

Research Passports, Honorary Research Contracts and Letters of Access Procedure

Category:	Governance procedure
Summary:	<p>Research in the NHS relies on working in partnership with the Higher Education Sector and is often undertaken by non-NHS staff, including staff employed by higher education institutions.</p> <p>The National Institute for Health Research (NIHR), in its implementation of the government White Paper 'Best Research for Best Health', identified the need for a streamlined approach for issuing and recognising honorary research contracts within the NHS. The response has been the development of the 'Research Passport' process. A common approach to the process is documented in detail in 'Research in the NHS – HR good Practice Resource Pack. Version 2.1, September, 2012</p>
Equality Analysis undertaken:	29 May 2014
Valid From:	2014
Date of Next Review:	June 2017
Approval Date/ Via:	<input type="checkbox"/> Trust Management Executive
Distribution:	<p>Via Research and Development to:</p> <p><input type="checkbox"/> Researchers within OUH Trust</p> <p><input type="checkbox"/> Research and Development Web Site</p>
Related Documents:	<p>Trust Management Approval Policy</p> <p>Monitoring and Audit of Research Studies</p> <p>Integrity in Research Policy</p> <p>Research Protocol Amendments Policy</p> <p>Safety Reporting in Clinical Research Policy</p> <p>Incident Reporting Policy.</p>
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This Document replaces:	Version 1.0

Lead Director: Medical Director

Issue Date: 2014

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Introduction

1. Research in the NHS relies on working in partnership with the Higher Education Sector and is often undertaken by non-NHS staff, including staff employed by higher education institutions. This relationship calls for clear understanding about responsibility, accountability, patient safety, and duty of care. The Research Governance Framework for Health and Social Care (2005) require all parties undertaking research in the NHS to be clear about responsibilities and liabilities. One way in which this can be achieved is the use of honorary research contracts.
2. The National Institute for Health Research (NIHR), in its implementation of the government White Paper 'Best Research for Best Health', identified the need for a streamlined approach for issuing and recognising honorary research contracts within the NHS. The response has been the development of the 'Research Passport' process. A common approach to the process is documented in detail in 'Research in the NHS – HR good Practice Resource Pack. 'Version 2.1, September, 2012, produced by the NIHR.

Policy Statement

- 3 It is the policy of the Trust to:
 - 3.1 Protect the safety, dignity, rights and well-being of all patients involved in clinical research.
 - 3.2 Ensure that arrangements are in place to ensure that anyone engaged in clinical research has the appropriate permissions for access to Trust patients and their data

Scope

- 4 This policy applies to all applications to the Trust for a Research Passport, Honorary Research Contract or for a Letter of Access.

Aim

- 5 This policy sets out a consistent procedure for the processing of all applications to the Oxford University Hospitals NHS Trust ('the Trust') for a Research Passport, Honorary Research Contract (HRC) or for a Letter of Access (LA).
- 6 It is the aim of this policy to ensure that these procedures are consistent with NIHR processes for implementation of the Research Passport process.

Definitions

- 7 Research Passport

The Research Passport consists of a single standard form for each researcher, which provides evidence of one set of checks on a researcher conducting research in the NHS. The form is completed by the researcher and her/his employer, and validated by an NHS organisation. The completed Research Passport is presented to all the relevant NHS organisations in order for an HRC or LoA to be issued rapidly, with no duplication of checks.

- 8 Honorary Research Contract (HRC)

Honorary employment can be described as performing work for the benefit of an organisation without remuneration.

An HRC may be issued to an individual who has no contractual relationship with the NHS, and who is conducting research activities within an NHS organisation that may have an impact on patient care.

- 9 Letter of Access (LA)

A letter issued to the researcher, to enable them to carry out research within a host NHS organisation. The terms of the letter will depend on whether it is an NHS to NHS letter of access or a non-NHS to NHS letter of access. N.B. Trust Management Approval/NHS Permission is still required for the study itself.

10 Confirmation of Pre-Engagement Checks

A letter issued by an employing NHS institution for NHS researchers who have a substantive NHS contract of employment or clinical academics with an honorary clinical contract with an NHS organisation, and who need an NHS to NHS letter of access from an NHS organisation hosting their research.

11 Lead NHS Organisation

The NHS organisation approached by the researcher for a Research Passport; the organisation that coordinates the process necessary to issue an HRC or LA.

12 Host NHS Organisation

An NHS organisation hosting the research, which, where appropriate, issues a Letter of Access, Honorary Research Contract or Letter of Agreement

13 List of Abbreviations:

CSP	Coordinated System for gaining NHS Permission'
CV	Curriculum Vitae
HRC	Honorary Research Contract
LA	Letter of Access
NIHR	National Institute for Health Research
PI	Principal Investigator
R&D	Research and Development
TMA	Trust Management Approval

Responsibilities**Researcher**

14 Collation of all the relevant documentation.

15 Communicate with all relevant departments in employing organization, Lead NHS Trust and other trusts as appropriate.

Principal Investigator

16 Assuring the suitability and experience of the researcher to undertake duties associated with the proposed research activities.

17 Ensures that members of the research team have the appropriate documentation in place for access to research site.

Research and Development Staff (R&D)

- 18 Provide advice and information on the Research Passport process.
- 19 Identify the level of checks required for issue of an HRC.
- 20 Review and retain copies of relevant documents provided by researcher.
- 21 Issue Research Passport, HRC, LA.
- 22 Maintain a record of those researchers to whom a Research Passport, HRC or LA have been issued.

Employing Organization

- 23 Provide confirmation of pre-engagement checks.
- 24 Where required to do so, undertake applications for Criminal Records Disclosure.
- 25 Undertake additional checks, where those specified as required in the Research Passport form exceed those already undertaken.

Human Resources Department

- 26 Provide advice and training to R&D staff, where required.
- 27 Completes pre-engagement checks for Trust employees.
- 28 Where required to do so, countersign applications for Criminal Records Disclosure.

Implementation**Who needs a Research Passport?**

- 29 A Research passport is not needed if the researcher is/has:
 - 29.1 Substantive employment with an NHS Organisation
 - 29.2 An independent contractor (e.g. GP) or employed by an independent contractor
 - 29.3 An Honorary Clinical Contract with the NHS (e.g. Clinical Academics)
 - 29.4 A student who will be supervised within clinical settings by an NHS employee or Higher Education staff member with an NHS clinical contract.
 - 29.5 Undertaking research that does not require any of the checks outlined in the Research Passport form; or an Honorary Research Contract.
- 30 These researchers will instead submit a Pre-engagement checks letter in support of their application for access to the trust available from the website:
http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx
- 31 Researchers not in any of the above categories and who have no contractual relationship with the NHS will need to complete the research passport process. Whether an HRC or a LA is required will also depend on the nature of the research.
- 32 A Research Passport may be project specific, or cover multiple projects and last for a period of three years.

Approach to R&D for Research Passport/Honorary Research Contract/ Letter of Access for Non-NHS Researchers (Lead NHS Organisation)

- 33 The researcher approaches R&D/Human Resources in the lead NHS organisation for a Research Passport.
- 34 R&D staff check the nature of the research proposed and identify whether a research passport is required, and the type of pre-engagement checks required.

Form Completion

- 35 The Research Passport Form available from this website (http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx) should be completed as follows:
- 35.1 The Researcher (sections 1-3)
 - 35.2 Substantive Employer, Line Manager/Academic Supervisor (section 4)
 - 35.3 Substantive Employer - Human Resources Department (section 5)
 - 35.4 The Researcher (Section 6)

Document Review

- 36 The Researcher returns the following original documents to the R&D Department:
- 36.1 Completed Research Passport Form -sections 1-6 and appropriate passport appendix
 - 36.2 An occupational health screening/clearance (where appropriate)
 - 36.3 Current signed and dated curriculum vitae (CV)
 - 36.4 Original evidence of professional registration (as appropriate)
 - 36.5 Original evidence of research related qualifications and training
 - 36.6 Evidence of Criminal Record Disclosure (where appropriate)
- 37 The documents are reviewed, copied, and filed by R&D staff in a secure location, the originals being returned to the researcher.
- 38 An Honorary Research Contract or Letter of Access issued as appropriate, along with a copy of the NHS Confidentiality Code of Conduct.
- 39 A copy of the HRC or Letter of Access, along with a copy of the NHS Confidentiality Code of Conduct, is sent to the substantive employer and a copy to the OUH Trust HR department. This process is detailed in Appendix 2, Research at one Site.

Approach to Host NHS Organisations

- 40 Where access is required to more than one NHS organisation, the Researcher can then take the HRC or completed and signed Research Passport to another host NHS organisation for Letters of Access. This process is covered in Appendix 1, NHS to NHS arrangements, or if not holding an NHS contract, Appendix 3, Research at more than one Site. (NB. Documents related to the research will also be submitted as part of the Trust Management Approval /NHS Permission Process, either to R&D or via the Coordinated System for Gaining NHS Permission (CSP) system)

Amendments to a Research Passport

- 41 A three-year Research Passport may be amended to add new studies, or to change the details of the researcher.
- 42 A study specific Research Passport may be amended to a three-year passport covering multiple studies.
- 43 In some circumstances a new research passport will be required.
- 44 The researcher approaches the R&D Department (where the Trust is the Lead NHS Organisation) to discuss amending the Research Passport.
- 45 To add a new study to an existing three-year passport the researcher completes a new Passport Appendix page with details of the new study. Pages should be sequentially numbered.
- 46 R&D reviews the project to determine whether any additional pre-engagement checks are required. If so the researcher is referred to their substantive employer.
- 47 If no further checks are required R&D will issue a Letter of Access to cover the new study. (A full review of documents is undertaken as part of the Trust Management Approval/NHS Permission Process).
- 48 If the researcher's employment status has changed an assessment is made about whether a new passport is needed. In such circumstances, the procedure outlined in above is repeated.
- 49 Where a study specific passport is to be amended to a three-year passport, to include a second study an appendix page is added.
- 50 R&D reviews the study and determines whether any additional checks are required. The process is then followed as above.

Letter of Access (where other NHS organisation is Lead)

- 51 A letter of Access issued by a host NHS organisation is project specific.
- 52 The Researcher approaches the R&D Department for access to the Trust for the conduct of research.
- 53 The nature of the proposed research is reviewed.
- 54 The researcher presents their Honorary Research Contract and completed and authorised Research Passport, as detailed in Appendix 1, NHS to NHS arrangements.

Letter of Access (where a Substantive or Honorary Contract is held with another NHS Organisation)

- 55 The Researcher approaches the R&D Department for access to the Trust for the conduct of research.
- 56 The nature of the proposed research is reviewed.
- 57 The researcher presents their Substantive or Honorary Contract or NHS to NHS letter of access: Confirmation of pre-engagement checks available from the NIHR website.
- 58 The documents are reviewed, copied, and filed by R&D staff in a secure location, the originals being returned to the researcher.
- 59 A Letter of Access is issued. This process is detailed in Appendix 1, NHS to NHS arrangements.
- 60 A copy of the Letter of Access is sent to the substantive employer. (NB. Documents related to the research will also be submitted as part of the Trust Management Approval/NHS Permission Process, either to R&D or via the CSP system)

Confidentiality

- 61 All NHS organisations work to a code of conduct for handling identifiable information in order to comply with the Data Protection Act.
- 62 The Research Passport process involves access to identifiable and potentially sensitive information about researchers.
- 63 All information gathered will be treated and stored to enable privacy and confidentiality to be maintained.

Training

- 64 Staff involved in the conduct of clinical trials will undertake training in Good Clinical Practice prior to beginning their involvement in a trial, as defined in the trust management approval for clinical research policy. This policy will be communicated as part of this training.

Monitoring Compliance

- 65 Staff of the Trust R&D Department are responsible for auditing compliance with the policy on an annual basis. The R&D Lead will be responsible for formulation and implementation of remedial action.
- 66 The Trust R&D Department will monitor and update this policy to reflect changes in legislation and examples of best practice.

Review

- 67 This policy will be reviewed in 3 years, as set out in the *Policy for the Development and Implementation of Procedural Documents*.

References

- 68 Research Governance Framework for Health and Social Care (2005)
- 69 NIHR Research in the NHS – Good HR Resource Pack, Version 2.1, September, 2012
- 70 NHS Confidentiality Code of Conduct

Equality Analysis

In accordance with Equality & Diversity legislation, this Policy has had an Equality Analysis undertaken. It has been determined that this Policy does not discriminate against any individual or group and a full copy of the analysis can be found in Appendix 1.

Document History

Date of revision	Version number	Reason for review or update
1.0	23/07/09	New Policy
2.0	15/04/14	Review and minor updates

Appendix 1: Equality Analysis

Please include this in the preparation to write a policy and refer to the “Policy on Writing Policies.”
Full guidance is available: <http://ouh.oxnet.nhs.uk/Equality/Pages/EqualityImpactAssessment.aspx>

Equality Analysis
Policy / Plan / proposal name: Research Passports, Honorary Research Contracts and Letters of Access Procedure
Date of Policy – May 2014
Date due for review – May 2017
Lead person for policy and equality analysis Heather House
Does the policy /proposal relate to people? If yes please complete the whole form. YES
The only policies and proposals not relevant to equality considerations are those not involving people at all. (E.g. Equipment such as fridge temperature)
<p>1. Identify the main aim and objectives and intended outcomes of the policy. Who will benefit from the policy? Based on the qualifications and requirements of Researchers, we grant access to OUHT facilities and patients. The needs of each specific trial and the patients there-in (and relevant legislation governing this) are considered on a case-by-case basis before access is granted.</p>
<p>2. Involvement of stakeholders. Based on the previous version (1.0) we have included NIHR national guidance as well as feedback from researchers</p>
<p>3. Evidence. Population information on www.healthprofiles.info search for Oxfordshire.</p>
<p>Disability: All trials are subject to R&D approval as well as the appropriate ethical review to ensure all patients are adequately protected, informed and supported as indicated by the appropriate legislation. All researchers are assessed in this regard based on relevant qualifications and experience before being granted access in any form.</p>
<p>Disability: learning disability All trials are subject to R&D approval as well as the appropriate ethical review to ensure all patients are adequately protected informed and supported as indicated by the appropriate legislation. All researchers are assessed in this regard based on relevant qualifications and experience before being granted access in any form.</p>
<p>Sex: All trials are subject to R&D approval as well as the appropriate ethical review to ensure all patients are adequately protected, informed and supported as indicated by the appropriate legislation. All researchers are assessed in this regard based on relevant qualifications and experience before being granted access in any form.</p>
<p>Age: All trials are subject to R&D approval as well as the appropriate ethical review to ensure all patients are adequately protected, informed and supported as indicated by the appropriate legislation. All researchers are assessed in this regard based on relevant qualifications and experience before being granted access in any form.</p>

Race: All trials are subject to R&D approval as well as the appropriate ethical review to ensure all patients are adequately protected, informed and supported as indicated by the appropriate legislation. All researchers are assessed in this regard based on relevant qualifications and experience before being granted access in any form.

Sexual orientation: All trials are subject to R&D approval as well as the appropriate ethical review to ensure all patients are adequately protected, informed and supported as indicated by the appropriate legislation. All researchers are assessed in this regard based on relevant qualifications and experience before being granted access in any form.

Pregnancy and maternity: All trials are subject to R&D approval as well as the appropriate ethical review to ensure all patients are adequately protected, informed and supported as indicated by the appropriate legislation. All researchers are assessed in this regard based on relevant qualifications and experience before being granted access in any form.

Religion or belief. All trials are subject to R&D approval as well as the appropriate ethical review to ensure all patients are adequately protected, informed and supported as indicated by the appropriate legislation. All researchers are assessed in this regard based on relevant qualifications and experience before being granted access in any form.

Gender re-assignment. All trials are subject to R&D approval as well as the appropriate ethical review to ensure all patients are adequately protected, informed and supported as indicated by the appropriate legislation. All researchers are assessed in this regard based on relevant qualifications and experience before being granted access in any form.

Marriage or civil partnerships: All trials are subject to R&D approval as well as the appropriate ethical review to ensure all patients are adequately protected, informed and supported as indicated by the appropriate legislation. All researchers are assessed in this regard based on relevant qualifications and experience before being granted access in any form.

Carers All trials are subject to R&D approval as well as the appropriate ethical review to ensure all patients are adequately protected, informed and supported as indicated by the appropriate legislation. All researchers are assessed in this regard based on relevant qualifications and experience before being granted access in any form.

Safeguarding people who are vulnerable: All trials are subject to R&D approval as well as the appropriate ethical review to ensure all patients are adequately protected, informed and supported as indicated by the appropriate legislation. All researchers are assessed in this regard based on relevant qualifications and experience before being granted access in any form.

Other potential impacts e.g. culture, human rights, socio economic e.g. homeless people All trials are subject to R&D approval as well as the appropriate ethical review to ensure all patients are adequately protected, informed and supported as indicated by the appropriate legislation. All researchers are assessed in this regard based on relevant qualifications and experience before being granted access in any form.

Section 4 Summary of Analysis

Does the evidence show any potential to discriminate? If your answer is no – you need to give the evidence for this decision.

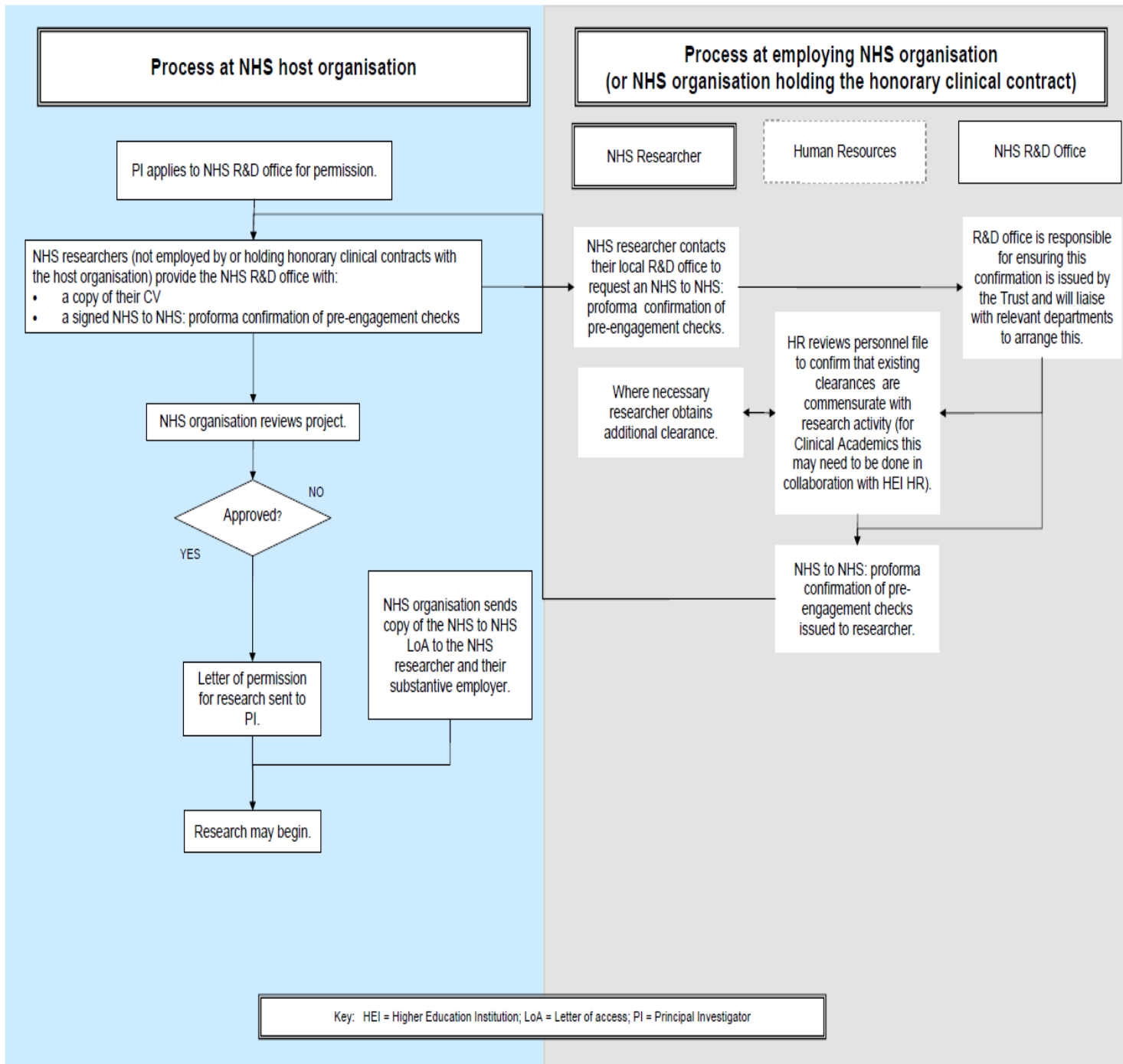
No – researchers assessed on qualifications in relation to trial specifics which have faced a separate review by R&D and the appropriate ethical review board

How does the policy **advance equality of opportunity?** researchers assessed only on qualifications in relation to trial specifics which have faced a separate review by R&D and the appropriate ethical review board

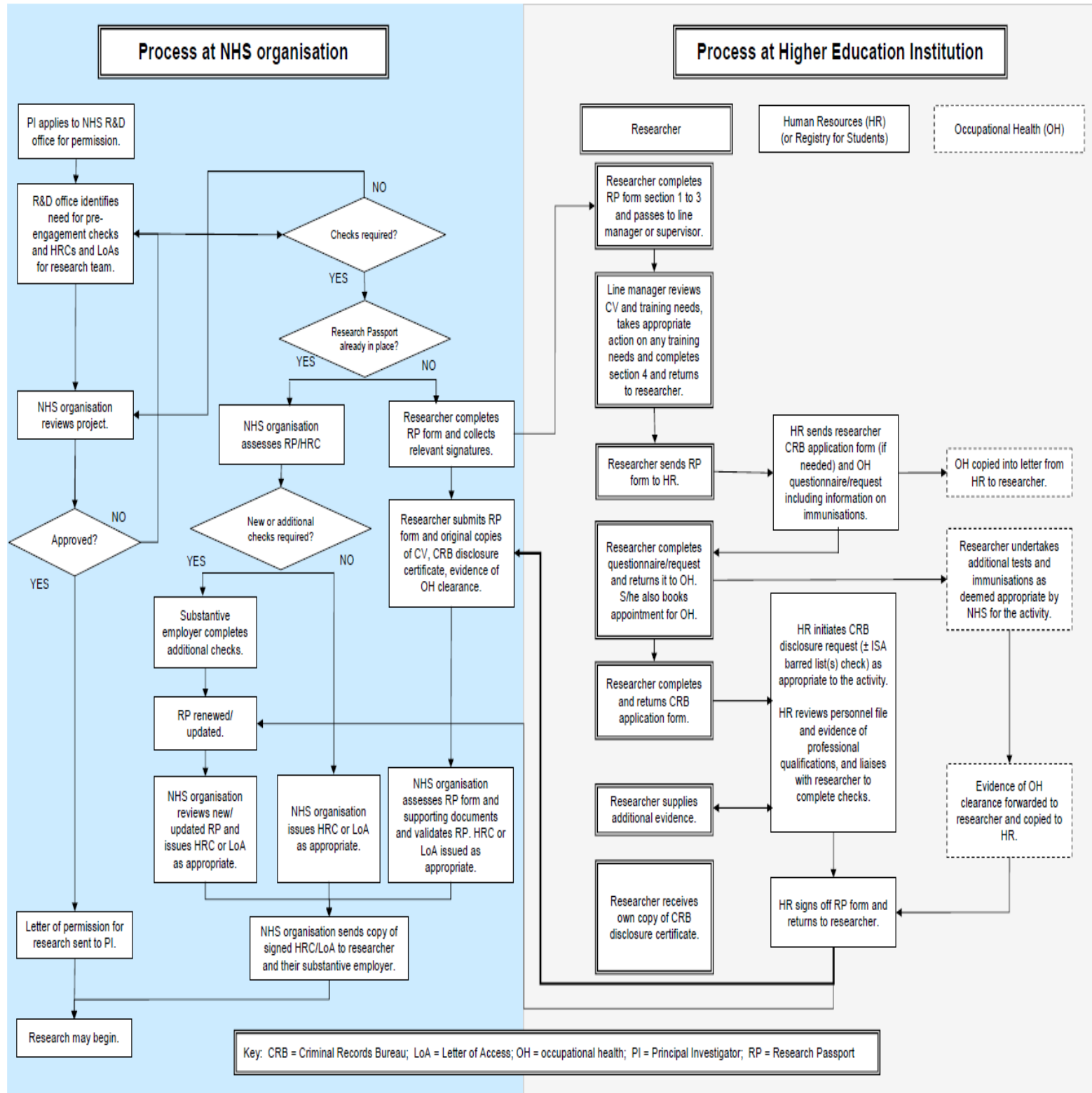
How does the policy **promote good relations between groups?** (Promoting understanding)
Researchers require proper qualifications to work with any particular group

Appendix 2:

NHS to NHS arrangements: all types of research



Appendix 3:
Research Passport system: research at one site



Appendix 4:
Research Passport system: research at more than one site

