Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

# Recording of Research Information in Patient Paper Case Notes

**This procedural document supersedes: CORP/COMM 17 v.3 - Recording of Research Information in Patient Case Notes**

**Did you print this document yourself?**

The Trust discourages the retention of hard copies of policies and can only guarantee that the policy on the Trust website is the most up-to-date version. **If, for exceptional reasons, you need to print a policy off, it is only valid for 24 hours.**

| | |
|---|---|
| Executive Sponsor(s): | Zoe Lintin, Chief People Officer |
| Author/reviewer: (this version) | Emma Adams – Research Management and Governance Manager |
| Date written/revised: | 24 March 2023 |
| Approved by: | Research & Innovation Committee |
| Date of approval: | 24 March 2023 |
| Date issued: | 24 March 2023 |
| Next review date: | March 2026 |
| Target audience: | Trust-wide |

# Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

| Version | Date Issued | Brief Summary of Changes | Author |
|---|---|---|---|
| Version 4 | March 2023 | • Minor changes only | Emma Adams |
| Version 3 | January 2016 | • Removal of communication page appendix<br>• Other minor changes to text | Emma Hannaford |
| Version 2 | January 2012 | • Amended process for studies where the only clinical intervention is the collection of a single tissue sample.<br>• Introduction of process for non-interventional studies.<br>• Clarification of process for studies where treatment is provided at an external NHS site but follow up is undertaken within DBTH. | Emma Hannaford |
| Version 1 | August 2010 | This is a new procedural document, please read in full | Emma Hannaford |

# Contents

**Page No.**

# 1 INTRODUCTION

This Policy details the procedure for recording research information in patient paper case notes for patients enrolled onto a research study, taking place within Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust (DBTH).

This Policy has been developed in accordance with the UK Policy Framework for Health and Social Care Research 2020 and the Medicines for Human Use (Clinical Trials) Regulations 2004 [and all subsequent amendments].

# 2 PURPOSE

This Policy:

- Outlines the process for documenting when patients are enrolled onto a research study, which makes them easily identifiable
- Outlines the process for clearly defined communication pathways should a patient enrolled onto an interventional research study be involved in an unexpected event.
- Details how to identify duration for which patient case notes should be retained, following a patient enrolling on a research study.

For the purpose of this Policy, an interventional study as defined by Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust is a study that falls into one or more of the following categories:

- Clinical trials of investigational medicinal products (CTIMPs) falling within the scope of the EU Clinical Trials Directive and the Medicines for Human Use (Clinical Trials) Regulations 2004
- Clinical trials or clinical investigations including but not limited to surgery, radiotherapy, imaging investigations, physiological investigations, mental health investigations or therapies and complementary or alternative therapies
- Studies involving medical devices as detailed in the Medical Devices (Amendment) Regulations 2007
- Studies involving the use of new human tissue sample or other human biological samples (other than those detailed below)

For the purpose of this Policy, a non-interventional study as defined by Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust is a study that falls into one or more of the following categories:

- Studies involving non-invasive approaches such as surveys, education and interviews
- Studies where the only clinical intervention is the collection of a single tissue sample

An unexpected event within research is defined as:

- Suspected Unexpected Serious Adverse Reactions (SUSAR)
- Serious Adverse Events (SAE) or Serious Adverse Reaction (SAR)

Full definitions are provided in the following section.

## 3 DEFINITIONS

**R&I** - Research and Innovation

**IRAS** - Integrated Research Application System (www.myresearchproject.org)

**Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR):** Any untoward medical occurrence or effect that at any dose results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.

**Suspected Unexpected Serious Adverse Reactions (SUSAR):** Any serious unexpected adverse reaction that:

a. Results in death,
b. Is life-threatening,
c. Requires hospitalisation or prolongation of existing hospitalisation,
d. Results in persistent or significant disability or incapacity, or
e. Consists of a congenital anomaly or birth defect

Important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed in the definition above should also be considered serious.

## 4 DUTIES AND RESPONSIBILITIES

All those who host, participate, undertake or are managing research regardless of their status within the Trust, including the following:

- all Trust employed staff
- independent contractors
- all learners
- all staff employed elsewhere covered by a Trust-issued Letter of Access or Honorary Research Contract

This policy is applicable to all research involving Trust premises or staff, NHS patients to whom the Trust has a duty of care, patient material, or patient data, conducted by Trust employees, independent contractors and other non- employees. This policy is of relevance to clinical research activity, but instead applies equally to all research.

# 5 PROCEDURE

## 5.1 Interventional research in scope of EC Directives for Clinical Trials/Medical Devices

Patients recruited onto these studies will be flagged on CAMIS to state they are taking part in a clinical trial. This will be carried out by a member of the R&I team, unless otherwise communicated during study setup.

The Principal Investigator (or delegated member of study team) should ensure the following is recorded in patient case notes once an eligible patient has been identified, recruited and consented onto an interventional study:

- Place a study notification sticker (identified by top line with 'This patient is on a trial of:') on the Alert/Hazard Notification page of the patient medical records. Study notification stickers should be obtained from the Research Governance office prior to first patient consent and as required thereafter.

The following information must be entered in the relevant fields:

- Details of the interventional study the patient is enrolled onto (in the case of Clinical Trials with Investigational Medicinal Products (CTIMPs) this should include the study drug).
- Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust reference number assigned to the study by the Research and Innovation (R&I) Department.
- The date which the patient consented to their participation in the study.
- Name and contact details of the Principal Investigator and a note that if out of office, advised to contact on call consultant in the relevant department to the study.
- Date to retain medical notes until, as stated in Study Protocol or IRAS Form.

- Create an easily identifiable research section where all relevant research related documentation should be filed. Two "research" A4 red index cards (obtained from the (R&I) Department) must be inserted in the current episode of care under the consultant whose department is leading on the study (e.g. for a renal study, under the patient's renal consultant). The required information on the front red card should be completed.

Within this section, between the two red index cards, the following must be filed:

- Signed and dated consent form, updated if amendment to approved documents dictates.
- Participant Information Sheet, updated if amendment to approved documents dictates.
- Letters and correspondence between study team and the patients GP, updated when appropriate.
- Schedule of study visits (template available in Appendix 1). This document should be updated at every patient visit until the patient withdraws or completes the

study and should record the study visit number and summarise all clinical interventions undertaken at each visit for the purpose of the study protocol. Note - this is not a requirement for single visit studies.
- Trust "Variables, Treatment and Continuation" sheet(s) recording contemporaneous written records of each study visit. This document should be updated at every patient visit until the patient withdraws or completes the study.
- All available documentation relating to any unexpected events the patient has encountered whilst participating in the research study. This information should be recorded in accordance with the outlined procedure in the Study Protocol and relevant R&I safety Standard Operating Procedures (SOPs).
- Deviations to protocol (where appropriate). This information should be recorded in accordance with the outlined procedure in the Study Protocol and relevant R&I safety SOPs. A Datix incident report should also be completed, where applicable.

In the event of a patient death whilst enrolled onto an interventional study, staff members are advised to follow normal Trust procedures.

The above process should be followed for interventional research studies where treatment is provided at an external research site. A note should be added to the 'Schedule of study visits' page to state the date treatment commenced at an external research site.

## 5.2 Interventional research not in scope of EC Directives for Clinical Trials/Medical Devices

Recommended best practice for the recording of research information in patient medical records for patients enrolled onto such interventional studies is for the Principal Investigator (or delegated member of study team) to ensure the following is recorded once an eligible patient has been identified, recruited and consented:

- Place a study notification sticker (sticker identified by top line with 'This patient is on a trial of:') on the Alert/Hazard Notification page of the patient case notes. Study notification stickers should be obtained from the Research Governance office prior to first patient consent and as required thereafter.

  The following information must be entered in the relevant fields:
  - Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust reference number assigned to the study by the Research Governance team at the time of submission.
  - Name of Principal Investigator and contact details for further information.
  - Date to retain medical notes until, as stated in Study Protocol or IRAS Form.

- Create an easily identifiable research section where all relevant research related documentation should be filed. Two "research" A4 red index cards (obtained from the Research Governance office) must be inserted in the current episode of care

under the consultant whose department is leading on the study (e.g. for a renal study, under the patient's renal consultant).

Within this section, between the two red index cards, the following must be filed:
- Signed and dated consent form, updated if amendment to approved documents dictates
- Participant Information Sheet, updated if amendment to approved documents dictates
- Deviations to protocol (where appropriate). This information should be recorded in accordance with the outlined procedure in the Study Protocol and relevant R&I safety SOPs. A Datix incident report should also be completed, where applicable.

In the event of a patient death whilst enrolled onto an interventional study, staff members are advised to follow normal Trust procedures.

## 5.3 Non-interventional research studies

Recommended best practice for the recording of research information in case notes for patients enrolled onto non-interventional studies is for the Principal Investigator (or delegated member of study team) to ensure the following is recorded once an eligible patient has been identified, recruited and consented onto a non-interventional study:

- Place a study notification sticker (sticker identified by top line with 'This patient is on a non-interventional research study:') on the Alert/Hazard Notification page of the patient case notes. Study notification stickers should be obtained from the Research Governance office prior to first patient consent and as required thereafter.

  The following information must be entered in the relevant fields:
  - Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust reference number assigned to the study by the Research Governance team at the time of submission.
  - Name of Principal Investigator and contact details for further information.
  - Date to retain medical notes until, as stated in Study Protocol or IRAS Form.

- Create an easily identifiable research section where all relevant research related documentation should be filed. Two "research" A4 red index cards (obtained from the Research Governance office) must be inserted in the current episode of care under the consultant whose department is leading on the study (e.g. for a renal study, under the patient's renal consultant).

  Within this section, between the two red index cards, the following must be filed:
  - Signed and dated consent form, updated if amendment to approved documents dictates
  - Participant Information Sheet, updated if amendment to approved documents dictates

- Trust "Variables, Treatment and Continuation" sheet(s) recording contemporaneous written records of each study visit. This document should be updated at every patient visit until the patient withdraws or completes the study.

Please note that the Schedule of Study Visits (template available in Appendix 1) is not applicable in this instance.

In the event of a patient death whilst enrolled onto a non-interventional study, staff members are advised to follow normal Trust procedures.

## 6 TRAINING/SUPPORT

The level of information, instruction and training given to staff will be appropriate to the scale of research activity within the Trust and appropriate to their roles within it. Any courses (for example Good Clinical Practice) can be coordinated through the Research & Innovation Department. A record of the training undertaken by Trust-employed staff will be maintained within the R&I department.

All staff will have access to relevant policies and Standard Operating Procedures, as well as access formalised Trust Research and Innovation training sessions as they are rolled out in accordance with the Trust Research and Innovation Strategy. Standard Operating Procedures are available on the Research & Innovation page of the Trust Intranet and also the external website http://www.doncasterclinicalresearch.org/.

## 7 MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

| What is being Monitored | Who will carry out the Monitoring | How often | How Reviewed/ Where Reported to |
|---|---|---|---|
| Inclusion of research section in notes for research-active patients | Research Management & Governance Manager | 10% of all participants on Trust-sponsored studies on an annual basis | Research & Innovation Committee |

## 8 EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment for All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and, if possible, remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation, or religious belief. No detriment was identified. (See Appendix 2)

## 9 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

There are a number of related policies within the Trust which should be read in conjunction with this policy, these include:

- CORP/RISK 13 – Policy for the Reporting and Management of Incidents and Near Misses
- CORP/RISK 15 – Serious Incidents (SI) Policy
- CORP/ICT 9 – Information Governance Policy
- CORP/REC 5 – Clinical Records Policy

## 10 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR) 2021.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

## 11 REFERENCES


- Trust R&I Strategy
- Health and Safety at Work Act (1974)
- NHS R&I Forum RM&G Toolkit (Version: March 2005)
- Policy on Adverse Event and Near Miss Management
- UK Policy Framework for health and Social Care Research
- The Mental Capacity Act 2005
- Medicines for Human Use (Clinical Trials) Regulations 2004
- Medicines for Human Use (Clinical Trials) Amendment Regulations 2006
- Research in the NHS – HR Good Practice Resource Pack available from the National Institute for Health Research http://www.nihr.ac.uk/policy-and-standards/research-passports.htm

# APPENDIX 1 – SCHEDULE OF STUDY VISITS

Affix patient label here

**Schedule of Study Visits -** to be updated at every patient visit until the patient withdraws or completes the study. **Page No……**

| Date | Person Entering Record | Visit Number (refer to protocol) | Study Procedures |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

# APPENDIX 2 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

| Service/Function/Policy/Project/ Strategy | Division | Assessor (s) | New or Existing Service or Policy? | Date of Assessment |
|---|---|---|---|---|
| Recording of Research Information in Patient Paper Case notes | Research & Innovation (R&I) | Emma Adams, Research Management & Governance Manager | Existing Policy | 24 March 2023 |

**1) Who is responsible for this policy?** Name of Division/Directorate: Research and Innovation (R&I) part of Education and Research Directorate

**2) Describe the purpose of the service / function / policy / project/ strategy?** Who is it intended to benefit? What are the intended outcomes? This policy is to ensure there is consistency and compliance in recording research information in patient case notes

**3) Are there any associated objectives?** Legislation, targets national expectation, standards:
The Policy has been developed in accordance with the UK Policy Framework for health and Social Care Research and the Medicines for Human Use (Clinical Trials) Regulations 2004 [and all subsequent amendments] to ensure that the Trust acts in accordance with the relevant legislation underpinning clinical research.

**4) What factors contribute or detract from achieving intended outcomes?** – There are no anticipated factors that will detract from achieving the intended outcomes

**5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief?** Details: [see Equality Impact Assessment Guidance] - No

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation] – Not applicable

**6) Is there any scope for new measures which would promote equality?** [any actions to be taken]

**7) Are any of the following groups adversely affected by the policy?**

| Protected Characteristics | Affected? | Impact |
|---|---|---|
| a) Age | No | This policy has no specific impact on any particular group, and applies across the board to all staff equally |
| b) Disability | No | This policy has no specific impact on any particular group, and applies across the board to all staff equally |
| c) Gender | No | This policy has no specific impact on any particular group, and applies across the board to all staff equally |
| d) Gender Reassignment | No | This policy has no specific impact on any particular group, and applies across the board to all staff equally |
| e) Marriage/Civil Partnership | No | This policy has no specific impact on any particular group, and applies across the board to all staff equally |
| f) Maternity/Pregnancy | No | This policy has no specific impact on any particular group, and applies across the board to all staff equally |
| g) Race | No | This policy has no specific impact on any particular group, and applies across the board to all staff equally |
| h) Religion/Belief | No | This policy has no specific impact on any particular group, and applies across the board to all staff equally |
| i) Sexual Orientation | No | This policy has no specific impact on any particular group, and applies across the board to all staff equally |

**8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box**

| | | | |
|---|---|---|---|
| **Outcome 1 ✓** | **Outcome 2** | **Outcome 3** | **Outcome 4** |

**If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form – see CORP/EMP 27.**

| | | | |
|---|---|---|---|
| **Date for next review:** | **March 2026** | | |
| **Checked by:** | **Emma Adams** | **Date:** | **24 March 2023** |