1. **Introduction**

This document has been developed by R&D to guide you through the requirements for carrying out PhD, MD and MSc research projects within York Teaching Hospital (YTH), the essential documents and certificates required, how to obtain them and contact details for who to speak to.

Research within the NHS often relies on working in partnership with Higher Education Institutes (HEIs) and is frequently undertaken by non-NHS staff including staff employed by Universities and colleges. This calls for clear understanding about responsibility, accountability, patient safety and duty of care. All parties involved must be clear about their individual responsibilities and liabilities.

It is the responsibility of the researcher and the researcher’s substantive employer to provide and verify the necessary information regarding the researcher’s suitability to conduct research in the NHS.

1. **Researchers in the NHS**

Those involved in conducting and supporting research in the NHS fall into a number of categories:

* staff with substantive NHS employment contracts;
* researchers with a substantive university employment and an honorary NHS clinical contract, e.g. clinical academics;
* researchers with substantive university employment contracts and no honorary NHS clinical contract;
* researchers who are contracted to provide NHS services, e.g. GPs, who may or may not have a substantive university employment contract;
* researchers with substantive employment contracts with other employers, e.g. social workers;
* university undergraduate or postgraduate students (some of whom may also have substantive NHS employment contracts);
* researchers in any of the above categories conducting research where the participants are NHS staff.

**Different arrangements are required for each of these categories, and these are outlined in the Checklist in Section 5 and appendices A and B. Further guidance is also available on the York Teaching Hospitals website.**

[**https://www.research.yorkhospitals.nhs.uk/**](https://www.research.yorkhospitals.nhs.uk/)

**In particular please refer to R&D/S20 Application Process for an Honorary Contract, Letter of Access or Research Passport. To access York Teaching Hospital SOPs please follow the link below.**

[**York Hospitals NHS Foundation Trust Research & Development Unit - SOPs and Guidance**](https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/)

1. **Important points to remember before embarking on your project:**
* Be clear about what your job role is and what your specific contract allows you to do.
* Do you have the appropriate access in place in order to be able to do your job?
* Check what specific training (if any) you require in order for you to carry out your role and the requirements of the individual research project on which you will be working.
* It is imperative you are always identifiable to fellow staff members and patients alike. Where uniform is not compulsory wear appropriate clothing and wear your ID badge at all times.
* IT access can take some time to arrange. Please be mindful of this. If your role requires you to have access to the hospital electronic patient system (CPD) then please ensure R&D are aware as soon as possible so they can liaise with IT and arrange this for you.
* Please check with the individual department in which you will be working what their hot-desking policy is. Due to limited office/work space and staff turnover it may not always be possible for you to have a designated desk space. There are often free hot-desking spaces in R&D; these do however need to be booked in advance. So as soon as you know your rota and think that work space may be an issue for you then please contact R&D.
* If you need to use any kind of hospital equipment/machinery/scanners for your role then please work with the clinical team and the department staff to determine the best time for you to access the relevant equipment and specific room. Clinics are often very busy and it is imperative that both you and the clinical team have the necessary access at the appropriate time.
1. **Useful Links**
* Always follow the correct and current Standard Operating Procedures (SOPs) for the project you are working on.SOPs are standardised step by step instructions compiled by an organisation to help staff execute certain tasks. SOPs help to improve efficiency, quality of output and error while also ensuring compliance to regulations.

For all York Teaching Hospital SOPs please follow the link below:

[**York Hospitals NHS Foundation Trust Research & Development Unit - SOPs and Guidance**](https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/)

* In order to work in the Trust you will require the appropriate access (please refer to the algorithm in Appendix B, Table 2 to determine what access is required for the project you are undertaking). Please follow the link below to download the NHS to NHS proforma for Research Passport/LoA/HC and complete this with your supervisor as soon as possible in order to avoid delays in processing your application:

 [**https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#Research-Passport**](https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#Research-Passport)

* The Health Research Authority (HRA) looks after the interests and wellbeing of patients and public involved in health and social care research. The HRA Website is a useful tool as it gives in depth guidance on approving research, ethics applications, policy guidance, and research delivery.

 [**http://www.hra.nhs.uk/**](http://www.hra.nhs.uk/)

* The National Institute for Health Research (NIHR) fund health and care research in the UK helping to translate findings into practical treatment for patients. The NIHR ensures NHS organisations are able to support the research of other funders to encourage investment in health research and offer advice, training and development for researchers. The NIHR website has information on many areas that may be useful to you including funding and support for research projects, Good Clinical Practice (GCP) training, patient and public involvement (PPI) in research .

[**https://www.nihr.ac.uk/**](https://www.nihr.ac.uk/)

1. **Student Checklist**

**It is advisable that you and your supervisor work through the checklist below at least one month before you are due to start at the Trust**

Your R&D contact is Mia Porteous – 01904(72)5129 Email: mia.porteous@york.nhs.uk

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| --- | --- | --- |
| **Before you begin:****Section 1. The following section are the absolute essentials required for working in the Trust** | **Apply to (if applicable):** | **Please circle:** |
| **You will need this if you:**1. **Have no contractual relationship with the NHS**
2. **Have no Honorary Contract with the NHS**
3. **Your research is not part of a healthcare placement**

**Research Passport (if applicable):**Single or multiple projects:Downloadable form:https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#Research-Passport | Substantive employer | Y N N/A  |
| **If you have a substantive NHS contract, an Honorary Contract with an NHS Trust or are conducting your research as part of a placement, you will require one of the following depending on the nature of the research you are undertaking.****Please refer to the Research Passport Algorithm in Appendix 1 and 2 to determine what access you require. This clarifies what interventions and access to patient information requires which contractual agreement and whether you will need a HC or LoA. Further guidance is also available on the YTH Website:** **R&D/S20 Application Process for an Honorary Contract, Letter of Access or Research Passport.** [**York Hospitals NHS Foundation Trust Research & Development Unit - SOPs and Guidance**](https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/)**Letter of Access OR****Honorary Contract (if applicable):**(Download proforma and complete with your supervisor as above) | YTH | Y N N/AY N N/A  |
| **DBS (Disclosure and Barring Service – previously CRB)****NB: If using a Research Passport this includes OH clearance, if not please ask your employer to provide this information** | Employer | Y N N/A  |
| **Occupational Health Check (if applicable):****NB: If using a Research Passport this includes OH clearance, if not please ask your employer to provide this information** | Employer | Y N N/A  |
| **For granting access to all Trust IT systems please liaise with your R&D contact at the Trust.****IT Access:****CPD (electronic patient database) access:****User Access form completed:**  | YTH R&D  | Y N N/AY N N/AY N N/A |
| **Please liaise with your R&D contact****Photo ID (form completed):****Date of appointment:** | YTH R&D | Y N N/A  |
| **Please liaise with your R&D contact****ID Badge (if required):****Date ordered:** | YTH R&D | Y N N/A  |
| **Please liaise with your Trust/Department supervisor****Uniform (if required):** |  Department | Y N N/A  |
| **Please liaise with your R&D contact if you require GCP training****Good Clinical Practice (GCP):****Date completed:****(GCP must be updated every 3 years for YTH)****Date of future GCP training:** | YTH R&D (if not already completed) |  Y N N/A  |
| **CV emailed to R&D contact:****(Research CVs are required annually by YTH. R&D can provide a template if required)****Name and contact details of primary R&D contact:** **Mia Porteous - Clinical Trial Manager, LaRC R&D Unit, YTH****mia.porteous@york.nhs.uk****Tel:01904** **(72)5129** | Student toprovide | Y N N/A  |
| **Please provide a copy your current training record to your R&D contact. You will also be provided with a Trust training log to complete for the duration of your work with the Trust.****Training Record:** | Student to provide | Y N N/A  |
|  |

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| --- | --- | --- |
| **Induction:** | **Apply to (if applicable):** | **Please circle:** |
| **Mandatory Trust Induction:****Date of induction:** | YTH R&D | Y N N/A  |
| **R&D induction:**Comments: | YTH R&D | Y N N/A  |
| **Labs induction (if applicable):**Comments: | YTH R&D |  Y N N/A  |
| **Pharmacy induction (if applicable):**Comments: | YTH R&D |  Y N N/A   |
| **Study Specific Training:**Comments: | Study Specific – check with R&D and line manager | Y N N/A  |
| **Department/Directorate induction:**Comments: | Study Specific – check with R&D and line manager | Y N N/A  |
| **Equipment (if applicable):**Comments: | Study Specific – check with R&D and line manager | Y N N/A  |
| **Patient specific training:** | Study Specific – check with R&D and line manager | Y N N/A  |
| **Patients lacking capacity:**Type of training:Date completed: | Study Specific – check with R&D and line manager | Y N N/A  |
| **Children or vulnerable adults:**Type of training:Date completed: | Study Specific – check with R&D and line manager | Y N N/A  |
| **Patients with learning difficulties:**Type of training:Date completed: | Study Specific – check with R&D and line manager | Y N N/A  |
| **Patient with disabilities:**Type of training:Date completed: | Study Specific – check with R&D and line manager | Y N N/A  |
| **Further training needs identified:(please specify)** | Study Specific – check with R&D and line manager | Y N N/A  |

**Appendix A: Table 1 Summary of forms of contractual arrangement available for individuals undertaking research in the NHS**

|  |  |
| --- | --- |
| **Forms of contractual****arrangement that can be****issued to cover research****activity** | **Substantive Employer** |
| HESubstantiveEmployer | SubstantiveHE withHonoraryClinical NHSContract(ClinicalAcademic) | HE Studentnot on aformalhealthcareplacement | HE Student ona formalhealthcareplacement | NHSSubstantiveEmployee | IndependentContractor e.g.GP | CommercialResearcher | CommercialResearcherunder contractto HE (non-commercialresearch) |
| HC | YES | NO | YES | NO | NO | NO | NO | YES |
| LoA accepting an HC | YES | NO | YES | NO | NO | NO | NO | YES |
| LoA (no HC required) | YES | NO | YES | NO | NO | NO | NO | YES |
| NHS to NHS LoA | NO | YES | NO | NO | YES | NO | NO | NO |
| Service Level Agreement | NO | NO | NO | NO | NO | NO | YES | NO |
| Healthcare PlacementAgreement | NO | NO | NO | YES | NO | NO | NO | NO |
|  |
| Is a Research Passportneeded? | YES | NO | YES | NO | NO | NO | NO | YES |

***Table 1 taken from “Research in the NHS: HR Good Practice Resource Pack, HR Good Practice: Information for researchers, R&D and HR staff in Higher Education Institutions and the NHS” version 2.1, September 2012***

**Appendix B: Table 2: Research Passport Algorithm**

|  |  |  |  |
| --- | --- | --- | --- |
| **Activity** | **Criminal Record Check****necessary?** | **Occupational Health****Clearance necessary?** | **LoA or HRC** |
| Researcher is a healthcare professional providinghealth care to an adult and/or child | Yes, if done once this is regulatedactivity (new definition). Requiresenhanced CRB +appropriatebarred list check. | Yes, if there is direct contact | HRC |
| Researcher provides healthcare to an adult and/orchild under the direction or supervision of a healthcareprofessional | Yes, if done once this is regulatedactivity (new definition). Requiresenhanced CRB +appropriatebarred list check. | Yes, if there is direct contact | HRC |
| Researcher provides personal care to an adult of childORResearcher is a social care worker providing socialwork which is required in connection with any healthcare or social services to an adults who is a client or potential client | Yes, if done once this is regulatedactivity (new definition). Requiresenhanced CRB +appropriatebarred list check. | Yes, if there is direct contact | HRC |
| Researcher undertakes the following activities unsupervised: teach, train, instruct, care for or supervisechildren, or provide advice/guidance on wellbeing, ordrive a vehicle only for children; with likely directbearing on the quality of care | Yes, if done once this is regulatedactivity (new definition). Requiresenhanced CRB + barred list check | Yes, if there is direct contact | HRC |
| Researcher has opportunity for any form of contactwith children in the same children’s hospital(formally aspecified place) but is not providing healthcare orother types of regulated activity and has no directbearing on the quality of care | Yes, if done regularly enhancedCRB (pre Sept 2012 definition). Nobarred list check. | Yes, if there is direct contact | LoA |
| Researcher has access to persons in receipt ofhealthcare services in the course of their normalduties but is not providing health care or other types of regulated activity and has no direct bearing on thequality of care (Access relates to where individuals willhave physical, direct contact with patients e.g.observation, qualitative interviews, focus groups…) | Yes, standard | Yes, if there is direct contact | LoA |
| Researcher has indirect contact with patients orservice users but is not providing healthcare or othertypes of regulated activity and has no direct bearingon the quality of care (e.g. some types of telephoneinterview) | No | No | LoA |
| Researcher requires access to identifiable patientdata derived from health records, tissues or organs with the likely direct bearing on the quality of care | No | Yes, only if working with tissuesor organs in NHS facilities | HRC |
| Researcher requires access to identifiable patientdata derived from health records, tissues or organswith no direct bearing on the quality of care | No | Yes, only if working with tissuesor organs in NHS facilities | LoA |
| Researcher requires access to anonymised patientdata derived from health records, tissues or organsonly (including by research staff analysing data) | No | Yes, only if working with tissuesor organs in NHS facilities | LoA(only ifreviewed inNHS facilities) |
| Researcher is working on NHS premises (e.g.Laboratory) only (no access to identifiable data | No | Yes, only if working with tissuesor organs in NHS facilities | LoA |
| Researcher requires direct contact with staff only butno access to patients (e.g. staff interviews) | No | No | LoA (if in NHSFacilities) |
| Researcher requires access to identifiable staff dataonly | No | No | LoA (if in NHSFacilities) |
| Researcher requires access to anonymised staff dataonly | No | No | LoA (if in NHSFacilities) |

*Table 2 taken from “Research in the NHS- HR Good Practice Resource Pack, The Research Passport: Algorithm of Research Activity and Pre-*

*Engagement Checks”, Version 3.0, September 2012*