RDSOP12 Research Passport – Issue of Honorary Research Contracts and Letters of Access

Greater Manchester Mental Health NHS Foundation Trust

Improving Lives
RDSOP12 Research Passport – Issue of Honorary Research Contracts and Letters of Access

<table>
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<tbody>
<tr>
<td>Document Summary:</td>
<td>To make all NHS / University staff involved in the preparation, administration and issue of Research Passports aware of how this must be carried out. This includes instructions for NHS and non-NHS Applicants. This SOP is in accordance with the National Guidance issued by the National Institute for Health Research (NIHR)/Health Research Authority (HRA).</td>
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<tr>
<td>Document Author:</td>
<td>Jennifer Higham Research Governance Manager</td>
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<tr>
<td>Target Audience:</td>
<td>Trust-wide, Research Community, Internal and External Researchers</td>
</tr>
<tr>
<td>Consultation:</td>
<td>R &amp; I Office, research community and R &amp; I Committee members</td>
</tr>
<tr>
<td>Approval Committee:</td>
<td>R &amp; I Committee</td>
</tr>
<tr>
<td>Cross Reference Document(s):</td>
<td>Research Approval Policy All Trust R &amp; I SOPs</td>
</tr>
<tr>
<td>Contact details for further information:</td>
<td>Sarah Leo Head of R &amp; I Office 0161 271 0076 <a href="mailto:researchoffice@gmmh.nhs.uk">researchoffice@gmmh.nhs.uk</a></td>
</tr>
<tr>
<td>Minimum Monitoring Requirement</td>
<td>Frequency</td>
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<tr>
<td>Review of SOP content</td>
<td>Annually</td>
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1. Introduction

1.1 Background

Research is an integral part of NHS activity, and is often undertaken in partnership with Higher Education Institutions (HEI’s) and others. As a result of the partnership arrangements that characterise research, this activity raises a number of HR management issues for NHS organisations. Research within the NHS is often undertaken by NHS staff not directly employed by the host NHS organisation, or by non-NHS staff, particularly researchers employed by universities. This raises issues about responsibility, accountability, patient safety and duty of care. Research is also frequently undertaken across a number of NHS organisations and requires arrangements for both NHS and non-NHS staff to work across those organisations.

The Research Governance Frameworks published by the UK Health Departments require all parties undertaking research within the NHS to be clear about responsibilities and liabilities. One of the ways this is achieved is through using HR procedures appropriately.

The NHS and HEIs have responsibilities as employers of researchers. Only the employer can be accountable for the suitability of the individual in terms of training, experience and conduct. The substantive employer retains the primary accountability and liability for the actions of their researchers. Once NHS organisations have confirmed capacity and capability for research to take place at their sites that affects their legal duty of quality and common law duty of care, they then accept vicarious liability for harm due to clinical negligence.

The HR Good Practice Resource Pack (available at https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm) clarifies the areas of responsibility, and hence liability, of NHS organisations and HEIs in relation to researchers. Neither NHS organisations nor HEIs should take responsibility for issues that are outside their ability to fully discharge.

Greater Manchester Mental Health NHS Foundation Trust (GMMH) has been using the Research Passport since the national launch and accepts Research Passports submitted from researchers outside the Greater Manchester area.

All staff involved with the preparation, administration and approval of Research Passports, issue of Honorary Research Contracts and Letters of Access on behalf of GMMH must refer to this SOP and to the National HRA Guidance on Research Passports. All forms are available on the website (via link above).
1.2 The Research Passport System

The Research Passport is a form which enables Non-NHS employers to share pre-engagement information about their researcher with NHS organisations hosting the researcher's activity. The Research Passport scheme provides:

- Clear guidance on the relevant checks required.
- A robust process for Non-NHS employers to document and evidence the checks which have been undertaken.
- Clear principles that enable NHS organisations to record and rely on those checks for the duration of the Research Passport.

What are the benefits of the Research Passport?

- Clear HR processes in line with NHS Employment Check Standards operated jointly by Non-NHS and NHS employers, thereby minimising duplication.
- Clarifies accountability and responsibility for researchers, resulting in increasing patient safety, improving risk management, and for employers, improving quality assurance of research staff.
- One set of checks is undertaken on a researcher conducting research in the NHS.
- One standard form is completed for each researcher.
- The form is completed by the researcher and their employer, and validated by an NHS organisation, enabling an Honorary Research Contract or Letter of Access to be issued, according to the nature of the research activity.
- The completed and validated Research Passport is presented to all the relevant NHS organisations where the research is taking place.
- Faster study start-up.

The NHS organisation hosting the research and the substantive employer should refer to the ‘Instructions for completing the Research Passport form’ and the Process Flowcharts on the Research Passport System for operational details at https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm

Once the Research Passport Form is validated, the host NHS organisation can issue a Honorary Research Contract (HRC) or Letter of Access (LoA) depending on the nature of the research activity. The Research Passport is usually valid for a three-year period.

2. Purpose

To make all NHS / University staff involved in the preparation, administration and issue of Research Passports aware of how this must be carried out. This includes instructions for NHS and non-NHS Applicants. This SOP is in accordance with the National Guidance issued by the NIHR Health Research Authority.
3. Roles and Responsibilities

3.1 Duties within the organisation

It is the responsibility of the Research Support Co-ordinator (or proxy) to make Trust R & I SOPs available to all research active staff working on Trust-approved research studies.

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that up-to-date copies of Trust R & I SOPs are available to research staff.

It is the responsibility of the study Chief Investigator or local Principal Investigator to inform the Research Support Co-ordinator of the names of all research staff involved on a study so that copies of SOPs can be distributed appropriately, and to ensure that up-to-date copies are filed in the Investigator Site file and are available to research staff.

It is the responsibility of the study Chief Investigator or Principal Investigator to designate if the SOPs of another organisation are to be followed for a study. For example, those of a Clinical Research Network or commercial sponsor. If there is significant conflict between the external SOP and the Trust R & I SOP it is the responsibility of the CI or PI to resolve these with the R & I Office prior to starting the study.

It is the personal responsibility of all staff to follow Trust (or the designated alternative organisations) procedural documents.

3.2 Specific to this SOP

Principal Investigator/Study Coordinator: To recognise individuals who are not contracted to the Trust and initiate a Research Passport application if appropriate.

The Applicant: To complete the Research Passport proforma and obtain all necessary signatures/authorisations required and to sign an HRC (if applicable) with the Trust confirming adherence to Trust rules and policies or to receive a Letter of Access.

Research Support Co-ordinator: It is the responsibility of the Research Support Co-ordinator to adhere to the guidance set out in this procedure. Advise researchers on the process, receive and check documents submitted, prepare HRC or LoAs, obtain signatures, return documents to researcher, log in the Research Manager database and record on Researcher Register.

Head of R & I Office: It is the responsibility of the Head of R & I Office to ensure that this procedure has been correctly followed by the R & I Office team and sign the Research Passport proforma and HRC/LoA on behalf of the Director of HR and Corporate Services for the Trust.
4. Details of Procedure

The Quick Guide below shows what is needed for each category of applicant.

RESEARCHER CONTRACTS QUICK GUIDE

<table>
<thead>
<tr>
<th>GMMH STAFF</th>
<th>NHS STAFF</th>
<th>NON-NHS STAFF: HONORARY RESEARCH CONTRACTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Researcher with substantive GMMH contract or honorary GMMH clinical contract:</strong></td>
<td></td>
<td></td>
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<tr>
<td>• No additional arrangements required</td>
<td></td>
<td></td>
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<tr>
<td>• If the researcher requires access to another NHS organisation for the purpose of research, an ‘NHS to NHS confirmation of pre-engagement checks’ form must be produced on behalf of the researcher (see 4.7)</td>
<td></td>
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</tr>
<tr>
<td></td>
<td><strong>Researcher with substantive NHS contract:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Researcher with university contract and no honorary NHS clinical contract:</strong></td>
<td></td>
</tr>
<tr>
<td>• Honorary Research Contract if the research activities include the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>✓ Researcher is a healthcare professional providing healthcare to an adult and/or child.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>✓ Researcher provides healthcare to an adult and/or child under the direction or supervision of a healthcare professional.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>✓ Researcher provides personal care to an adult or child.</td>
<td></td>
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</tr>
<tr>
<td>✓ Researcher is a social care worker providing social work which is required in connection with any healthcare or social services to an adult who is a client or potential client.</td>
<td></td>
<td></td>
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<tr>
<td>✓ Researcher undertakes the following activities unsupervised: teach, train, instruct, care for or supervise children, or provide advice/ guidance on wellbeing, or drive a vehicle only for children; with likely direct bearing on the quality of care.</td>
<td></td>
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</tr>
<tr>
<td>✓ Researcher requires access to identifiable patient data derived from health records, tissues or organs with a likely direct bearing on the quality of care.</td>
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</tr>
</tbody>
</table>
Researcher with substantive university contract and no honorary NHS clinical contract:

- **Letter of Access if the research activities include the following:**
  
  ✓ Researcher has opportunity for any form of contact with children in the same Children’s Hospital (formerly a specified place) but is not providing healthcare or other types of regulated activity and has **no direct bearing** on the quality of care.
  
  ✓ Researcher has access to persons in receipt of healthcare services in the course of their normal duties but is not providing healthcare or other types of regulated activity and has **no direct bearing** on the quality of care (‘Access’ relates to where individuals will have physical, direct contact with patients e.g. observation, qualitative interviews, focus groups).
  
  ✓ Researcher has **indirect contact** with patients or service users but is not providing healthcare or other types of regulated activity and **has no direct bearing** on the quality of care (e.g. some types of telephone interview).
  
  ✓ Researcher requires access to identifiable patient data derived from health records, tissues or organs with **no direct bearing** on the quality of care.
  
  ✓ Researcher is working on NHS premises (e.g. laboratory) only (no access to identifiable data)

Researcher with substantive university contract and no honorary NHS clinical contract:

- **Letter of Access if the research activities are performed in NHS premises:**
  
  ✓ Researcher requires access to **anonymised patient data** derived from health records, tissues or organs only (including by research staff analysing data).
  
  ✓ Researcher requires direct contact with staff only but no access to patients (e.g. staff interviews).
  
  ✓ Researcher requires access to **identifiable** staff data only.
  
  ✓ Researcher requires access to **anonymised** staff data only.
4.1 Who needs to apply for an Honorary Research Contract or Letter of Access and submit a Research Passport?

The Research Passport: Algorithm of Research Activity and Pre-Engagement Checks (Sept 2012) at Appendix 1 outlines the types of activities researchers may do and whether a DBS or OH check is necessary and also whether a HRC or LoA is required to undertake that activity.

Who doesn’t need to apply for a Research Passport?
- Those employed by an NHS organisation
- Independent contractors (e.g. GPs) or employed by an independent contractor
- Those having an honorary clinical contract with the NHS (e.g. clinical academics)
- Undergraduate students of University of Manchester who are covered by the Memorandum of Understanding with the University.
- Higher Education Student on formal healthcare placement.
- Medical students who will be supervised within clinical settings by an NHS employee or HE staff member with an honorary clinical or honorary research contract
- Volunteers with no employer and who are not a student cannot complete a Research Passport as there is no-one to take responsibility. These volunteers would need to apply for a Volunteer Honorary Contract via the HR Dept at the Trust.
- The research being carried out does not require any checks or honorary research contract/letter of access.

Whether an HRC/LoA is required or not, each applicant must be reviewed and assessed in terms of their normal role, relevant experience, supervision and pre-employment checks required.

Note: Section 4.7 provides instructions on how to process requests for access by NHS contract holders.

Those who MAY need a HRC/LoA (see Quick Guide on previous page and Appendix 1)
- Non NHS employed Researchers, including:
  - HE Substantive Employee
  - HE Student not on a formal healthcare placement.
  - Volunteers with an honorary contract from the University and no NHS or other employer (the Research Passport would be completed via the University).

Note: use the same principles for researchers using the Wellcome Trust Clinical Research Facility (WTCRF) whether they are seeing patients, service users or healthy volunteers.
4.2 Application Process

Researchers are either NHS or non-NHS. For NHS researchers see Section 4.7 below. An NHS-NHS Proforma is completed by the employing Trust and a Letter of Access is issued.

For non-NHS researchers a Research Passport will be needed and, if appropriate, a Honorary Research Contract or Letter of Access will be issued. Where a Research Passport application is appropriate, researchers must complete and submit the Research Passport form for authorisation to their employer, line manager and then to the Trust for review and signature.

Research Passport Form and Guidance

The Research Passport form and guidance are available in electronic format via the Research Support Co-ordinator in the R & I Office or directly from the national guidance pages: https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm

The Research Passport form must be submitted with:

- The original DBS (if applicable), within 6 months of issue
- Evidence of Occupational Health screening (if applicable)
- An up-to-date CV, including relevant training undertaken

Completion of the Research Passport form

The Principal Investigator/Study Coordinator will initiate the completion of the Research Passport form with the Applicant.

The Research Passport must be completed up to and including Section 6. This includes signatures by the Applicant, by the Line Manager and by HR representatives from the Employer of the Applicant. Section 7 is completed by the Trust issuing the first HRC/LoA.

Appendices should be completed when there are a number of studies, or additional studies after the Research Passport has been issued.

The completed Research Passport with original documents should be forwarded to the Research Support Co-ordinator in the R & I Office at the Trust.

Approval of Research Projects

All Research Passport applications will refer to one or more research projects. These projects must have received confirmation of capacity and capability by the Trust prior to issue of an HRC/LoA and prior to any research activities commencing on Trust premises (see Research Approval Policy and RDSOP22 Approval Procedure for Clinical Trials of Investigational Medicinal Products).
Validation of the Application

If the Research Passport is completed correctly, signed as instructed on the form and is accompanied by the enclosures (as required), this is a valid submission and can be processed. Otherwise, the R & I Office will notify the Applicant as soon as possible and request additional information as required.

Issue of Honorary Research Contract / Letter of Access

Once a valid application is received, the application is processed usually within two days. The Quick Guide above and the Algorithm at Appendix 1 gives details of whether a HRC or LOA should be issued following submission of the Research Passport. It is usual to issue a Letter of Access so that the employer retains liability for the non-NHS researcher. Only if there is a direct (or possibly direct) bearing on care (e.g. the researcher is performing an intervention) will a HRC be issued. In almost all other circumstances a LoA will be issued.

If an HRC is to be issued, two copies of the HRC with covering letter will be sent to the Applicant, who must sign both copies and return one to the Research Support Coordinator in the R & I Office to file.

A HRC will not become active until the valid Research Passport application has been reviewed, a signed HRC issued and the Applicant has returned a signed copy. Appropriate Trust signatories for the HRC/LoA are the Head of R & I Office or Senior R & I Managers.

If a LoA is to be issued the letter will be signed by an appropriate Trust signatory, scanned and emailed electronically to the Applicant. All original application documents and signed LoA will be posted recorded delivery to the Applicant.

4.3 Revisions to Research Passport Access

Access to the Trust and/or patients will be on the basis described in the Research Passport Application and any changes (e.g. additional projects within the Trust, the Trust added as a new site) must be discussed with the R & I Office, and the Research Passport Appendix used to revise the signed Research Passport.

4.4 Pre-employment Checks

Refer to the Algorithm at Appendix 1 for a summary of the pre-employment checks required (e.g. DBS and occupational health) when conducting different types of research activity:

Occupational Health clearance

See Appendix 1 for when an Occupational Health check is required.
For non-NHS employed researchers, where occupational health screening is required, this must be arranged with the employer’s Occupational Health Department.

NHS employees must have received appropriate OH checks on employment, unless deemed inappropriate by the HR Advisor, this check would normally suffice. (Refer to Section 4.7).

**Disclosure and Barring Service (DBS) checks**

A clear, valid DBS (within 6 months of issue) is required at the level specified in Appendix 1.

The original DBS must be enclosed with the Research Passport application (dated within 6 months for the NHS organisation issuing a HRC or LoA).

The original DBS must be seen by the Research Support Co-ordinator and this is returned with the Research Passport application pack to the Researcher with the HRC or LoA. Information may only be shared between organisations with the consent of the applicant.

**Foreign Nationals**

The Trust requires foreign nationals to have a DBS (or similar) issued by their country, within 3 years prior to the application. Additionally, if they have been living in this country more than 1 week a DBS from this country is required.

**Students on healthcare placements**

Students must provide an appropriate level of DBS disclosure when they start working in the NHS, although the level of supervision must be taken into account if their role has changed.

4.5 **Accepting a Research Passport issued by another Trust**

**Research Passports used to obtain a HRC/LoA at another Trust**

These must be submitted to the new Trust with the following:

- A copy of the Research Passport form (authorised by the R & I Lead)
- A copy of fully signed HRC or copy of LoA issued by lead Trust
- A current CV
- A completed Research Passport Appendix outlining details of the project, the local supervisor/collaborator and the Applicant’s role in the project

**Processing a request**

The Research Passport form must be reviewed by the Research Support Co-ordinator to ascertain level of DBS check and confirm that OH checks were carried out. The checks must be appropriate to the level of involvement of the Applicant in the project at GMMH.
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If the researcher does not have the appropriate DBS check, the Applicant must apply for one through their employer.

If pre-employment checks are satisfactory the Research Support Co-ordinator will write to the Applicant with reciprocal agreement for access to the Trust and/or its patients/staff. An HRC agreement accepting the first Trust’s HRC will be issued. If a HRC is not required see 4.6 below.

4.6 Non-NHS Applicants who DO NOT require an Honorary Research Contract

Some Applicants may be carrying out low risk research or their involvement in the research project may not have any impact on the care provided to the patients involved. Appendix 1 must be used to establish if this is the case.

The Research Passport process is still completed in the same way, however, the Research Support Co-ordinator will not offer an Honorary Research Contract, but will issue a Letter of Access to the Applicant outlining the conditions of access, who the Applicant will report to within the Trust and confirming that the Employer of the Applicant retains the liability for the Applicant’s actions. Section 7 on the Research Passport form will be completed and returned to the Applicant along with the LoA.

4.7 Researchers holding an NHS Contract with another Trust (Substantive or Honorary Clinical)

These researchers do not require an Honorary Research Contract and must not be processed using a Research Passport. The HR Department (or R & I Office) of the employing NHS Trust should complete a NHS to NHS Proforma on behalf of the staff member and forward directly to the Research Support Co-ordinator at GMMH to process. This confirms their NHS status and expiry date if on a fixed term contract.

If the level of access required differs from the employee’s usual role, i.e. they have not received DBS or enhanced DBS then the Applicant may be required to apply for an enhanced DBS check, and/ or undergo additional Occupational Health checks or may be required to undergo additional training and/ or supervision.

Once a valid application is received and the checks are deemed satisfactory after review, a Letter of Access will be issued to the Applicant and copied to their employer.

4.8 Review, Renewal and Expiration

The maximum duration of a Research Passport is three years. If a researcher requires a Research Passport for longer than this, a repeat application should be completed and the relevant checks should be re-assessed. This is in line with the advice on
arrangements for highly mobile NHS staff groups, where criminal record and other appropriate checks should be undertaken at three-yearly intervals.

Applicants must start their renewal application at least 2 months prior to the expiry date (a reminder will be sent by the R & I Office (see RDSOP02, 4.3), the Applicant must contact the R & I Office to confirm if they will need their HRC or LoA extending. The Applicant must reapply for DBS and OH when a new Research Passport is completed and processed and as required by the guidance.

5. Researcher Register

The purpose of the Researcher Register is to maintain a current list of all researchers working on Trust-approved studies and all investigators (external and internal) undertaking research at the Trust. The register is on an Excel spreadsheet and contains the following fields:

- Name
- Type of contract issued
- Start and end date of contract
- Which Portfolio and/or non-Portfolio studies the researcher is working on
- Job title
- Employer
- Usual base
- Email address.

The Research Support Co-ordinator will maintain the spreadsheet in the R & I Office and record details when HRC’s/LoA’s are issued or renewed.

The Research Support Co-ordinator will interrogate the spreadsheet at regular intervals as part of the monthly audits to identify when contracts are about to expire. Researchers will be emailed asking if they require an extension. A reminder email will be sent if no response is received.

The contract will lapse if an extension is not requested by the due date. The researcher will not be able to work on studies at the Trust if the contract is terminated.

If an extension is required, a HRC/LoA will be issued after reviewing the Research Passport or NHS to NHS Proforma to ensure they are still valid, i.e. the Research Passport including DBS check is less than 3 years old, or the NHS-NHS Proforma does not indicate a NHS contract end date, meaning another one will need to be requested.

The Research Passport will contain details of DBS check, OH check and training details on the CV.
The Annual Project audit (RDSOP02) checks what training is in place for each researcher working on each study audited, i.e. Information Governance, Informed Consent and Good Clinical Practice training.

Chief/Principal Investigators are responsible for ensuring training is in place for their research team and renewed as appropriate and proportionate to the study.

6. References and Bibliography

UK policy framework for health and social care research (2017)

Research in the NHS: Human Resource (HR) Good Practice Resource Pack
https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm
## Appendix 1 – Research Passport Algorithm

**Version 3.0, September, 2012**

*The Research Passport: Algorithm of Research Activity and Pre-Engagement Checks*

<table>
<thead>
<tr>
<th>Activity</th>
<th>Criminal record or DBS check necessary?</th>
<th>Occupational Health Clearance necessary?</th>
<th>LOA or HRC to be issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researcher is a health care professional providing health care to an adult and/or child</td>
<td>Yes, if done once this is Regulated Activity (new definition). Requires enhanced DBS + appropriate barred list check</td>
<td>Yes, if there is direct contact</td>
<td>HRC</td>
</tr>
<tr>
<td>Researcher provides health care to an adult and/or child under the direction or supervision of a health care professional</td>
<td>Yes, if done once this is Regulated Activity (new definition). Requires enhanced DBS + appropriate barred list check</td>
<td>Yes, if there is direct contact</td>
<td>HRC</td>
</tr>
<tr>
<td>Researcher provides personal care to an adult or child OR Researcher is a social care worker providing social work which is required in connection with any health care or social services to an adult who is a client or potential client</td>
<td>Yes, if done once this is Regulated Activity (new definition). Requires enhanced DBS + appropriate barred list check</td>
<td>Yes, if there is direct contact</td>
<td>HRC</td>
</tr>
<tr>
<td>Researcher undertakes the following activities unsupervised: teach, train, instruct, care for or supervise children, or provide advice/guidance on well-being, or drive a vehicle only for children; with likely direct bearing on the quality of care.</td>
<td>Yes, if done regularly this is Regulated Activity. Requires enhanced DBS + barred list check</td>
<td>Yes, if there is direct contact</td>
<td>HRC</td>
</tr>
<tr>
<td>Researcher has opportunity for any form of contact with children in the same Children’s Hospital (formerly a specified place) but is not providing healthcare or other types of regulated activity and has no direct bearing on the quality of care.</td>
<td>Yes, if done regularly enhanced DBS (pre-Sept 2012 definition). No barred list heck.</td>
<td>Yes, if there is direct contact</td>
<td>LoA</td>
</tr>
<tr>
<td>Researcher has access to persons in receipt of healthcare services in the course of their normal duties but is not providing health care or other types of regulated activity and has no direct bearing on the quality of care (‘Access’ relates to where individuals will have physical, direct contact with patients e.g. observation, qualitative interviews, focus groups).</td>
<td>Yes, standard</td>
<td>Yes, if there is direct contact</td>
<td>LoA</td>
</tr>
</tbody>
</table>

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3 Please refer to [https://www.gov.uk/guidance/dbs-check-requests-guidance-for-employers](https://www.gov.uk/guidance/dbs-check-requests-guidance-for-employers) for guidance on specific activities which are eligible for DBS checks.

4 “health care professional” means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002.

5 “Health care” includes all forms of health care provided for individuals, whether relating to physical or mental health and also includes palliative care and procedures that are similar to forms of medical or surgical care but are not provided in connection with a medical condition.

6 A “direct bearing on the quality of care” suggests that the actions of researchers could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to an individual to whom the organisation has a duty of care.
Algorithm continued:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Criminal record or DBS check necessary?</th>
<th>Occupational Health Clearance necessary?</th>
<th>LOA or HRC to be issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researcher has indirect contact with patients or service users but is not providing healthcare or other types of regulated activity and has no direct bearing on the quality of care (e.g. some types of telephone interview).</td>
<td>No</td>
<td>No</td>
<td>LoA</td>
</tr>
<tr>
<td>Researcher requires access to <strong>identifiable</strong> patient data derived from health records, tissues or organs with a likely direct bearing on the quality of care</td>
<td>No</td>
<td>Yes, only if working with tissues or organs in NHS facilities</td>
<td>HRC</td>
</tr>
<tr>
<td>Researcher requires access to <strong>identifiable</strong> patient data derived from health records, tissues or organs with no direct bearing on the quality of care</td>
<td>No</td>
<td>Yes, only if working with tissues or organs in NHS facilities</td>
<td>LoA</td>
</tr>
<tr>
<td>Researcher requires access to <strong>anonymised</strong> patient data derived from health records, tissues or organs only (including by research staff analysing data)</td>
<td>No</td>
<td>Yes, only if working with tissues or organs in NHS facilities</td>
<td>LoA (only if reviewed in NHS facilities)</td>
</tr>
<tr>
<td>Researcher is working on NHS premises (e.g. laboratory) only (no access to identifiable data)</td>
<td>No</td>
<td>Yes, only if working with tissues or organs in NHS facilities</td>
<td>LoA</td>
</tr>
<tr>
<td>Researcher requires direct contact with staff only but no access to patients (e.g. staff interviews)</td>
<td>No</td>
<td>No</td>
<td>LoA (if in NHS facilities)</td>
</tr>
<tr>
<td>Researcher requires access to <strong>identifiable</strong> staff data only</td>
<td>No</td>
<td>No</td>
<td>LoA (if in NHS facilities)</td>
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<td>No</td>
<td>No</td>
<td>LoA (if in NHS facilities)</td>
</tr>
</tbody>
</table>