Dorset County Hospital
NHS Foundation Trust

RESSOP002 - INFORMED CONSENT OF RESEARCH PARTICIPANTS

SOP Title	RESSOP002 - Informed Consent of Research Participants		
SOP Number	RESSOP002	**Policy Version Number**	1.1
Applicable to	For all research staff undertaking Informed Consent		
Aim of the Policy	The purpose of this Standard Operating Procedure (SOP) is to explain the local process by which the Dorset County Hospital NHS Foundation Trust research staff seek informed consent from patients who wish to participant in research.		
Next Review Due Date	06/03/2026		
Author/ Reviewer	Donna Wixted Research Midwife and Dennise Hill Bank Nurse Anthony Homer Research and Governance Lead		
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 department (active in research)		

Document Version Management			
Version	Date	Reviewer	Description of Change(s)
3.1	01/09/2022	Anthony Homer, Dennise Hill & Donna Wixted	Renaming of SOP number Update of information New Quick reference Guide Amendment of version number

Content

Quick Reference Guide

Training to Complete:	• GCP Training • Study specific training as per protocol • NHIR Consent Training Course or complete local consent pathway for new research staff (11.2) • Update training logs	☐ ☐ ☐
Delegation:	• Study Delegation Log – the PI assigns the duty/role of receiving informed consent	☐
Opt-Out Tool:	• Check the Opt-Out tool for research preference	☐
Approach Participant:	• The method of approach will be determined by the study protocol, for example, in-person, via telephone or post	☐
Provide Study Information:	• Provide the patient the study's version-controlled Patient Information Sheet (PIS) • Give a reasonable amount of time to consider the PIS as per the protocol	☐ ☐
Arrange Consent Visit to discuss the patient's potential participation in the study:	• Check the timing of the appointment is compliant with the protocol and sufficient time has been given for the patient to consider the PIS • Ensure the patient has the opportunity to ask questions • Assess the patient's understanding of what participating in the study entails (randomisation/number of study visits) • Reassure the patient that informed consent is voluntary • Inform the patient of their right to withdraw at any time without affecting their care • Assess capacity for the patient to consent (legally competent) unless the protocol states otherwise	☐ ☐ ☐ ☐ ☐ ☐
Receive Valid Informed Consent in a GCP compliant manner:	• Read each point of the study's version-controlled consent form aloud with the patient • Ensure the patient is happy to comply with the different points/all aspects of the study • Invite the patient to sign and date the version-controlled consent form • Retain the original consent form for the site file or process as per the study specific protocol • Provide the patient with a copy of the signed consent form • Place a copy of the signed consent form and patient information sheet in the patient's medical notes or upload to DPR • Update/document the patient's medical notes and/eCRF	☐ ☐ ☐ ☐ ☐ ☐ ☐

Reaffirm the patient's consent:	• Reaffirm and document the patient's ongoing consent at every appointment	☐

1. Introduction

1.1

Informed consent in the context of clinical research is the process by which a competent subject (participant) voluntarily confirms his or her willingness to participate in a particular study, having comprehended all aspects of the study. Performing any research related procedure on someone without first obtaining their informed consent, is in breach of UK Regulations, which were developed according to the European Directive on Good Clinical Practice in Clinical Trials (2001). A comprehensive definition of informed consent is to be found in The Declaration of Helsinki (1964).

1.2

ICH Good Clinical Practice guidelines also state: "The investigator or person designated by the investigator, should fully inform the subject" and the subject must have "ample time and opportunity to inquire about details of the trial and to decide whether or not to participate" and the subject and the person conducting the informed consent discussion should sign and personally date the informed consent form.

The investigator/delegated responsible person must ensure that subjects have fully understood what they are consenting to.

Written documentation consists of three elements:

- **Documentation in the patient's medical notes,** together with a copy of the signed consent form and Participant Information Sheet (PIS).
- The **(Patient / Participant) Information Sheet (PIS)**. Describes the trial in layperson's terms.
- The **Informed Consent Form** (ICF), documents that informed consent has been taken, when and by whom.

2. Aims and Objectives of this SOP

2.1

The primary objective of this Standard Operating Procedure (SOP) is to explain the local process by which the Dorset County Hospital NHS Foundation Trust research staff seek informed consent from patients who wish to participate in research.

2.2

This Standard Operating Procedure (SOP) describes the procedure for obtaining written informed consent from a study participant. This SOP does not outline the procedure for the consent of more ‘vulnerable’ (minors, mentally impaired, unconscious, etc.), or physically and/or educationally impaired participants. In the context of research an adult is defined as somebody 18 years of age or over. The SOP briefly refers to the consent of incapacitated adults.

3. Scope

3.1

This SOP applies to everyone who obtains informed consent for research studies.

4. Definitions

Acronyms	Definition	Description
CRF	Case Report Form	A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.ICH GCP - 1. GLOSSARY
CTIMP	Clinical Trial of an Investigational Medicinal Product	A clinical trial that is within the scope of the UK Medicines for Human Use (Clinical Trials) Regulations 2004. An investigation in human subjects, other than a non-interventional trial, intended: a) to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products b) to identify any adverse reactions, or c) to study absorption, distribution, metabolism and excretion, with the object of ascertaining the safety and/or efficacy of those products. Glossary | Clinical Trials Toolkit
DCH	Dorset County Hospital	About Us | Dorset County Hospital
DPR	Digital patient Record	A database for storing of patient medical records
Ecrf	Electronic Case Report Form	An electronic equivalent of a CRF as above.
GCP	Good Clinical Practice	This is a set of internationally recognised ethical and scientific quality requirements that must be followed when designing, conducting, recording and reporting clinical trials that involve people. Good Clinical Practice - Health Research Authority

HRA	Health Research Authority	As part of the Research Ethics Service, HRA approval is required across the NHS as an assessment of governance and legal compliance. https://www.ct-toolkit.ac.uk/glossary#letter-i
ICF	Informed Consent Form	A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate.
ICH	International Conference for Harmonisation	A collaboration between regulators and the pharmaceutical industry in Europe, the United States and Japan to establish common standards for clinical trials. ICH GCP is a widely recognised standard for Good Clinical Practice in clinical trials. https://www.hra.nhs.uk/approvals-amendments/glossary/
MHRA	Medicines and Healthcare products Regulatory Agency	"The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK". About us - Medicines and Healthcare products Regulatory Agency - GOV.UK (www.gov.uk)
PI	Principal Investigator	The lead person at a single Site designated as taking responsibility within the research team for the conduct of the study. Responsible for all aspects of the study conduct at a Site.
REC	Research Ethics Committee	A Research Ethics Committee (REC) established in any part of the UK in accordance with GAfREC and/or recognised by the UKECA under the Clinical Trials Regulations. Glossary - Health Research Authority (hra.nhs.uk)
SOP	Standard Operating Procedure	Detailed written instructions designed to achieve uniformity of the performance of a specific function.
PIS	Participant Information Sheet	The participant information sheet describes in lay (clear and easy) language a research project, explaining its purposes and methods, and outlining the risks and benefits of participation. Information sheets are also referred to as 'Patient Information Sheet'. Glossary of Terms - University of Birmingham

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

- Research nursing, midwifery & clinical trials assistant staff at Dorset County Hospital.
- Research Leadership Review at Dorset County Hospital.
- Research Quality Group at Dorset County Hospital.

- Governance sign off
- Research SOP Working Group

8. Roles and Responsibilities

It is the responsibility of Research staff to ensure they receive, understand, and document all necessary training to fulfil the requirements of this SOP.

- The staff member must have a comprehensive understanding of the study, potential treatment toxicities and the associated disease area. They should be qualified by experience and/or should have received appropriate training for this study. All training must be documented.
- There is a written agreement between the Principal Investigator (PI) and all staff involved in the consent process describing the respective roles and responsibilities. Delegation of responsibility for aspects of the process should be documented on the Study Delegation Log.

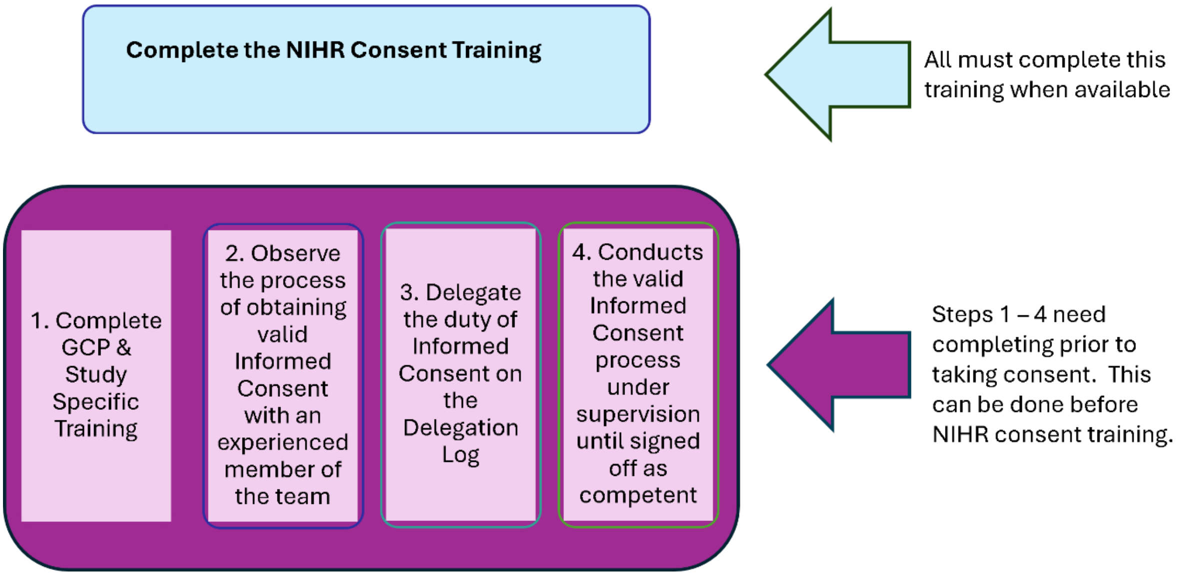
It is the responsibility of the PI and the delegated member of staff to ensure effective communication is maintained. The PI is ultimately responsible for the patient's care.

9. Training and Implementation

NIHR Consent training: In accordance with latest training version online

National & Local Consent Pathway for New Research Staff:

Both the national and local consent training must be completed by all staff delegated to receive consent. The local training may be completed first and signed off to allow staff to take consent prior to completing the NIHR Consent Training.



- 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 in accordance with the Policy and Procedure for the Development and Management of Policies and Clinical Guidance (Ref 1126).

12. Monitoring and Reviewing Arrangements

- Monitoring:

  To be reviewed every three years, unless agreed otherwise, 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 Delegation of Responsibility to Obtain Informed Consent

14.1.1

The delegation of informed consent to an appropriate, suitably qualified member of the research team should be considered on a trial-by-trial basis, taking account of local circumstances and in accordance with GCP Guidelines and the trial protocol.

If staff other than the PI are to accept responsibility for the informed consent process and/or being the sole signatory on the ICF it is important the following criteria are met:

- The designee is prepared to take on this additional responsibility AND feels confident to take informed consent in line with their Code of Professional Conduct or other professional organisational guidelines if applicable.
- They have a comprehensive understanding of the study, potential pharmacological interactions/treatment toxicities and the associated disease area. The designee should be qualified by experience and/or should have received appropriate training for this study. All training must be documented.
- The delegation of responsibility should be documented on the Study Delegation Log. If a member of staff is being delegated to consent, having already been signed off by the PI for other duties, a new line should be completed to reflect the new duty.
- It is the responsibility of the PI and the delegated member of staff to ensure effective communication is maintained. The PI is ultimately responsible for the patient’s care.
- Healthcare professionals taking delegated consent are responsible for ensuring they have received training to take consent for specific procedures and are competent to do so.
- Ensure that participants have fully understood what they are consenting to. All relevant ICFs must be completed and filed appropriately, and the process of consent must be described in the patient notes.
- The participant must sign the ICF **prior** to any study related procedures being conducted. The informed consent process should not cease once the ICF has been signed, the practice of giving information about the study to participants should be an ongoing process performed by all members of the research and/or multidisciplinary team (as appropriate). This is particularly significant with the introduction of protocol amendments and the availability of important new information that may be relevant to the participant’s willingness to continue participation in the study. In these circumstances, it

may require the study participant to re-consent on the amended ICF in order to continue involvement in the study.

- The timing of the signing of the ICF relative to study registration and the initiation of study procedures is subject to audit by the Research Department, sponsor and governing bodies (Research Ethics Committee (REC) and Medicines and Healthcare products Regulatory Agency (MHRA) as applicable).

- If a healthcare professional is asked to seek consent when they do not feel competent to do so, this should be raised in the first instance, with either their Line Manager or Lead Research Nurse.

- If a member of staff takes consent but is not delegated to do so, an incident report **and** a trial specific adverse event form will be completed. These incidents will be robustly investigated and where appropriate the individual would be referred to their professional body

Informed consent can be seen as a two-step process, informing the subject and taking consent.

14.2 Informing the participant

14.2.1

We have a duty to offer each patient the opportunity to be involved in a research study. If a potential participant cannot read the PIS and/or ICF (for example; non English speaking or blind) they should be offered appropriate assistance as per the individual study protocol (for example; translators, braille or large print documents).

- Patient information should be provided to potential study participants in both an oral and written format, as per study specific protocol.

- The participant should be provided with ample time and opportunity to read the PIS and ICF and discuss the study with family, friends or others, as detailed in the study protocol.

- Sponsors specify a different time period between initial patient contact and obtaining informed consent and undertaking any research activity refer to specific study protocol. Prior to the participant signing the ICF, all questions should be answered by appropriate members of the research team.

- Any information imparted to the participant (written or verbal) should not contain any language that causes the subject to waive (or appear to waive) any legal rights, or that releases (or appears to release) the investigator, institution or sponsor from liability for negligence.

- Neither the investigator nor any member of the clinical research team should coerce or unduly influence a participant to participate or to continue to participate in a trial.

- The ICF should be revised when necessary, i.e. when new information becomes available that may be relevant to the participants consent. Any revisions should be undertaken by the sponsor and approved by the REC / MHRA as appropriate **before** use. The participant should be informed of new information in a timely manner. The communication of this information should be documented in the participant's medical notes.

- The ICF should be identifiable by date and/or version number and be printed on Dorset County Hospital NHS Foundation Trust (DCHFT) headed paper and should include DCHFT's PI/investigators name and contact details as well as the Patient Advise and Liaison Service (PALS) contact details.

14.3 Interpreters

It is not appropriate to use family members or friends of the patient to interpret. A non-independent interpreter could:

- influence or bias information given by health professionals
- have conflicting interests
- means we have no way of knowing the quality of the interpreting
- potential for confidentiality and information governance breaches
- the use of someone who is not adequately qualified to medically interpret and pose a risk to both the patient and staff if anything is misunderstood

It is **not** appropriate to use staff members. Staff members can be used to have a conversation with a patient in order to ease their anxieties but under no circumstances should staff members be utilised for any kind of medical interpreting unless they hold the relevant qualifications.

Local Policy for Interpreting and Translation Policy EM58 (via link below):

Home

Link to Language Line (via DCHFT SharePoint):

https://dchftnhs.sharepoint.com/sites/Procurement/SitePages/Processes.aspx

14.4 Taking Informed Consent

- Consent is often wrongly equated with a participant's signature on an ICF. A signature on an ICF is *evidence* that the participant has given consent, however, is not *proof* of valid consent. If a participant is rushed into signing a form, on the basis of too little information, the consent may not be valid, despite the signature.

- When the person receiving informed consent is satisfied that the research participant has been fully informed and understands what study participation entails, the ICF should be signed and dated by the research participant with the participant also initialling relevant boxes on the ICF. The ICF should then be counter-signed by the person delegated to conduct the informed consent discussion. A copy of the completed consent form must be provided to the participant.

- The process of obtaining informed consent should be documented in the participant's medical records, detailing the study title and/or acronym, patient trial I.D., the study visit title (e.g. Consent Visit), and the date that consent was obtained. The entry should be dated and, signed by the person authorised and responsible for conducting and obtaining the participants informed consent and any research activities undertaken documented.

- Good quality information underpins sound decision-making at every level in the NHS and most importantly contributes to improvements in healthcare. Patients would receive safer care if the information held about them is accurate, up to date and readily available.

- All staff must take responsibility for ensuring the quality of their work in relation to record keeping. Information entered into systems and paper records must be accurate, relevant, clear and timely. Staff must take responsibility for improving poor data, including that entered by other staff. Consistent problem areas should be monitored and reported to the Research Governance & Quality Lead, for corrective action.

- Alternative processes - some studies allow telephone, remote witnessed or e-consent. The role of the witness is determined by the study protocol. Telephone consent and e-consent may be with or without a witness. The completed consent form can be documented on a paper or electronic form.

  With the use of Electronic Medical Records (EMR), **all** documentation to be filed into EMR should be forwarded to EMR within 24 hours (or at the soonest possible opportunity) of being completed. Please use the appropriate research folder on DPR.

- Two copies of the signed and dated ICF should be made; the original should be filed in the relevant section of the Study Site File, a copy should be given to the research participant and a copy should be filed in the participant's medical records and EMR/DPR along with a copy of the PIS. Research participants should get copies of all relevant, updated and new information, regarding the study throughout their participation.

14.5 Minors

*Please refer to study specifics within the current protocol.

For research involving those under the age of 16 years the initial approach for informed consent of a child must be done through the parent. If a parent is unavailable a guardian may be approached.

The PI or delegate must ensure that prior to the discussing a research study with a child, the parent or guardian (non-CTIMP) or legal representative (CTIMP) of the child has had the opportunity to review the REC approved information sheets. There would usually be a patient information sheet or informed consent form (PIS or (ICF) for parents or guardians, and an age-appropriate PIS for children.

The PI or delegate must ensure that the child has full age-appropriate information about the research in order to receive their full consent to participate. Consent must be freely volunteered by the child. The protocol will set out what age groups of children are expected to provide consent in addition to parent or guardian or legal representative.

The PI or delegate must ensure that the information presented to the child and parent explains fully what will happen in the study, what is being asked of the child and it must be conveyed that the child or parent can decline to participate without adverse consequences.

If the PI or delegate deems the child incapable of understanding the implications of taking part in a research study or where the child is regarded as unable consent, parental consent alone is acceptable.

14.6 Patients unable to sign the consent form

- Please refer to study specifics within the current protocol.
- If a participant has capacity but is unable to sign the ICF for whatever reason i.e. unable to write, the patient may use a mark to indicate consent. This should be witnessed by a person other than the healthcare professional seeking consent and the reason the participant has chosen to mark the ICF in this way should be documented in the participant’s medical records. Similarly, if the patient has the capacity to and wishes to give consent but is physically unable to mark the ICF, all the facts should be recorded in the participant’s medical records.
- The mental capacity Act (2005) permits urgent research in emergencies to start when it is not practical to consult someone about involving a person who lacks capacity. The study protocol will outline the study specific criteria.

14.7 Informed Consent Form Corrections

- Please refer to study specifics within the current protocol.
- Where **minor** errors (such as wrong date) have occurred after the participant has signed the ICF, the error should be struck through (but still legible) and initialled and dated by the person making the amendment, this

could be the research participant or person undertaking the informed consent. When striking through ICF and initialling errors please ensure that the initialling of the error/deletion cannot be confused with the initialling of the ICF boxes. Do not use correction fluids.

- Where **major** errors (such as wrong spelling of participant's name) have occurred after the participant has signed the ICF, it may be more appropriate to re-consent the participant.

14.8 Informed consent of incapacitated adults

**** Please refer to study specifics within the current protocol****

- The definition of an incapacitated adult under the Medicines for Human Use (Clinical Trials) Regulations 2004 is *"an adult unable by virtue of physical or mental incapacity to give informed consent"*. **N.B** All patients are assumed to have capacity but an assessment must take place where capacity is in doubt.
  Points 1 & 2 below sets out the hierarchy prescribed in the Regulations for determining what type of legal representative should be approached to give informed consent on behalf of an incapable adult prior to inclusion of the participant in the trial. The hierarchy below is for England, Ireland and Wales.

1. *Personal legal representative*

A person not connected with the conduct of the trial who is:

a) suitable to act as the legal representative by virtue of their relationship with the adult,

and

b) available and willing to do so.

2. Professional legal representative

A person not connected with the conduct of the trial who is:

a) the doctor primarily responsible for the adult's medical treatment

Or

b) a person nominated by the relevant health care provider (e.g. an acute NHS Trust or Health Board).

A professional legal representative may be approached if no suitable personal legal representative is available.

The process is the same as detailed previously with the addition of the following conditions and principles which apply to the inclusion of an incapable adult in a clinical trial;

- The legal representative has had an interview with the investigator, or another member of the investigating team, in which opportunity has been given to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.
- The legal representative has been provided with a contact point where further information about the trial may be obtained.
- The legal representative has been informed of the right to withdraw the participant from the trial at any time.
- The legal representative has given informed consent to the participant taking part in the trial.
- The legal representative may, without the participant being subject to any resulting detriment, withdraw the participant from the trial at any time by revoking the informed consent.
- The participant has received information, according to his or her capacity of understanding, about the trial and its risks and benefits.
- The investigator must consider the explicit wish of a participant’s capable of forming an opinion and assessing the information provided. This applies both to the wish of a participant to refuse to take part, or to withdraw from the trial at any time.
- No incentives or financial inducements are given either to the participant or to their legal representative, except the provision of compensation for injury or loss.
- There are grounds for expecting that administering the medicinal product to be tested in the trial will produce a benefit to the participant outweighing the risks or produce no risk at all.
- The trial is essential to validate data obtained:

  a) in other clinical trials involving persons able to give informed consent,

  <u>Or</u>

  b) by other research methods.
- The clinical trial relates directly to a life-threatening or debilitating clinical condition from which the participant suffers.

14.9 Principles

Informed consent given by a legal representative shall represent the presumed will of an incapacitated adult.

- The trial has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the cognitive abilities of the patient.
- The risk threshold and the degree of distress have to be specially defined and constantly monitored.

The interests of the patient always prevail.

15. Legislation, References, local Policies and Guidelines

Legislation:

Capacity: Mental Capacity Act 2005:
https://www.legislation.gov.uk/ukpga/2005/9/contents

1. Mental Capacity Act and Deprivation of Liberty Safeguards (sharepoint.com)
2. Assessment_of_Mental_Capacity_form_A (word).docx (sharepoint.com)

Guidelines & Principles:

Guidelines for Clinical Practice, *http://ichgcp.net/*
NIHR Good Clinical Practice (GCP): https://www.nihr.ac.uk/health-and-care-professionals/training/good-clinical-practice.htm

NHS Research Authority Informing participants and seeking consent last updated 25 Mar 2024: https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/

Policies:

https://www.nihr.ac.uk/documents/nihr-crn-recruitment-policy-document/11347#consent-by-a-legal-representative

NHS Health Research Authority – Principles of consent: Adults not able to consent for themselves (England and Wales): https://www.hra-decisiontools.org.uk/consent/principles-ALC-EnglandandWales.html

Appendix 1

EQUALITY IMPACT AND COMPLIANCE ASSESSMENT

1. General	
Title of Document	Informed Consent
Purpose of Document	The purpose of this Standard Operating Procedure (SOP) is to explain the local process by which the Dorset County Hospital NHS Foundation Trust research staff seek informed consent from patients who wish to participate in research.
Intended Scope	Reference document for research staff to receive informed consent

2. Consultation	
Which groups/ associations/ bodies or individuals were consulted in the formulation of this document?	Circulated for review and comment to Research staff, Management team and the research Quality Group
What was the impact of any feedback on the document?	Feedback was considered and incorporated into the final document as appropriate
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: who it may impact		
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?	Individual projects are assessed through feasibility
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	Consent of research participants
Brief description	The purpose of this Standard Operating Procedure (SOP) is to explain the local process by which the Dorset County Hospital NHS Foundation Trust research staff seek informed consent from patients who wish to participant in research.
Completed by:	
Name	Anthony Homer
Title	Research Governance & 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?		☑	

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[1]

	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? *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 Date 22/04/2025

Signed by Information Governance Date:
(if appropriate)