Dorset County Hospital NHS Foundation Trust

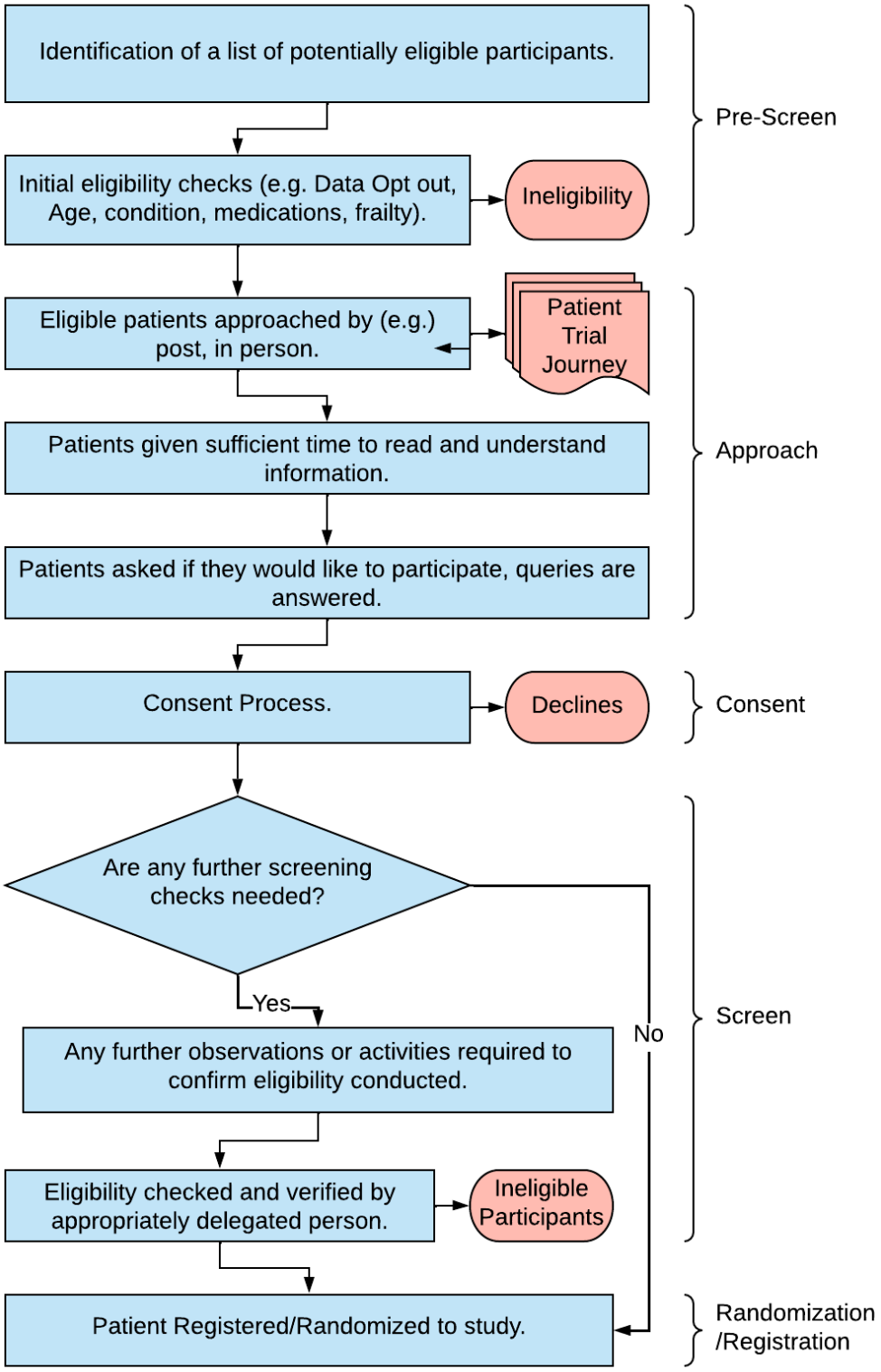
RESSOP001- RECRUITMENT OF RESEARCH PARTICIPANTS

SOP Title	RESSOP001 - Recruitment of Research Participants		
SOP Number	RESSOP001	**Policy Version Number**	1.1
Applicable to	All Staff actively recruiting participants in research		
Aim of the Policy	Standardisation of the Research Recruitment process to achieve quality and safety standards at Dorset County Hospital when recruiting participants to Research		
Next Review Due Date	06/03/2026		
Author/ Reviewer	Anthony Homer Research Governance & Quality Lead Donna Wixted Research Midwife Dennise Hill Research Bank Nurse		
Policy Sponsor	Sarah Doyle Head of Research		
Responsible Executive	N/A– Local SOP		
Expert Group	Research Quality Group		
Date Approved	06/03/2025		
Ratified by	Sarah Doyle- Head of Research		
Date Ratified	22/04/2025		
Primary Specialty	Research		
Secondary Specialty	All departments (active in research)		

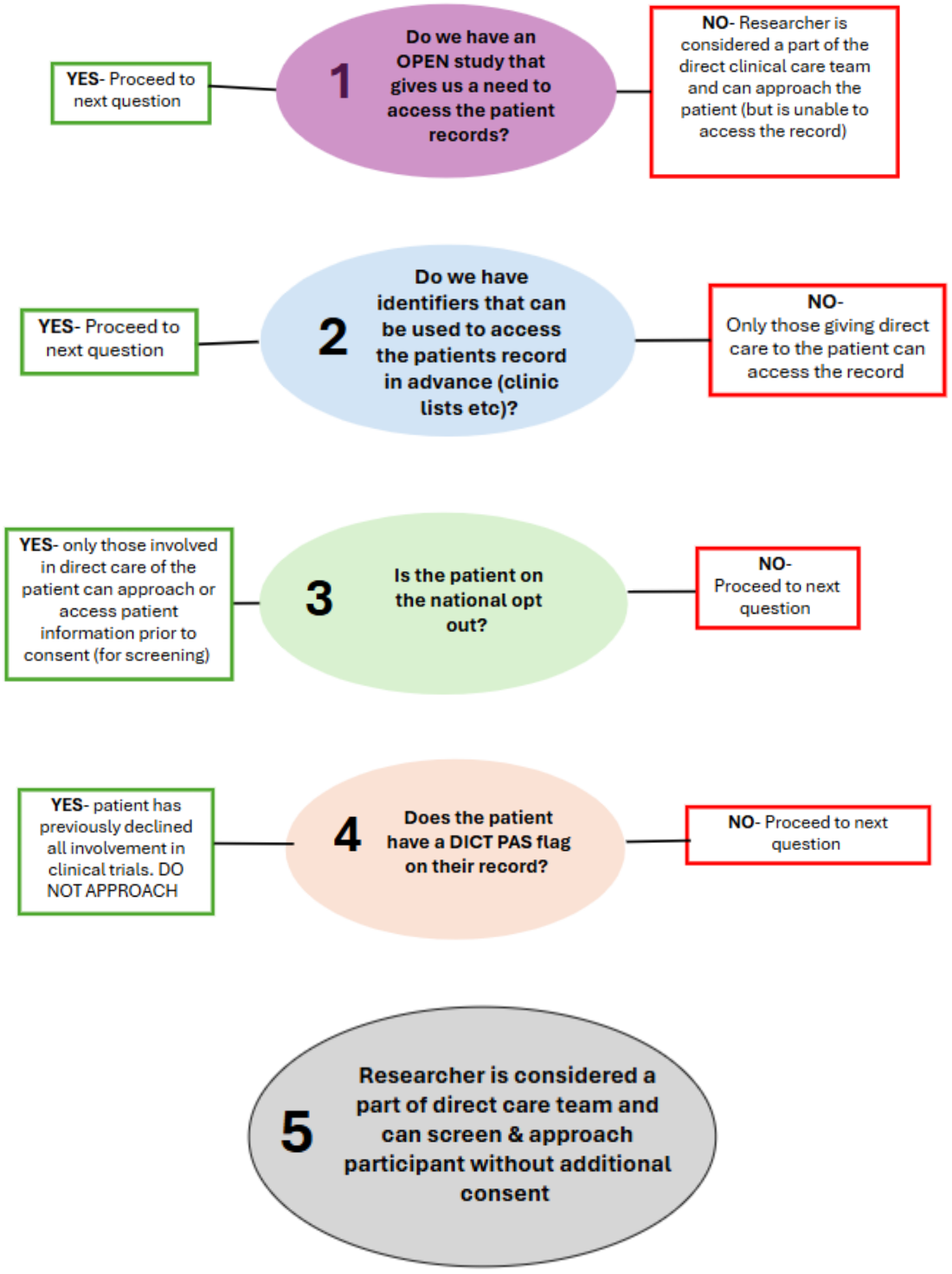
Document Version Management			
Version	Date	Reviewer	Description of Change(s)
1	03/2025	Anthony Homer / Amy Thomson	Update/ renew policy Allocated new policy number from previous DCH RES 001

Content

Quick Reference Guide



Approach Quick Reference Guide:



1. Introduction

1.1

Research recruitment follows a certain pathway in order to achieve best practice, ensure that the Trust has central oversight of the number of research recruits, and to provide assurance to participants and the public that their wishes and needs are considered when performing research activity in compliance with Good Clinical Practice (GCP).

1.2

This Standard Operating Procedure follows the research recruitment process from start to enrolment and sets out principles to be applied in all recruitment to all studies, whether the participants be patients, staff, or the public.

1.3

This Standard Operating Procedure does not cover the process of consent in detail, which is covered in the "Consent of Research Participants" SOP here. (If hyperlink does not work, contact research@dchft.nhs.uk to be given access to documents).

2. Aims and Objectives of this SOP

2.1

To achieve Trust-wide standardisation of the process of recruiting participants into research studies in a GCP compliant manner.

2.2

To set out principles and expectations for the recruitment of research participants in all studies.

3. Scope

3.1

Primarily, this SOP will apply to Research Department staff.

3.2

This SOP also applies to all staff in DCH conducting research involving human participants.

3.3

Staff involved in the recruitment of participants and related activities must be clearly identified on the study's Delegation Log.

4. Definitions

Definition	Description
Pre-screen	This stage relates to all checks and confirmations obtained prior to the patient being approached; these checks happen prior to the patient's knowledge of a study.
Approach	This stage relates to supplying the participant information about the study with a version controlled PIS.
Consent	This stage relates to obtaining permission from the participant to proceed with study activities.
Screening	This stage involves any study activities which involve an intervention and therefore occur after consent.
Randomisation/Registration	This stage involved the patient's enrolment in the study, where their participant pathway is defined and finalised.
Participant	This term has been used throughout the document to highlight that research participants are not always patients but could be staff or members of the public. For brevity, the term has been used throughout the process and is taken to also mean "potential participant".
Research Sponsor/Sponsor	These terms have been used interchangeably to refer to the (usually external) organisation responsible for the conduct of the study, or any external organisation delegated a part of that responsibility (such as a Clinical Research Organisation, a Study/Trial Office, a lead NHS Site, etc).
Researcher	This term has been used to refer to any appropriately delegated member of staff. Where the principles in this SOP differ between researchers dependent on their status (for e.g. as members of the research department, or members of the team providing treatment) this distinction is made clear.
Edge	Edge is a research study database used by DCHFT and managed as an Information Asset.

5. Equality Impact and Compliance Assessment

- Equality has been considered, see Appendix 1.

6. Data Protection Impact Assessment

- Data protection and confidentiality has been considered, see Appendix 2.

7. Stakeholders and Consultation

- Clinical Research Delivery Team
- Research Support Teams
- Research Quality Group
- Governance Sign off
- Research SOPs Working Group

8. Roles and Responsibilities

The policy applies to all staff of the research department, and those who have an active role in the study. The following 'key staff' also have responsibilities listed here:

- Head of Department has the responsibility to implement the contents of the SOP across the department
- Research Governance and Quality Lead has the responsibility to ensure that this document is accessible to all those who require it.
- All members of the Research Senior Leadership Team are responsible for collectively raising awareness of and ensuring compliance to the SOP across the Trust and raising gaps identified with the Research Governance and Quality Lead.
- Author of this document has the responsibility to ensure that this document is relevant and up to date.
- Principal Investigator/s are responsible for appropriate study conduct on site and ensuring protocol is followed.

9. Training and Implementation

- New users must read and understand this SOP before carrying out this procedure
- Existing users must read and understand the revisions section
- All users must have undergone recent GCP training
- Data Security Awareness mandatory training Equality and Diversity
- Health Safety and Welfare
- PAS training and Refresher training
- Safeguarding Adults
- NIHR Fundamentals of Research Course
- Study Specific Training as per individual sponsor/ study team

10. Risk Management

- Risk Management for this SOP is conducted via three key processes;
    - The SOP approval process involves governance and risk subject matter experts identifying generalized risks and mitigations to be written into the draft SOP prior to approval.

- The delivery of this SOP will be monitored both by the review periods identified and the datix incident reporting system to implement corrective and preventative actions through this SOP.
- The study feasibility process (RESSOP009) identifies risks related to individual study delivery and their compliance with this SOP.

11. Approval

- This SOP has been approved by the Research Governance and Quality Lead as well as the Research Quality Group, in accordance with the Policy and Procedure for the Development and Management of Policies and Clinical Guidance (Ref 1126).

12. Monitoring and Reviewing Arrangement

- Monitoring:

  Monitoring of this procedure and SOP will take place annually in the first instance, when changes to the procedure take place and in accordance with the following link: Home

- Reviewing Arrangements:

  This SOP will be reviewed at least every three years, in accordance with the Policy and Procedure for the Development and Management of Policies and Clinical Guidance (Ref 1126).

13. Dissemination

- This approved SOP will be uploaded to the Trust Policies and Clinical Guidance database and published and accessible via the Trust intranet, StaffNet.

14. Policy Content

14.1 Pre-Screen

14.1.1

Pre-screening can be done through any number of methods, including but not exclusive to:

- Obtaining a report from a clinical database with a list of patients with a certain condition.
- Obtaining a clinic list of all patients attending a particular clinic.
- Attending MDTs or other clinical meetings where eligible patients may be discussed.
- Being notified automatically of a potentially eligible participant.

- Being notified manually (by a member of the patient's treating team) of a potentially eligible participant.
- The principles of confidentiality must be adhered to at all times during the pre- screening process.

14.1.2

Where hospital numbers are available to the researchers, potential participants opt out status must be checked prior to accessing ANY information about the patient, this can be done by:

14.1.3

When receiving a report, clinic list or automatic notification, the report should be set up to ONLY provide Hospital Numbers as identifiable information, these can then be fed into the National Data Opt Out Query Tool before proceeding to pre-screen only those participants who do have not opted out.

14.1.4

When being notified manually, care should be taken to alert the patients treating team to the importance of only giving the patients NHS ID number, and no further treatment details, to the research staff to check the National Data Opt Out Query Tool prior to further pre- screening activity.

14.1.5

When attending MDTs or other clinical meetings, research staff should only take note of NHS IDs of potentially eligible patients discussed at those meetings, and check the National Data Opt Out Query Tool prior to further pre-screening activity.

Once the opt out has been checked, the patients PAS record should be checked for a DICT (Declined Involvement in Clinical Trials) flag. This flag indicates that the patient has previously expressed a desire not to be approached for any research projects. Their treating clinician may discuss the study with them if they believe the option is important, but any other researcher should not approach them for this study.

14.1.6

There are some settings (e.g. emergency settings, questionnaires, anonymous feedback forms) where the researchers will not know who participants are prior to them presenting. In these cases, if the researcher is able to check the

patients opt out status at any time prior to approach, this should be done, and the steps outlined in section 1.2 taken. The principle is that the participants information should not be accessed at any point prior to approach; if there is time to check the records, there is time to check the opt out status.

14.1.7

In scenarios where Hospital Numbers will not be known in order to check the opt-out status (for e.g., staff or members of the public), it is expected that the participants hospital records are not checked for eligibility, and the information obtained amounts to that which is lawfully available to the researcher (contact details, employment details in the case of staff, for e.g.).

14.1.8

Once the above checks are complete, any eligibility checks required prior to patient approach can be undertaken by any appropriately delegated staff. These eligibility checks will be defined by the protocol, and it is not expected that the researcher will access any information beyond that which they need to check the participants eligibility for approach.

14.1.9

Staff involved in the treatment of the patient may perform eligibility checks with the information they have access to lawfully as the patients direct clinical care team without checking the national data opt out if those staff do not inform the research department of the details of the patient.

14.1.10

Participants who are pre-screened may be recorded on a screening log, this log should not contain any identifiable information of participants who have opted out, and should not be shared with any other organisation, including the research sponsor, if they contain identifiable information of participants who have not consented.

DCHFT is a research active Trust and as such Research staff are considered to be a part of the direct clinical care team, the exception here is where participants have specifically opted out via the National Data Opt Out, or where there is not an open and active research study giving researchers a reason for accessing patient data. This consideration does not extend to external staff given temporary or restricted access to patients on a case-by-case basis.

14.1.11

Consideration at this stage should be given as to “Confirming eligibility”. For those studies with no further eligibility checks, an appropriately delegated person should confirm eligibility prior to consent. For studies with screening tests after consent, there may need to be two eligibility checks, one prior to consent, and one prior to randomisation. These eligibility checks must be performed by an appropriate member of staff as per protocol (usually, but not always, a doctor).

14.2 Approach & Consent

14.2.1

Participants can be approached through a number of methods as defined in the protocol, including but not limited to the below. Alongside the below examples are a few specific principles to bear in mind through each method of approach. In order to skip to the general principles of approach, please click here:

Mail/post

- Mail/post is usually used alongside another method of approach, however for cases where large numbers of participants are being approached at once, mail outs may be the only method. Always consider the rate of return expected on mail outs.
- Checks should be done prior to mail out to ensure multiple letters are not sent in the same envelope, and addresses are clearly visible and accurate.
- PAS should always be used as the primary source of patient address details.

In person

- Consideration should be given to the participants surroundings; is the space private enough to discuss the study? Is the space quiet enough for the participant to hear and concentrate?

Phone call

- When approaching by phone, be mindful of information provided to individuals who are not the participant.

- If the call goes to voicemail, do not state the full name of the individual you are calling, their diagnosis, or any other information about them a recommended message would be; “Hello, this is a message for *first name*, my name is *first name* and I’m calling from Dorset County Hospital, and you can catch me on *contact details*.
- Dialling “191” before dialling out on a hospital phone number will reveal the number to the participant, encouraging transparency.
- Dialling “*67” before dialling out from any phone hides the phone number, meaning use of personal phones etc. when working from home does not share your details.
- SMS text service – sponsor may provide text

Email/Electronic forms of approach.

- Participants may be emailed study information, this is not usually done prior to any other contact with the participant. Trust Policy with regard to emailing must be followed at all times, where protocols deviate from Trust policy a specific process must be approved during study set up (refer to RESSOP005).
- Participant expression of interest via self-referral.

14.2.2

The following section outlines principles which are universal to all forms of approach, unless specifically mentioned otherwise, or specific to the protocol.

14.2.3

An informal assessment can be done at this stage to identify the suitability of approaching the patient for the study. This assessment could include an initial judgement of capacity and a confirmation from the treating team that they would find approaching the patient appropriate. This assessment is done at the researcher’s discretion but should be done with the principles of equity of access and assumed capacity in mind.

14.2.4

When approaching a participant, the researcher must make clear their name, role, and reason for approaching. The researcher must then clarify the participants identification (if known) (Patient Identification Policy - https://dchftnhs.sharepoint.com/sites/ClinicalGuidance/CG%20docs1/Forms/Live%20Documents.aspx?id=%2Fsites%2FClinicalGuidance%2FCG%20docs1%2

F0703%2Dpat%2DID%2Epdf&parent=%2Fsites%2FClinicalGuidance%2FCG%20docs1) and make clear that the researcher is presenting a research project, that any involvement in the project is optional, and ask permission before providing further information.

14.2.5

If the participant has had information about them accessed in order to identify them, it should be clear what and how this information has been accessed and who by. If they have not had this information accessed, this should be made clear also, and why they are being approached.

14.2.6

If a patient indicates that they do not wish to be contacted about this study, and any other study in future, the existence of the "DICT" PAS Flag should be made aware to them. This PAS flag, "Declined Involvement in Clinical Trials" will indicate to all research and DCHFT staff that the patient does not wish to participate in research studies. It will not prevent clinicians from approaching them about a study they think would be beneficial.

14.2.7

A record of the participant contact must be made in the medical records. The research department often use pre-written pro-formas to save time in recording patient contact, the record must be specific to the individual patient. If they accepted or were provided with a PIS, a record of that document should be filed in their records. Participants who have declined a PIS or were not provided one do not need one to be filed in their patient record.

A patient trial journey, usually study specific, must be started at the point where the participant has been provided with information. For some studies, they may have a journey by this point already.

14.2.8

All patients who have been approached will be recorded edge, and may be recorded on study-specific screening logs. Some studies may record patients on edge prior to this as a matter of best practice. The data recorded on edge (unless information recorded is anonymous) should be at minimum; postcode, gender, date of birth, ethnicity, name, NHS number, Hospital Number.

14.2.9

This SOP does not go into detail of Consent of Research Participants, which is covered in RESSOP003. Where further screening checks are not needed, proceed to section 1.4. Where further screening checks are needed, consent should be obtained prior to proceeding to section 1.3.

14.3 Screen

14.3.1

Post-consent screening activities only occur on certain studies, as such this section may not apply. When following this SOP, consider section 1.4 alongside section 1.3 in order to ensure the participant is provided with all necessary reimbursements and information needed for their involvement in the study.

14.3.2

The participant should be fully informed and remain fully informed throughout the screening process of what procedures they have undertaken, what they are currently undertaking, and what they will have to undertake in order to demonstrate eligibility for the study.

14.3.3

The participant should know the likelihood of being eligible for the study, what will happen if they are not eligible, and what will happen if they are. If at any point their understanding is lacking, the researcher should assess capacity to remain in the screening process.

14.3.4

It is expected that screening activity will largely be co-ordinated by research staff with support from other Trust services – as such, consideration should be given to alerting those services to what requirements there are of them, arranging couriers, clinic space, consumables, and ensuring that there are enough appropriately delegated staff available to perform screening tests, process samples and confirm eligibility,

Sample logs and other protocol specific activities must be maintained.

Edge must be updated with future appointments and costs of each visit, and the participant expenses must be recorded and refunded (see section 1.4).

14.3.5

Appointments and contact (e.g telephone contact) with participants must be added to PAS. All visits must be recorded on the patients' medical records, as should the results of the tests and any screen failures.

14.3.6

Where a participant is found ineligible (Also "screen failure") they should be contacted at the earliest opportunity, the reason for their ineligibility explained, thanked for their time and effort so far, and refunded any expenses they incurred before explaining how standard care will proceed for them.

14.4 Randomization & Registration

14.4.1

Randomization or Registration may sometimes occur concurrently with consent, and so the following principles may be adhered to when randomizing, registering, or consenting a participant to a research study.

14.4.2

The researcher should be prepared for the visit, including identifying appropriate space with appropriate technology to smoothly conduct the visit. Consideration should be given to what access the researcher may need to PCs, iPads, internet, in order to randomize/register the participant.

14.4.3

The participant will usually be given a Trial ID at this point of the study. They should be made aware of it, and all relevant systems (e.g. Edge, trial database) updated with it.

14.4.4

The participant should have a CLTR ("Patient Involved in Clinical Trials") Flag added to their PAS record at this stage.

14.4.5

The participants should, where appropriate, be added to the SAE (Serious Adverse Event) Register so that researchers will be notified of their hospital admissions for safety purposes. A Working Instruction can be provided upon request with the Research Department.

14.4.6

The participants should, where appropriate, have PDocs uploaded to DPR and a PAS flag added to their PAS record. Pdocs should refer staff to a location on

share point with the protocol available. Share point can be located here: Home. Appendix C can also be referred to for trust guidance.

14.4.7

The participant should have a visit plan, schedule of events or other diary plan for their study involvement provided or explained to them.

14.4.8

The participant should, where appropriate, have their financial details collected in order to reimburse their expenses while on-study. This information will only be stored by the finance department for the length of their accounting audit records requirements, and will be deleted from research department documentation once finance have confirmed receipt.

14.4.9

The participant should, where appropriate, have a parking concession form completed so that they are not charged parking during their involvement in the study.

14.4.10

The patient should be provided with or informed of how and when they will receive any appropriate technology, devices, or medicines and when they should take them.

14.4.11

The researcher should check that all support services and investigators are aware of the patient's status.

14.4.12

Edge should be updated and maintained with the patient's status and appointments. There may be a study specific randomization, registration or enrolment log that also needs to be update.

15. Legislation, Policies, Guidelines and Principles

Legislation:

The Data Protection Act 2018 (https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted)

The Medicines for Human Use (Clinical Trials) Regulations 2004 (and subsequent amendments) (https://www.legislation.gov.uk/uksi/2004/1031/contents)

The Health and Social Care Act 2012 (And subsequent amendments) (https://www.legislation.gov.uk/ukpga/2012/7/contents)

Policies:

Policies and Guidance - Policy and Procedure for the Development and Management of Trust Policies and Clinical Guidance - Live Documents (sharepoint.com)

Data Protection and Confidentiality Policy (Ref 1751) https://dchftnhs.sharepoint.com/sites/ClinicalGuidance/_layouts/15/viewer.aspx?sourcedoc={ddf9c5c9-9832-4f04-9a48-c13b8d3b3033}

1141-Health-records-operational-policy.pdf

Guidelines & Principles:

The Caldicott Principles (https://www.gov.uk/government/publications/the-caldicott-principles#:~:text=Every%20use%20of%20confidential%20information,and%20under%20the%20common%20law)

https://www.ukcrfnetwork.co.uk/app/uploads/2023/07/Advisory-Notes-Data-Integrity_v01_Oct2019.pdf

GDPR The General Data Protection Regulation (GDPR) came in to force on 25 May 2018: GDPR guidance - Health Research Authority (hra.nhs.uk)

NIHR CRN Recruitment Policy Document | NIHR

NHS Dorset County Hospital NHS Foundation Trust

Appendix 1

EQUALITY IMPACT AND COMPLIANCE ASSESSMENT

1. General	
Title of Document	Recruitment of Research Participants
Purpose of Document	Provide standard procedure for recruitment of research participants
Intended Scope	Trust-wide

2. Consultation	
Which groups/ associations/ bodies or individuals were consulted in the formulation of this document?	Per 'Stakeholders Consultation' above
What was the impact of any feedback on the document?	Removal of in appropriate/ out of date links and references. Refinement of procedure Graphic for patient data usage
Who was involved in the approval of the final document?	The Research Quality Group
Any other comments to record?	None

3. Equality Impact Assessment/Analysis		
Reference:		
Age **Disability** **Ethnicity** **Gender reassignment** **Marriage/ Civil Partnership** **Pregnancy/ Maternity** **Religion and Belief** **Sex** **Sexual Orientation**	**Patients** **Members of the local community** **Voluntary Sector Groups**	**Staff Groups** **Volunteers**

ED&I Considerations: (Access, Communications, Service delivery, Cultural competence).	
Does the document positively or negatively affect certain staff or groups of staff? If so, please state how this is justified.	No
Does the document positively or negatively affect certain patients or groups of patients? Please state how this is justified.	No
What measures are proposed to address any inequity?	Measures implemented on a study by study basis at feasibility. Prioritisation of equity of access and assumed capacity emphasized. Promotion of translation capability to sponsors.
Can the document be made available in alternative format or in translation?	No, due to cost restrictions.

4. Compliance Assessment	
Does the document comply with relevant employment/ equality legislation or Trust standards? Please specify.	Yes

5. Document assessed by:	
Name	Anthony Homer
Post Title/ Position	Research Governance and Quality Lead
Date	22/04/2025

Appendix 2

Data Protection Impact Assessment (DPIA) Screening Questions

These screening questions should be used to inform whether a full DPIA is necessary - if you are uncertain, please talk to information.governance@dchft.nhs.uk. See the last page for information about why we must do this.

Please complete all sections

Title of Project	*Recruitment of Research Participants*

Brief description	Standardisation of the Research Recruitment process to achieve quality and safety standards at Dorset County Hospital when recruiting participants to Research *Please note: Projects may collect data themselves with a lawful basis of consent but this procedure does not cover that process*
Completed by:	
Name	Anthony Homer
Title	Research Governance and Quality Lead
Department	Research
Email	Anthony.homer@dchft.nhs.uk
Date	22/04/2025

		Yes	No	Unknown
1.	Will the project involve the collection of new, person identifiable information[1], or potentially identifiable information, about individuals (patients and/or staff)?		☑	
2.	Will the project compel individuals to provide information about themselves, or involve the processing of personal data not obtained directly from the individual? *i.e., where they will have little awareness or choice, or it is impossible, or would involve disproportionate effort to inform the individuals that the processing is taking place.*		☑	
3.	Will identifiable information about individuals be shared with other organisations or people who have not previously had routine access to the information?		☑	
4.	Are you using information about individuals for a purpose it is not currently used for? *i.e., using data collected to provide care for an evaluation of service development, or data matching from multiple sources.*		☑	
5.	Where information about individuals is being used, would this be likely to raise privacy concerns or expectations? *i.e., will it include health records, criminal records, or other information that people may consider to be sensitive** and private, and may cause them concern or distress.*		☑	
6.	Will the project require you to contact individuals in ways which they may find intrusive? *i.e., telephoning or emailing them without their prior consent.*		☑	
7.	Will the project result in you making decisions in ways which could have a significant impact on individuals? *i.e., will it affect the care a person receives?*		☑	
8.	Does the project involve you using new technology which might be perceived as being privacy intrusive? *i.e., using biometrics, facial recognition, artificial intelligence, or automated decision making.*		☑	
9.	Is a service being transferred to a new supplier (re-contracted) and the end of an existing contract, or is the processing of identifiable/potentially identifiable data being moved to a new organisation?		☑	
10.	Will the project involve systematic monitoring of a publicly accessible area on a large scale?		☑	

1

	i.e., use of CCTV.			
11.	Will the project involve the targeting of children or other vulnerable individuals? *i.e., for marketing purposes, profiling or other automated decision making*		☑	
12.	Will designated staff need approved access to this information, either by team membership or individual log-in? *i.e., shared file access, separate software username and password, information asset*		☑	
13.	What is the lawful basis for using this data? *√ all that apply*			
	A. Article 6(1)(e) - Public Task (direct healthcare)			
	B. Article 9(2)(h) (the processing is necessary for health or social care purposes)			
	C. Consent			☑
	D. Unknown			

- If all answers are **NO** then please file this with your project files to document that you have considered any possible risk to data.
- If any are **YES** or **UNKNOWN** please forward this document for review and next steps to informationgovernance@dchft.nhs.uk

OUTCOME

☑ No Risk to data, or No data – file locally

Risk to data – forward to informationgovernance@dchft.nhs.uk

- ☐ Low Risk - approved by IG – file locally
- ☐ High Risk – complete full DPIA template and submit to IG

Name of Information Asset Owner: Anthony Homer

Name of Information Asset Administrator: Amy Thomson

Signed by Project Lead: Anthony Homer Date 22/04/2025

Signed by Information Governance Date:
(if appropriate)