Dorset HealthCare University NHS Foundation Trust

Standard Operating Procedure for Research Passports, Honorary Research Contracts and Letters of Access

Objectives	The aim of this SOP is to define the procedure for issuing honorary research contracts and letters of access to researchers external to the Trust.
Scope	Research & Development Department at Dorset HealthCare
Responsibility	It is the responsibility of the Research & Development Facilitator to ensure that this SOP is adhered to.
Related Document	Research in the NHS – HR Good Practice Resource Pack.

1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure that all staff involved in the preparation, administration and issue of Honorary Research Contracts (HRC) and Letters of Access (LoA) are aware of the process and how this is carried out.

2 Introduction

Research in Dorset HealthCare (DHC) is often undertaken in partnership with other NHS Trusts and with Higher Education Institutions (HEI). Current national guidelines call for a clear understanding about responsibility, accountability, patient safety, and duty of care in relation to research. One of the ways that this can be achieved is through the use of Research Passports, Honorary Research Contracts and Letters of Access.

2.1 Definitions

- **Research Passport**

  The Research Passport is the standard form which provides information about a non-NHS researcher, including evidence of the pre-engagement checks that have already been conducted by the substantive employer. This enables the NHS Trust hosting the research to issue an HRC or a LoA.

- **Honorary Research Contract**

  The HRC permits access to patients (excluding patient records) and confirms responsibilities of a researcher who has no contractual relationship with the NHS. An HRC is only issued if the planned activities of the researcher involve interacting with individuals in a way that has a direct bearing on the quality of their care.

- **NHS to NHS Confirmation of Pre-engagement Check**

  This is the standard form which provides information about a NHS researcher, including confirmation of pre-engagement checks that have already been conducted.

  This enables the NHS Trust hosting the research to issue a LoA. This form is completed by the researcher's employer.

- **Letter of Access (Non-NHS)**

A LoA is the standard letter permitting access to patients and confirming the responsibilities of a researcher who has no contractual relationship with the NHS and does not need an HRC.

- **Letter of Access (NHS)**

  This LoA is the standard letter permitting access to patients and confirming the responsibilities of a researcher who is either an employee of another NHS Trust or holds an honorary clinical contract with another NHS Trust.

3 Training

New users must read and understand this SOP before participating in clinical trials. Existing users must read and understand the Revisions Section.

4 Revisions

This is the second version of this SOP.

5 Procedure

The procedure for an external researcher to gain access to DHC for research will vary depending on the researcher's employment status and the nature of the project. The processes involved are detailed in the Research in the NHS – HR Good Practice Resource Pack.

5.1 Pre-engagement Checks

Pre- engagement checks are determined by Trust procedure and the nature of the research project following the algorithm in the Research in the NHS –HR Good Practice Resource Pack.

The R&D department will accept Occupational Health clearance given by another NHS organisation, or other substantive employer provided that the clearance was at the level required by the research. The R&D department will confirm that the NHS to NHS pre-engagement checks for NHS employees/clinical academics has been accurately completed and received. For non-NHS employees the R&D department will confirm that the relevant section of the Research Passport has been completed and appropriate evidence has been supplied.

For criminal record checks the R&D department will accept a Disclosure Barring Service (DBS) clearance requested by another NHS organisation or other substantive employer provided that the clearance was at the level required by the research and was issued less than 12 months prior to the validation of the Research Passport. Individuals whose research activity is concerned with the provision of health services and is of such a kind as to enable the researcher to have access to persons in receipt of such services in the course of their normal duties are required to provide a standard DBS. Individuals, whose research involves regulated activity as defined by the Safeguarding Vulnerable Groups Act 2006, are required to provide an enhanced DBS with checks against the relevant Independent Safeguarding Authority (ISA) barred list(s).

The Trust retains the right to request any additional pre-engagement checks or evidence it considers necessary in line with its legislative entitlements.

5.2 ID Badges and Access

Researchers with HRCs will be issued with an ID badge which must be worn whilst on Trust property.

If a researcher requires access to patient records as part of the research project, the researcher must hold an HRC and via their nominated manager should apply to the appropriate Trust department for access to records and systems.

5.3 Renewal or Termination of HRC or LoA

Researchers must notify the R&D department when they complete the research or when there are any changes in their circumstances (e.g. health, employment status).

Where researchers wish to extend their contract or access arrangements, review of the initial pre-engagement checks should be carried out and consideration be given to any checks being repeated in line with current national legislation.

On termination of the contractual or access arrangements, access to the Trust and its associated data systems must cease.

The Trust reserves the right to terminate access to the Trust including data systems and patients.

5.4 Further Provisions

- The substantive employers will retain responsibility for other research activities that do not affect the Trust's duty of care to a participant e.g. study management, data entry.
- HRCs do not provide a mechanism for access to confidential patient information without consent from the participant. The necessary regulatory approvals must be in place to access data without consent.
- Before issuing an HRC or LoA, the R&D department will verify that an identified Trust Manager, who is to provide managerial supervision for the research activity, is in place.
- HRCs and LoA will not be issued for a period that will exceed the remainder of the life of the researchers' substantive contract, the researcher's right to reside and work in the UK or 3 years after the DBS was issued.
- All HRC and LoA are copied to the substantive employer
- The R&D department will maintain an electronic record of HRCs and LoA.

6 Appendices

There are no appendices to this SOP.

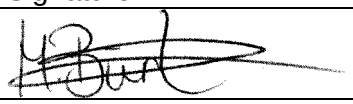
7 Responsibilities

It is the responsibility of the Research & Development Facilitator to ensure that this SOP is adhered to.

8 Review

This SOP should be reviewed every two years unless new guidance or legislation dictates a review any sooner.

Date reviewed: 12/04/2019 Date of next review: 12/04/2021

Written By	Signature	Date
Hazel Burt		12/04/2019
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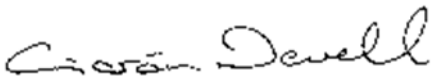
Dr Ciarán Newell		12/04/2019
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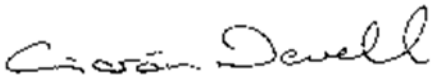
Dr Ciarán Newell		12/04/2019