

Research Placement Agreements, Letter of Access and Clinical Placement Agreements for external staff

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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) HR Payment checklist HR Placement process map HR Placement fee description and payment methods
Date equality analysis completed.	
<u>This is a controlled document</u>	
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Version Control

Version	Date	Author	Status	Comment
1.1	24/02/2017	Rachel Fay	FINAL	Correction to typo on date of review and update to SOP template V2.0
2	16/11/2017	Lucy Parker	Final	Update to SOP template v.30 Correction of links Addition of all the different NIHR groups of researchers and further expansion of explanation of process Change from Research Governance Framework to UK Policy Framework for Health and Social Care (2017)
2.1	17/10/2018	Lucia Possas	Draft	Correction of links Introduction of the Research Placement Agreement Introduction of the Service-Level Agreement for researchers hired by commercial sponsors
2.4	05/03/2019	LP	Draft	Update to clinical placement
2.5	07/03/2019	FN	Draft	Minor changes prior to R&D committee review
2.6	15/05/2019	RF/LPo	Final	Placement Agreement added. Flowchart updated and table added. Updated link

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1. INTRODUCTION

Research within the NHS is often undertaken by NHS staff not directly employed by the Royal Free London NHS Foundation Trust, or by non-NHS staff, particularly researchers employed by universities.

A clear process for handling contractual HR arrangements for external researchers who require access to the Royal Free London NHS Foundation Trust (RFL) premises, patients and patient data is needed to ensure that the issues of responsibility, accountability, patient safety and duty of care are appropriately addressed and that all parties undertaking research at RF are clear about their responsibilities and liabilities.

The Research Passport procedure is the process by which researchers can obtain a research placement agreement (RPA) or a Letter of Access (LoA). The procedure enables researchers to complete a single set of documents in order to be able to access a single or multiple NHS sites, smoothing out the process of obtaining permission to attend NHS sites.

The system was devised by the National Institute for Health Research (NIHR) and allows all parties undertaking research in the NHS to have clearly defined responsibilities and liabilities as laid out in the UK Policy Framework for Health and Social Care (2017).

The current source of information is the HR Good Practice (Resource Pack): Information for Researchers, R&D and HR staff in the NHS and Higher Education Institutes (HEIs) (<https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm>)

The guiding principles for the system are to ensure that legal liability is clear should research activity have adverse incidents, to ensure that non-NHS researchers are bound contractually, to ensure NHS duty of care, to ensure that they follow research governance and regulations, and that most importantly, research participants are protected.

The system can be used by researchers taking part in studies which could have a foreseeable or direct impact on patient care and clearly defines what documentation and checks in-house that should be undertaken without duplicating the checks made by another NHS organisation.

“The research passport” is a single set of a standard form and associated documents. These documents include identity checks, Occupational Health (OH) clearance, Disclosure and Barring Service (DBS), (formerly Criminal Record Bureau) checks etc.

2. OBJECTIVE

This document defines the Trust’s SOP for issuing Research Placement Agreements, Letters of Access and Service Level Agreements to researchers external to the Trust.

This SOP implements the Research Passport Scheme via the adoption of the Research in the NHS – HR Good Practice Resource Pack and the related guidance which is available from:

www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm

The form will detail what needs to be included with your application. The above link also contains any other documents that may need to be completed.

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

It is important that the link above is used to fill out the form as NHS organisations can only accept the latest version of the form and if an older version is used, it will be refused.

3. DEFINITIONS

RFL - Royal Free London NHS Foundation Trust

RM&G - Research Management & Governance

R&D - Research & Development

TROIKA - is a sub-committee of the Research and Development (R&D) Committee and comprises of the Dean of the Medical School, the Director of the R&D Office and the RF's Medical Director

HEI – Higher Education Institution

4. SCOPE

This SOP describes the process for completing the forms necessary for obtaining a Research Placement Agreements (RPA), Letter of Access (LoA) and Clinical Placement Agreement (CPA) for external staff in order to undertake research related activity in the Royal Free London NHS Foundation Trust.

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

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7. PROCEDURE

The PI is responsible for declaring external staff to R&D before delegating any RFL research activities to individuals, regardless of who they are employed by.

7.1. NHS and University staff

If you have a contract with the NHS already, you will need to complete the [NHS to NHS confirmation of pre-engagement checks](#) which is available on the NIHR website. This must be completed by your employer and sent directly rf.randd@nhs.net.

If you do not have an employment contract with any other NHS organisation but are paid by a University then you will need to complete the [Research Passport form](#) paperwork, if you do not already have one.

What is a Research Passport?

The Research Passport is a validated “pack” of documents and includes all necessary employment checks which are required prior to undertaking research in the NHS.

You need a Research Passport if you will be undertaking research within RFL and you have a university contract.

There are two types of Research passport. One is specific just for the project you are working on (project specific) and the other covers multiple projects and lasts for up to three years (three year passport). For the three year passport, studies must be defined and appended to the document pack and must be agreed with your substantive employer (who will decide if any new checks are needed) and if added to your passport, you must inform each R&D office.

The Research Passport is validated for accuracy and completeness by the first NHS organisation to receive it. The Research Passport does not guarantee you access to an NHS organisation but is the mechanism by which you apply for access.

The Research Passport is issued and completed by your substantive employer. They are responsible for undertaking the Occupational Health, DBS, and qualification checks to the appropriate level. You should contact your HR Department (not RFL HR) and ask them how to apply for a Research Passport.

Once you have your Research Passport and supporting documents, send these to R&D Department rf.randd@nhs.net, informing them to which study your documentation relates.

If your study will be carried out in more than one NHS organisation, once you have your Research Passport, you will need to approach the lead NHS Trust to validate it.

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You can then submit the validated Research passport to other NHS Trusts/organisations to which you need access.

Please note that the Disclosure and Barring Service (DBS) Code of Practice prohibits the photocopying of DBS check documents. You will need to bring or send the original DBS which we will be checked and returned to you. Please do not send by e-mail.

Letters of Access

A Letter of Access (LoA) will be issued when it is judged that the researcher's activity will not have a direct bearing on patient care (as per NIHR algorithm - see link on page 4).

i) For HEI researchers where the researcher needs to access RFL facilities or patients or data to undertake a research.

In this case a Research Passport form is required for the Letter of Access to be issued (<https://www.nihr.ac.uk/02-documents/policy-and-standards/Faster-easier-clinical-research/Research-passports/Hr%20Good%20Practice%20Resource%20Pack/Flowchart-1-RP-Research-at-a-single-site.pdf>)

ii) For NHS researchers and clinical academics with existing substantive employment contract with an external NHS trust and RFL accepts the existing research relationship with the external NHS trust.

In this case an NHS to NHS confirmation of pre-engagement checks will be used for issuing a Letter of Access (<https://www.nihr.ac.uk/02-documents/policy-and-standards/Faster-easier-clinical-research/Research-passports/Hr%20Good%20Practice%20Resource%20Pack/Flowchart-3-NHS-to-NHS-arrangements.pdf>).

The researcher's substantive NHS employer (i.e. not RFL) remains fully responsible for undertaking and updating the pre-engagement checks.

Research Placement Agreement

A Research Placement Agreement will be issued for NHS and University staff when the researcher's activities are judged to have direct impact on patient care. Note that RFL R&D stopped issuing Research Honorary Contracts in 2018. The Research Placement Agreement is now used instead.

A researcher's activity will be deemed to have a direct bearing on the quality of patient care if it could directly influence:

- A patient's access to care
- The care pathway which the patient followed
- The type, quality or extent of prevention, diagnosis or treatment of illness.

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- The researcher's action could foreseeably cause injury or loss to patients or service users
- To whom the NHS organisation has a duty of care, leading to a possible case of clinical negligence being made against the NHS organisation.

To obtain a research placement agreement, the researcher should complete the research passport or NHS-to-NHS form as per NIHR guidance (<https://www.nihr.ac.uk/02-documents/policy-and-standards/Faster-easier-clinical-research/Research-passports/Hr%20Good%20Practice%20Resource%20Pack/Flowchart-1-RP-Research-at-a-single-site.pdf>).

R&D can only give access to open research studies at RFL (that have received confirmation of capacity and capability). R&D will need the IRAS number of the study and confirmation and evidence from the PI that they have given permission for the researcher to join the study.

The PI will need to sign the research placement agreement as evidence of their oversight of the third party joining the study. The PI's responsibilities to the 'research placement' holder are outlined in the agreement. These include liaising with security when the researcher leaves.

Once the research placement agreement has been authorised by the PI, R&D director and individual, R&D will liaise with HR to ensure the person has an ID badge.

The researcher will need to contact HR to get an ID badge application form and ID check appointment: rf-tr.hrbpadmin@nhs.net

All letters of access and research placement agreements are coordinated by R&D: rf.randd@nhs.net

Researcher may present the validated research passport with supporting documents to RFL R&D that has been validated by another trust's R&D department. RFL may choose to accept the following evidence:

- a copy of the HRC issued by the external lead site only, or
- a photocopy of the validated RP only, or
- the original validated RP only, or
- the original validated RP with photocopies of supporting documents.

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7.2. Staff employed by non-university or non-NHS organisations i.e. commercial companies and charities

This applies to individual applicants undertaking research who are employed by:

- Commercial organisations
- Charities
- Public sector but NOT NHS or university employed
- No 'sponsor' employee
- International researchers/student (non-UK universities and hospitals)

Clinical Placement Agreement

This is a trust-wide process for individual applicants undertaking research who may have patient contact or where their activities may have an impact on patient care (see HR honorary and placement map). The external staff cannot work on the study until they have a clinical placement agreement (CPA). R&D will coordinate the CPA on behalf of the PI.

FEES

RFL Human Resources may charge fees for commercially employed individuals for the pre-employment checks which will be included in the clinical trial agreement (CTA). For non-commercial studies fees will be reviewed on a study-by-study basis by HR. Please see HR documents:

- HR Payment checklist
- HR Placement process map
- HR Placement fee description and payment methods

The workforce team will cross-charge the pre-employment check fee to R&D. This will be charged to the study/PI's cost centre. For studies that are open fees may be included via a contract amendment and sponsor invoiced accordingly.

PROCESS - CPAs

R&D coordinate will request a CPA via Trac on behalf of the PI as per HR guidance. <http://freenetplus/sites/HROnline/Placement%20and%20clinical%20agreement/Pages/default.aspx>

HR recruitment team will conduct the pre-employment checks and issue the ID badges/ Cerner cards and send a copy of the contract to the R&D coordinator. The R&D coordinator will send the contract to the PI so that the researcher can begin working on the study.

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Placement Agreement

This is a trust-wide process for individual applicants undertaking research WILL NOT have any patient contact or any impact on patient care and they will not have access to any patient data (see HR honorary and placement map). Form can be downloaded from the RFL HR website:

<http://freenetplus/sites/HROnline/Placement%20and%20clinical%20agreement/Pages/default.aspx>

Mandatory and statutory training (MaST)

Please note that LOAs, RPAs, CPAs do not give the individuals access to MaST training. In circumstances where MaST training is needed the RFL line manager or PI should contact HR for a different contract route. See HR intranet for details:

<http://freenetplus/sites/HROnline/Placement%20and%20clinical%20agreement/Pages/default.aspx>

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

Please see NIHR website for the latest version of documents:

<https://www.nihr.ac.uk/search-results.htm?sitekit=true&search=research+passport&task=search&indexname=site-search>

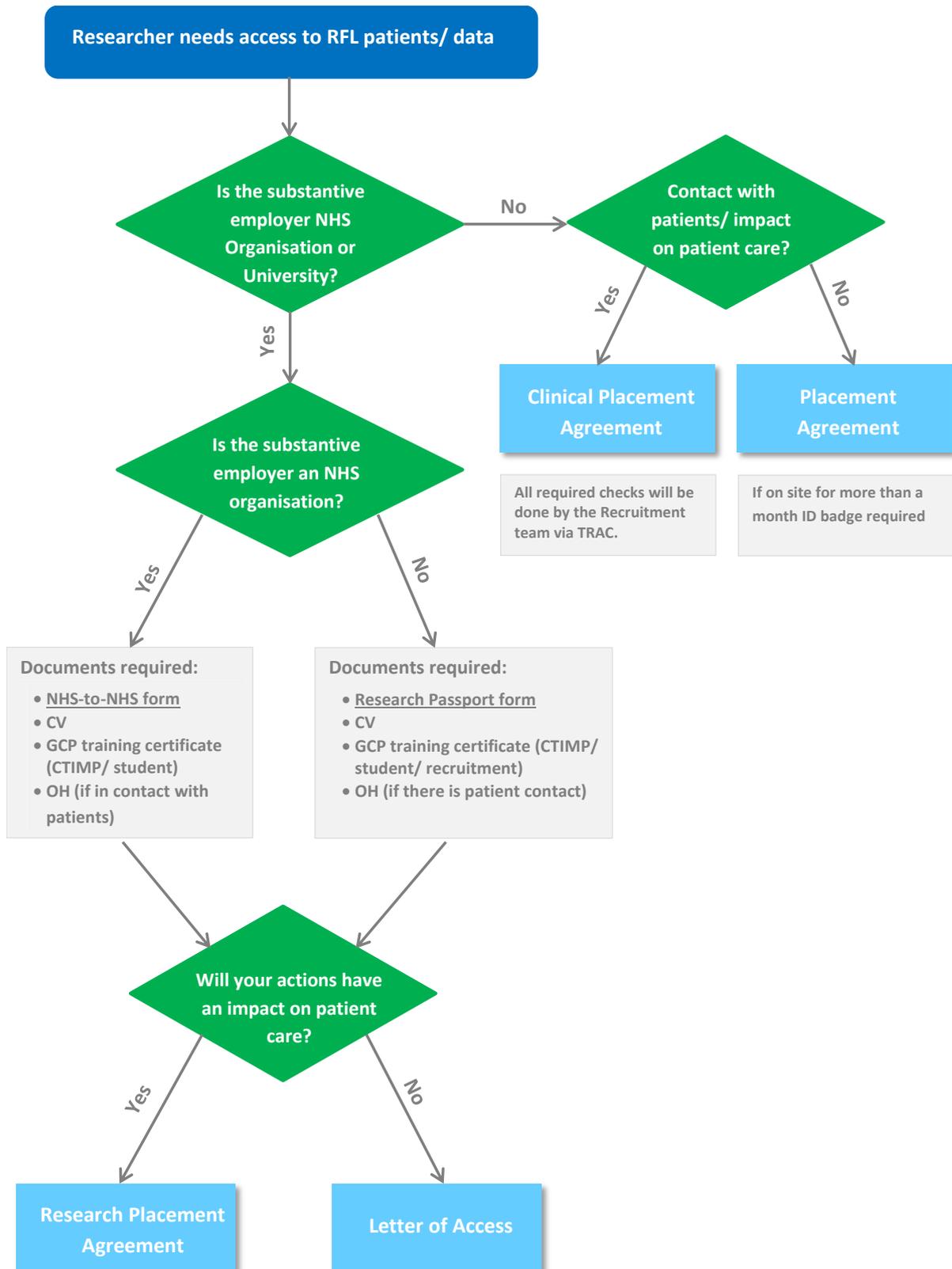
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11. FLOWCHART AND TABLE



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TABLE OF DOCUMENTS REQUIRED BY INDIVIDUAL APPLICANTS UNDERTAKING RESEARCH AT RFL			
Employer	Contact with patients/ impact on patient care		Issued by
	YES	NO	DEPARTMENT
NHS	RPA	LoA	R&D
University	RPA	LoA	R&D
Non- NHS/University	CPA	PA	HR (initiated by R&D)
International researcher/ student	CPA	PA	HR (initiated by R&D)

APPENDIX 1

Further reading re. research passports and letters of access

See NIHR website (pages 5 and 6 of “The Research Passport: Algorithm of Research Activity and Pre-Engagement Checks” version 3.0, September, 2012)

<https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm>

<https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#HR-Good-Practice-Resource-Pack>

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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	
Briefly describe its aims and objectives:	
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.

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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 document	NA	NA	

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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
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
QMS Group	Royal Free London NHS Foundation Trust	
R&D Committee	Royal Free London NHS Foundation Trust	

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