



*Please Note: This policy is currently under review and is still fit for purpose.*

# Recording of Research Information in Patient Casenotes

This procedural document supersedes: CORP/COMM 17 v.2 - Recording of Research Information in Patient Casenotes



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Author/reviewer: (this version)	Emma Hannaford - Research Management & Governance Manager
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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 3	14 January 2016	<ul style="list-style-type: none"> <li>Removal of communication page appendix 1</li> <li>Other minor changes to text</li> </ul>	Emma Hannaford
Version 2	January 2012	<ul style="list-style-type: none"> <li>Amended process for studies where the only clinical intervention is the collection of a single tissue sample.</li> <li>Introduction of process for non-interventional studies.</li> <li>Clarification of process for studies where treatment is provided at an external NHS site but follow up is undertaken within DBHft.</li> </ul>	Emma Hannaford
Version 1	August 2010	<ul style="list-style-type: none"> <li>This is a new procedural document, please read in full</li> </ul>	Emma Hannaford

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## 1. INTRODUCTION

This Policy details the procedure for recording research information in patient casenotes for patients enrolled onto a research study, taking place within Doncaster and Bassetlaw Hospitals NHS Foundation Trust.

This Policy has been developed in accordance with the Research Governance Framework 2005 and the Medicines for Human Use (Clinical Trials) Regulations 2004 [and all subsequent amendments].

## 2. PURPOSE

This Policy:

- Ensures patients who are enrolled onto an interventional research study are easily identifiable.
- Ensures there are clearly defined communication pathways should a patient enrolled onto an interventional research study be involved in an unexpected event.
- Provide details of a revised process for patients enrolled onto an interventional research study, where the only clinical intervention is the collection of a single tissue sample.
- Provides details of a revised process for patients enrolled onto an interventional research study where treatment is provided at an external NHS site, but follow up is undertaken within DBHft.
- Recommends best practice for the recording of research information in casenotes where a patient is enrolled onto a non-interventional research study.
- Ensures the duration for which patient casenotes should be retained is clearly detailed.

## 3. DUTIES AND RESPONSIBILITIES

This Policy is applicable to:

- All employees of Doncaster & Bassetlaw Hospitals NHS Foundation Trust
- Employees of external organisations who hold a letter of access/honorary contract with Doncaster & Bassetlaw Hospitals NHS Foundation Trust for the purpose of research.

## 4. PROCEDURE

### 4.1 Interventional research studies which fall within scope of EC Directives for Clinical Trials or Medical Devices

The Principal Investigator (or delegated member of study team) should ensure the following is recorded in patient casenotes 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 CTIMPs this should include the study drug).
  - Doncaster and Bassetlaw Hospitals NHS Foundation Trust reference number assigned to the study by the Research Governance team at the time of submission.
  - 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 R&D 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.
- 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.
- 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&D 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&D 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.

## **4.2 Interventional research studies which DO NOT fall within scope of EC Directives for Clinical Trials or 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 casenotes. 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 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 R&D 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&D 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.

### 4.3 Non-interventional research studies

Recommended best practice for the recording of research information in casenotes 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 casenotes. 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 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 R&D 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.

### 4.4 Interventional research studies where treatment is provided at an external NHS site, but follow up is undertaken within DBHft

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

- 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 casenotes. 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 CTIMPs this should include the study drug).
  - Doncaster and Bassetlaw Hospitals NHS Foundation Trust reference number assigned to the study by the Research Governance team at the time of submission.
  - 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 call switchboard and be put through to on call consultant in the relevant department to the study.
  - Date to retain medical notes until, as stated in Study Protocol or IRAS R&D 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.
- Letters and correspondence with the patients GP, and team providing study treatment
- Schedule of study visits (template available in Appendix 1). This document should be updated at every patient visit at this site until the patient withdraws or completes the study and should record the study visit number and all clinical interventions undertaken at each visit for the purpose of the study protocol. It should be recorded on this form when the patient starts receiving study visits at sites outside Trust, because relevant research records relating to these visits will be recorded in external NHS sites medical records.
- Trust "Variables, Treatment and Continuation" sheet(s) recording contemporaneous written records of each study visit. This document should be updated at every patient visit at this site 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&D safety SOPs.
- Deviations to protocol (where appropriate). This information should be recorded in accordance with the outlined procedure in the Study Protocol and relevant R&D 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. 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 & Development Department. A record of the training undertaken by Trust-employed staff will be maintained within the R&D department.

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

## 6. MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Audit of casenotes (random sample)	Research Governance team	Quarterly basis	Breaches addressed through the Trust's disciplinary policy and procedure

## 7. DEFINITIONS

For the purpose of this Policy, an interventional study as defined by Doncaster and Bassetlaw 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 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  
*(Please note that although these are actually interventional, due to their extremely low risk associated there is no clinical follow-up is required for these patients)*

For the purpose of this Policy, an unexpected event as defined by Doncaster and Bassetlaw Hospitals NHS Foundation Trust covers the following:

- Suspected Unexpected Serious Adverse Reactions (SUSAR)
- Serious Adverse Events (SAE)

**R&D** - Research and Development

**IRAS** - Integrated Research Application System ([www.myresearchproject.org](http://www.myresearchproject.org))

## 8. EQUALITY IMPACT ASSESSMENT

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/COMM 14 – Research Governance Policy
- 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. REFERENCES

- Trust R&D Strategy
- Health and Safety at Work Act (1974)
- NHS R&D Forum RM&G Toolkit (Version: March 2005)
- Policy on Adverse Event and Near Miss Management

- Research Governance Framework for Health and Social Care, Department of Health, first edition, 2002
- Research Governance Framework for Health and Social Care, Department of Health, second edition, March 2005
- 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	CSU/Executive Directorate and Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Research Governance Policy	Research & Development	Emma Hannaford Research Management & Governance Manager	Existing Policy	11 November 2015
<b>1) Who is responsible for this policy?</b> Name of CSU/Directorate Research and Development				
<b>2) Describe the purpose of the service / function / policy / project/ strategy?</b> 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 casenotes				
<b>3) Are there any associated objectives?</b> Legislation, targets national expectation, standards <ul style="list-style-type: none"> <li>All research receives Trust approval, in line with the regulatory requirements</li> <li>The key roles within research (for example Chief Investigator, Principal Investigator, Sponsor) are detailed and the responsibilities of those roles explained</li> </ul>				
<b>4) What factors contribute or detract from achieving intended outcomes?</b> – R&D Strategy and Trust commitment in respect to encouraging research and considering it core activity				
<b>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?</b> Details: [see Equality Impact Assessment Guidance] - No <ul style="list-style-type: none"> <li>If yes, please describe current or planned activities to address the impact [e.g. Monitoring, consultation] – N/A</li> </ul>				
<b>6) Is there any scope for new measures which would promote equality?</b> Trust wide policy with no specific impact on particular groups				
<b>7) Are any of the following groups adversely affected by the policy?</b>				
<b>Protected Characteristics</b>	<b>Affected?</b>	<b>Impact</b>		
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		
<b>8) Provide the Equality Rating of the service / function /policy / project / strategy</b> – tick (✓) outcome box				

<b>Outcome 1 ✓</b>	<b>Outcome 2</b>	<b>Outcome 3</b>	<b>Outcome 4</b>
<i>*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 in Appendix 4</i>			
<b>Date for next review: November 2018</b>			
<b>Checked by:</b>		<b>Emma Hannaford, Research Management &amp; Governance Manager</b>	<b>Date: 11 November 2015</b>