

Document Title: Assessing costs of RF research studies

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| Department: | Research and Development |
| Name of responsible individual: | Thomas Jenkins, Research Costing and Contracts Manager |
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| Key related documents: | SOP014 Contract Negotiation and Review SOP029 Applying for RFL Sponsorship SOP 048 Submitting Clinical Research Studies for Review at a Trial Feasibility Committee SOP051 Confirmation of capacity and capability for non- Harmonised Studies SOP052 Confirmation of capacity and capability for Harmonised Studies RFLRDDOC0037 First Contact Questionnaire |
| This document supports: <i>Standards and legislation</i> | Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care (2017) |

SOP 049: Assessing Costs of RF Research Studies

V2.1, 10 SEP 2019

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<https://www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/>

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| | Attributing the costs of health and social care Research & Development (AcoRD, DH 2012) |
| Date equality analysis completed. | 22/02/2018 |
| <u>This is a controlled document</u> | |
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Version Control

| Version | Date | Author | Status | Comment |
|---------|-------------|----------------|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.2 | June 2017 | RF | Final | Update SOP template. Include HRA approval process |
| 2 | 30 NOV 2017 | Thomas Jenkins | Final | Updated SOP template. Update to new referenced SOPs Update definition of Sponsor and responsibilities based upon the UK Policy for Health Social Care Research (2017) |
| 2.1 | 10/09/2019 | Neil Hubbard | Final | Change of statement of activity for Organisational document. |
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1. INTRODUCTION

The purpose of this SOP is to ensure a robust system is put into place when costing and setting up studies at Royal Free London NHS Foundation Trust (RF). This SOP is applicable to costing of:

- Studies applying for Royal Free Sponsorship.
- RF led studies applying to secure funding from commercial and non-commercial funders i.e. research charities.
- RF site costs for applications led by other NHS or academic institutions.
- Studies applying for RF NHS Permission in line with SOP051 Confirmation of capacity and capability for non- Harmonised Studies

The SOP is not applicable to studies applying for NHS Permission within the harmonisation processes (i.e. studies on the NIHR portfolio and commercial studies) where a single costing is carried out by the North Thames Clinical Research Network (CRN) harmonisation process in line with SOP052 Confirmation of capacity and capability for Harmonised Studies

This SOP should be read alongside:

- The RF SOP on Sponsorship (SOP029) which identifies studies eligible for RF sponsorship.
- Attributing the costs of health and social care Research & Development (AcoRD, DH 2012) for guidance on attribution of research costs.

2. OBJECTIVE

This SOP describes a process to ensure costs associated with the delivery of RF research are appropriately assessed within the agreed timescales. The SOP describes the responsibilities of the Lead Investigator, RF R&D Office and the Finance Department and timescales / milestones associated with the process. It includes a flow diagram containing guidance on the associated time points.

The Sponsor of a study is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. (UK Policy for Health Social Care Research (2017))

Adequate funding ensures the study has the required staff, equipment and consumables to run at the required number of sites and to the required procedures. For studies taking place in the NHS, there may also be NHS costs to consider.

A key part of Sponsorship review process is to ensure that a study Sponsored by RF has adequate resource and funding to deliver the study in line with the agreed protocol and any contracts and agreements. All partners involved in research require that the sponsor assures adequate funding is in place. Its purpose is to ensure that all RF sponsored studies are adequately funded to completion and do not have any unmet costs to RF.

3. DEFINITIONS

RF Royal Free London NHS Foundation Trust

RM&G - Research Management & Governance

R&D - Research & Development

Sponsor - Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities in this research governance framework that are relevant to the study.

AcoRD - Attributing the costs of health and social care Research and Development

NIHR – National Institute for Health Research

HRA – Health Research Authority

PI - Principal Investigator

CI - Chief Investigator

TFC – Trial Feasibility Committee

4. SCOPE

This SOP applies to all grants application and studies that are sponsored by RF (or include costs for RF) and non-NIHR portfolio studies that are 'hosted' by RF.

Where a funding review is required, the R&D procedure has been designed to reflect the complexity of the study to be Sponsored. It takes into account the need to ensure NHS costs are identified and supported. A costing review may not be required for all studies. For the purposes of funding review, a complex study is considered to involve any of the following:

- a. procedures outside of standard treatment (therefore not covered by existing sources of funding)
- b. a cost incurred by the service hosting the study
- c. third parties or service providers
- d. requirements for additional (above standard care) monitoring and oversight activities
- e. equipment or infrastructure costs
- f. additional staff resource
- g. multiple research sites

This guidance does not apply to the funding review for studies which are considered to be CTIMPS and/or Medical Device trials

Costing of new commercial studies is undertaken by North Thames CRN, as part of the Harmonisation process. (See SOP052)

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 (2).

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.

Royal Free R&D Office (usually represented by the Research Costing and Contract Manager, deputised by the Research Portfolio Manager or R&D Manager during periods of absence) will coordinate and facilitate the grant costing process and maintain a central record of all RF studies costed in line with this SOP.

Royal Free Finance Department (usually represented by the R&D Accountant, deputy to be identified in the periods of absence) will contribute to the costing process by providing costs for staff employed by RF and treatment costs not included on the NIHR costing template.

Lead Investigator: will liaise with the RF R&D Office in a timely manner, providing information on the design and delivery of the proposed research study.

7. PROCEDURE

| Person Responsible | Task |
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| Lead Investigator | <p>7.1 Grant funding costing and Sponsorship</p> <p>Complete the first contact questionnaire and provide the R&D Office with trial documentation (e.g. protocol where available, grant guidance document, primary funding application or other written account of the intended trial) and proof of any quoted costs at least 20 working days before the submission deadline.</p> <p>Identify and liaise with external collaborators to ensure that their costs (including any overheads,</p> |

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| | <p>where applicable) are appropriately reflected in the funding application. This includes mainly staff costs but it might also include NHS treatment costs at other sites.</p> <p>For UCL studies, the UCL Investigator will provide costs in liaison with their departmental administrator and UCL research services.</p> <p>For multi-site grants, the lead investigator will coordinate costs of all other sites trust and NHS costs.</p> |
| <p>Research Costing and Contract Manager</p> | <p>7.2 Grant funding costing and Sponsorship</p> <p>Act as a first point of contact for the Lead Investigator and liaise with other internal services (including Finance, Pharmacy and Imaging where relevant).</p> <p>Provide advice on the requirements of funding bodies as per published guidance (where this is available, especially for NIHR grants and Medical Charities).</p> <p>Provide advice on the classification of costs in line with the AcoRD guidance to ensure that research, service support and treatment costs are appropriately allocated.</p> <p>Support the Lead Investigator to identify the types of costs relevant for their project.</p> <p>Provide estimates of costs in discussion with the Lead Investigator (e.g. support the Investigator in estimating travel costs etc.)</p> <p>Provide support costs, including support staff (e.g. Research Nurses).</p> <p>Provide pharmacy costs in liaison with pharmacy, imaging costs in liaison with the RFL Research Imaging team and other service support costs. Ensure that service support costs are in line with the CRN North Thames agreed tariffs.</p> <p>Provide a comprehensive costing spreadsheet template to the Lead Investigator.</p> <p>Organise the sign-off of grant funding applications by the authorised Trust signatory.</p> |
| <p>Trust Finance Department</p> | <p>7.3 Grant funding costing and Sponsorship</p> <p>They will provide the RF R&D team with the actual pay costs for RF members of research staff.</p> <p>Provide the RFL R&D team with estimates of NHS treatment costs, such as costs of hospital stay and costs of standard care interventions, where these are</p> |

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| | not covered by the existing NIHR Tariffs and approve costs for all funding applications prior to submission. |
| Lead Investigator and Research Costing and Contract Manager | <p>7.4 Timescales</p> <p>The timescales for costing will vary depending on the complexity of the trial. The RF R&D Office estimates that the full costing process for complex trials will take 6-8 weeks. Complex trials will be trials involving multiple sites and multiple research interventions.</p> <p>Submissions to the R&D office need be made at least 20 working days before the submission deadline. For more complex studies as defined above, 6-8 weeks' notice should be given. The R&D Office will aim to consider late applications as it is recognised that at times submission deadlines provided by funding bodies are limited. It is however, not guaranteed that the deadline will be met.</p> <p>It is essential to meet with the RF R&D Office before submission of your grant application to discuss the costing of your trials to ensure you have identified all appropriate costs.</p> |
| Chief Investigator, and Research Costing and Contract Manager | <p>7.5 Studies applying for Confirmation of Capacity and Capability</p> <p>7.5.1 Commercial & NIHR adopted studies</p> <p>Costings are confirmed by North Thames CRN as per of harmonisation process (see SOP052).</p> <p>7.5.2 Non-commercial and non-NIHR adopted studies</p> <p>Where RF is the study Sponsor, the Research Costing and Contract Manager will assist the CI in drafting the HRA Organisational document. Schedule 1, the Finance Schedule provides clarity on what funding the Sponsor will be providing to cover Research Costs at participating organisations, as well as what Service Support and/or other resources are required locally.</p> <p>Identify any funding shortfalls and notify the Lead Investigator and escalate where appropriate to the R&D Research Portfolio Manager responsible for study set-up or Sponsorship.</p> |
| Assigned Research Portfolio Manager | <p>7.6 Issuing Confirmation of Capacity and Capability</p> <p>Request TFC authorisation before issuing Confirmation of Capacity for any study which has impact on NHS resources, in line with RF R&D SOP</p> |

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| | <p>048 (Submitting Clinical Research Studies for Review at a Trial Feasibility Committee).</p> <p>Where a study has a funding shortfall, RF reserves the right to decline capacity or request the CI reduces the scope of the study before issuing Sponsorship (See SOP029 Sponsorship)</p> |
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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 Office 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 R&D Office is responsible for the ratification of this procedure.

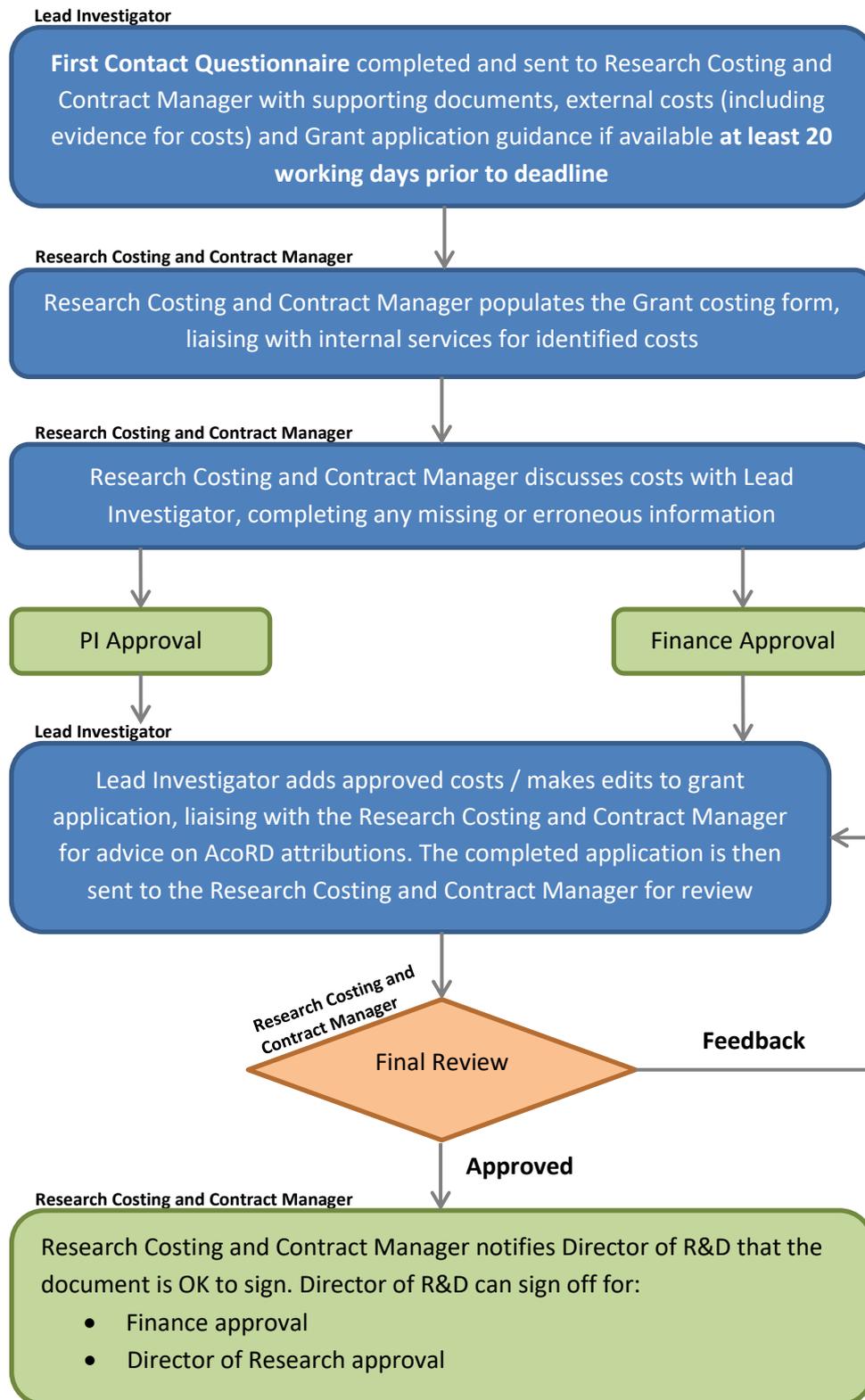
10. FORMS/TEMPLATES TO BE USED

Costing process for NIHR awarded grants Version 01 16th July 2015
RFLRDDOC0037 First Contact Questionnaire

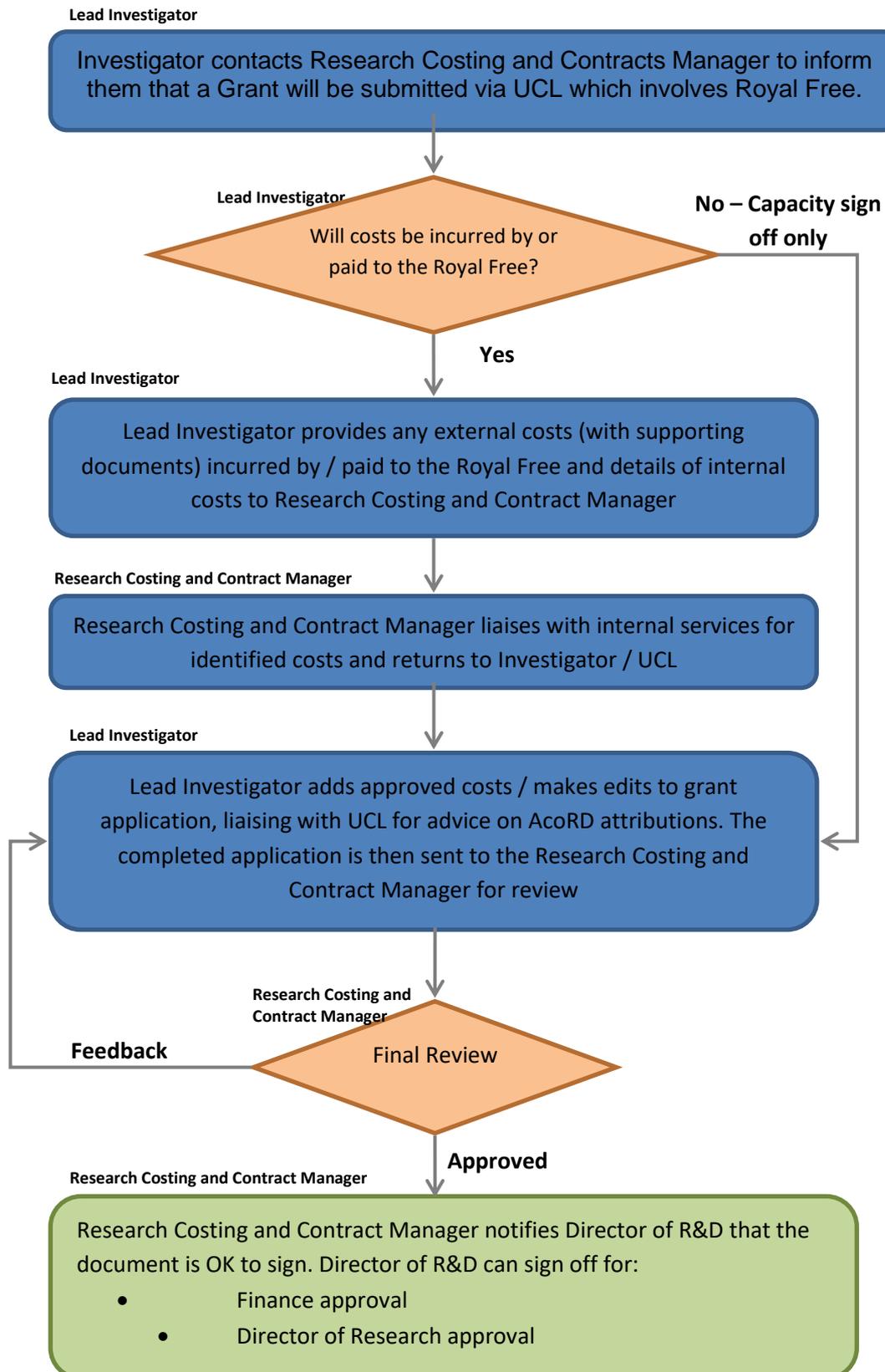
11. FLOWCHARTS

See below

11.1 RF Sponsored Studies



11.2 UCL Sponsored Studies



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.

| | |
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| Name of the policy / function / service development being assessed | Assessing Costs of RF Research Studies |
| Briefly describe its aims and objectives: | The purpose of this SOP is to ensure a robust system is put into place when costing and setting up studies at Royal Free London NHS Foundation Trust (RF). |
| Directorate and Lead: | Rachel Fay, R&D Manager, R&D Office |
| 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 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 | NA | NA | This SOP includes the Trust Equality Statement, as well as the results from the Equality Assessment for this SOP. These actions are designed to embed the equality agenda and promote equality compliance within the Trust. |
| Disability | None identified | R&D administrative document | NA | NA | |
| Gender Reassignment | None identified | R&D administrative document | NA | NA | |
| Marriage and Civil Partnership | None identified | R&D administrative document | NA | NA | |
| Pregnancy and maternity | None identified | R&D administrative | NA | NA | |

| 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 |
|---------------------------|---------------------------|---------------------------------------------------|---------------------------------------------|----------------------------------------------------------------------|--------------------------------------------------------------|
| | | document | | | |
| Race | None identified | R&D administrative document | NA | NA | |
| Religion or Belief | None identified | R&D administrative document | NA | NA | |
| Sex | None identified | R&D administrative document | NA | NA | |
| Sexual Orientation | None identified | R&D administrative document | NA | NA | |
| Carers | None identified | R&D administrative document | NA | NA | |

It is important to record the names of everyone who has contributed to the policy, practice, function, business case, and 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 | 13/02/2018 |
| | Royal Free London NHS Foundation Trust | 22/02/2018 |

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