, use demographic / census data (available from public health and other sources), surveys (past or maybe carry one out), talk to staff in PALS and Complaints and Patient Experience.

Please ensure any remedial actions are Specific, Measureable, Achievable, Realistic, and Timely (SMART).

Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
Age	None identified	R&D administrative document	N/A	N/A	This SOP on applying for TFC approval introduces a requirement to include the Trust Equality Statement in all SOPs that describe the standard activities used in Research Studies and Clinical Trials at the Royal Free London Hospital NHS Foundation Trust.
Disability	None identified	R&D administrative document	N/A	N/A	
Gender Reassignment	None identified	R&D administrative document	N/A	N/A	
Marriage and Civil Partnership	None identified	R&D administrative document	N/A	N/A	
Pregnancy and maternity	None identified	R&D administrative document	N/A	N/A	
Race	None identified	R&D administrative document	N/A	N/A	

SOP 048: Submitting Clinical Research Studies for Review at a Trial Feasibility Committee (TFC)

V 2.1 10 SEPT 2019

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Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
Religion or Belief	None identified	R&D administrative document	N/A	N/A	It also introduces a new Equality Analysis Template for the SOPs, that requires the presence of the Equality statement. These actions are designed to embed the equality agenda and promote equality compliance within the Trust.
Sex	None identified	R&D administrative document	N/A	N/A	
Sexual Orientation	None identified	R&D administrative document	N/A	N/A	
Carers	None identified	R&D administrative document	N/A	N/A	

It is important to record the names of everyone who has contributed to the policy, practice, function, business case, project or service change.

Equality Analysis completed by: (please include every person who has read or commented and approval committee(s). Add more lines if necessary)	Organisation	Date
SOP Working Group	Royal Free London NHS Foundation Trust	20/10/2017
R&D Committee	Royal Free London NHS Foundation Trust	30/11/2017

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