

Research and Development SOP029 - Informed Consent Standard Operating Procedure

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Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and Uk General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and Uk General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

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1. Introduction

- 1.1. The Medicines for Human Use (Clinical Trials) Regulations 2004 (“the Clinical Trials Regulations”) as amended by the Medicines in Human use (Clinical Trials) (Amendment) Regulations 2025 (referred to as the “amended Clinical Trials Regulations”) Section 37 states “Clinical trials must be conducted in accordance with the principles of good clinical practice set out in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice, as amended from time to time.”
<https://www.legislation.gov.uk/ukxi/2025/538/regulation/37>
- 1.2. The International Council for Harmonisation (ICH), Good Clinical Practice (GCP) Section II (1) states “Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with GCP and applicable regulatory requirement(s).”
[ICH E6\(R3\) Step4 FinalGuideline 2025 0106.pdf](#)
- 1.3. The principles of the Declaration of Helsinki (2024) state “Free and informed consent is an essential component of respect for individual autonomy. Participation by individuals capable of giving informed consent in medical research must be voluntary. Although it may be appropriate to consult family members or community representatives, individuals capable of giving informed consent may not be enrolled in research unless they freely agree.” [WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants – WMA – The World Medical Association](#)
- 1.4. Participants are generally only entered into a clinical trial or research study after they have received detailed information about the trial or study and they have given their informed consent (certain exemptions do apply, please see [Section 4](#) of this SOP details). No trial or study related procedure should take place prior to informed consent. The explanation of the clinical trial or research study will in the first instance be given by the Principal Investigator (PI) or delegate and will be provided in either verbal and/or written format through ethically approved trial or study documents.
- 1.5. Informed Consent must be given freely and voluntarily by the participant with no coercion from any party. It must be made clear that should consent be given, the participant has the right to withdraw from the trial or study at any time, without giving a reason for their withdrawal. The decision to withdraw will not prejudice future medical treatment.
- 1.6. GCP guidelines highlight that informed consent is an on-going process for the participants of a clinical trial or research study. If there are changes in the trial or study design or the medication used or the risks associated with participation, the participant may be required to re-consent if the information constitutes a substantial modification to the trial or study.
- 1.7. This version supersedes any previous versions of this document.

1.8. Scope

- 1.8.1. This SOP applies to all staff involved in receiving consent from participants of clinical trials and research studies being conducted for the Royal Cornwall Hospitals NHS Trust (RCHT).
- 1.8.2. This SOP does not apply to projects which fall outside of the definition of research within UK Policy Framework for Health and Social Care Research for example, clinical audits, service evaluations, standard care practice.
- 1.8.3. This SOP does not apply to studies where consent is not required or where the Confidentiality Advisory Group (CAG) has approved the project to obtain identifiable patient data for research purposes without consent.

1.9. Definitions / Glossary

- 1.9.1. **Good Clinical Practice (GCP)** is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.
- 1.9.2. **Clinical Trial of Investigational Medicinal Product (CTIMP)** is any investigation in human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal products(s) and/or study absorption, distribution, metabolism and excretion of one or more investigational product(s) with the object of ascertaining its (their) safety and/or efficacy.
- 1.9.3. **Clinical Investigations of Medical Devices** means the systematic study of an investigational medical device in or on participants to assess its safety, performance or effectiveness. An investigational medical device is any healthcare product that does not achieve its primary intended purposes by chemical action or by being metabolised and is subject to a clinical study to evaluate the effectiveness and/or safety of the device. A relevant ethics committee opinion is required. This opinion should be sought either before or in parallel with the notification to the MHRA, normally by the Chief Investigator.
- 1.9.4. **Declaration of Helsinki** is a statement of ethical principles developed by the World Medical Association (WMA) for medical research involving human participants, including research on identifiable human material and data.
- 1.9.5. **Sponsor** is an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among

the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities that are relevant to the trial or study in line with the UK Policy Framework for Health and Social Care Research.

- 1.9.6. **Chief Investigator (CI)** is the authorised health care professional who takes primary responsibility for the conduct of the trial or study. The CI must be a senior individual, with appropriate experience, expertise, and training to undertake the design, conduct and analysis of the trial or study to meet the requirements set out in legislation.

They must also lead and manage others who have been delegated responsibilities as part of the research project.

- 1.9.7. **Principal Investigator (PI)** is the person who takes responsibility for the initiation and conduct of the trial or study at site. There is one Principal Investigator at each site participating in a research study. For a single site trial or study, the Chief Investigator (CI) may also take on the role of Principal Investigator (PI).

- 1.9.8. **The Research Team** is a group of people involved in the conduct of a research project at site. It may include care professionals, academics, patients and service users, members of the public, research professionals, students and/or scientists.

- 1.9.9. **Parental Responsibility** – a parent or person with parental responsibility in law. Guidance around who has parental responsibility is available via [Parental rights and responsibilities: Who has parental responsibility - GOV.UK](#)

- 1.9.10. **Personal Legal Representative (PerLR)** is a person not connected with the conduct of the trial who is suitable to act as the legal representative by virtue of their relationship with an adult who lacks capacity or a minor, and available and willing to do so.

- 1.9.11. **Professional Legal Representative (PrLR)** is a person nominated by the relevant healthcare provider (e.g., an acute NHS Trust or Health Board) who is not connected with the conduct of the trial.

- 1.9.12. **Investigator Site File (ISF)** – contains the essential documents which show that the investigator and the conduct of the trial or study are following the regulatory requirements.

- 1.9.13. **Consent Form (CF) or Informed Consent Form (ICF)** is an essential controlled document required for capturing a participant's willingness to participate in research.

- 1.9.14. **Participant Information Sheet (PIS)** is the written information, describing the research project and what participation would involve for participants.

- 1.9.15. **EDGE** is a dedicated, web-based, research database which is used within, and managed by the R and D Department at RCHT.

Acronyms:

CI: Chief Investigator.

CTIMP: Clinical Trial of an Investigational Medicinal Product.

GCP: Good Clinical Practice.

GDPR: General Data Protection Regulation.

HRA: Health Research Authority.

HTA: Human Tissue Authority.

ICF: Informed Consent Form.

IRAS: Integrated Research Application System.

ISF: Investigator Site File.

MHRA: Medicines and Healthcare products Regulatory Agency.

MRC: Medical Research Council.

PI: Principal Investigator.

PIS: Participant Information Sheet.

PerLR: Personal Legal Representative.

PrLR: Professional Legal Representative.

QMS: Quality Management System.

R and D: Research and Development.

RCHT: Royal Cornwall Hospitals NHS Trust.

REC: Research Ethics Committee.

SOP: Standard Operating Procedure.

Sub-I: Sub Investigator.

WI: Work Instruction.

2. Purpose of this Standard Operating Procedure (SOP)

- 2.1. This Standard Operating Procedure (SOP) describes the process for receiving informed consent from a potential participant for a clinical trial or research study being conducted for the Royal Cornwall Hospitals NHS Trust.
- 2.2. This SOP also outlines the participant informed consent process, including the required documentation and procedures for completing and filing the essential study documentation.

3. Ownership and Responsibilities

3.1. Role of R and D Clinical Director

The R and D Clinical Director is responsible for:

- Having oversight of the implementation of robust arrangements to ensure staff follow processes described in [Section 4](#), Standards and Practice.
- Gaining assurance from the Senior Management Team (SMT) to ensure compliance with the processes outlined in [Section 4](#), Standards and Practice.

3.2. Role of the Senior Management Team (SMT)

The SMT is responsible for:

- Providing assurance to the R and D Clinical Director of the compliance with the processes outlined in [Section 4](#), Standards and Practice.
- Ensuring adequate provision of training for staff to perform their roles and responsibilities in association with the processes described in [Section 4](#), Standards and Practice.
- Arranging monitoring and auditing of the systems and processes associated with the standards and practice described in [Section 4](#).
- Supporting the Principal Investigator (PI) to fulfil the duties, responsibilities, and obligations in executing the processes described in [Section 4](#), Standards and Practice.
- Ensuring any non-compliance associated with the standards and practice described in [Section 4](#) are processed in accordance with the R and D SOP004 Reporting and Managing Non-compliance and Serious Breaches (see Documents folder in EDGE).

3.3. Role of the Chief Investigator (CI)

The CI is responsible for:

- Ensuring compliance with the applicable regulatory requirements and adhering to the principles of GCP and to the ethical principles that have their origin in the Declaration of Helsinki.
- Having overall responsibility for ensuring that all staff involved in the study are adequately trained. At each site this will be a delegated responsibility to the PI.
- Ensuring that all sites are informed of any modifications to the clinical trial or research study documentation throughout the life of the trial or study.

3.4. Role of Principal Investigator (PI)

The PI is responsible for ensuring:

- Compliance with the applicable regulatory requirements, adhering to the principles of GCP and to the ethical principles that have their origin in the Declaration of Helsinki.
- All appropriate individuals delegated to receive consent have up to date GCP training.
- All participants are approached and enrolled into the clinical trial or research study in accordance with the process that has received a favourable opinion from a Research Ethics Committee (REC).
- Capacity is assessed to ensure that a participant can freely give informed consent by evaluating their ability to understand information, make decisions, and communicate those decisions. If the participant lacks capacity, alternative measures must be in place. Refer to the Standards and Practice [Section 4.4](#).
- Informed Consent is documented for all participants enrolled in a clinical trial or research study in accordance with the protocol, approved trial or study documentation and ethical approval.
- The participant's decision on whether to participate in the clinical trial or research study is documented in their medical notes.
- That participants are informed in a timely manner of any new information that becomes available that may be relevant to their willingness to continue in the trial or study. The discussion with the participant should be documented and where applicable, the participant should be re-consented using the revised participant information sheet (PIS) and informed consent form (ICF).
- That all site personnel are informed of any modifications to the protocol and study documentation, and that research teams are working to the most up to date versions of all documentation.
- Ensuring episodes of non-compliance with the standards and practice described in [Section 4](#) are investigated and processed in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (see Documents folder in EDGE).

3.5. Role of the person receiving informed consent

All appropriate members of the research team who have been delegated responsibility for receiving informed consent are responsible for:

- Ensuring they are familiar with all aspects of the clinical trial or research study, described in the latest REC approved version of the protocol, and throughout the trial or study any protocol modifications, as approved by the Sponsor, HRA, REC and where appropriate the MHRA.

- Ensuring they demonstrate an understanding of the trial or study protocol and disease area in order to offer a full explanation of the trial or study to participants.
- Establishing that the participant has the capacity to provide consent. If there are concerns about capacity, appropriate expert advice should be sought if required.
- Ensuring the information presented verbally to the participant uses a non-technical language and other resources as appropriate.
- Ensuring the participant is given sufficient information at an appropriate level to be able to understand and weigh up the risks and benefits of participating in the trial or study.
- Ensuring potential participants are given adequate time to consider the information in line with the trial or study protocol and the opportunity to ask questions and have these answered to their satisfaction.
- Ensuring potential participants are encouraged to consult with friends, relatives or other healthcare professionals as required and for as long as practical to come to a decision on whether to participate.
- Ensuring the participant is not coerced or unduly influenced to participate or to continue to participate in the trial or study.
- Ensuring the informed consent process and discussion are documented in the participant's medical records.
- Supporting the PI with investigating episodes of non-compliance with the standards and processes described in [Section 4](#), in accordance with R and D SOP004 Reporting and Managing Non-compliance and Serious Breaches (see Documents folder in EDGE).
- Supporting monitors, regulators, auditors, investigators and other persons undertaking official duties, with queries relating to episodes of non-compliance.

3.6. **Role of Team Leader**

The appropriate member of SMT is responsible for:

- Supporting the PI to ensure all staff involved in the trial or study fulfil their duties, responsibilities, and obligations in executing the processes described in [Section 4](#), Standards and Practice and in accordance with the principles of GCP.
- Identifying training needs for RCHT staff involved in the standards and processes described in [Section 4](#).
- Supporting the PI with investigating episodes of non-compliance with the standards and processes described in [Section 4](#), in accordance with R and D SOP004 Reporting and Managing Non-compliance and Serious Breaches (see Documents folder in EDGE).

- Supporting monitors, regulators, auditors, investigators and other persons undertaking official duties, with queries relating to episodes of non-compliance.

3.7. **Role of Research Administration Team**

The Research Administration Team is responsible for:

- Providing administrative functions to support the PI with processing and managing documentation for the informed consent process.
- Ensuring protocol modifications are processed in a timely manner, and that the PI and research team are notified and trained on the changes.
- Ensuring the Investigator Site File contains the latest REC approved version of the Informed Consent Form (ICF) and Participant Information Sheets (PIS).
- Supporting the PI with documentation for episodes of non-compliance with the standards and processes described in [Section 4](#), in accordance with R and D SOP004 Reporting and Managing Non-compliance and Serious Breaches (see Documents folder in EDGE).
- Supporting the PI to ensure monitors, auditors and regulators have supervised access to the study files and documentation as directed.
- Supporting monitors, regulators and auditors with queries relating to the study files and documentation.

4. **Standards and Practice**

4.1. **Training**

- 4.1.1. All personnel receiving informed consent must have appropriate training for the process. They must be familiar with all aspects of the trial or study, described in the latest version of the protocol, and throughout any protocol modifications, as approved by the sponsor, Health Research Authority (HRA), Research Ethics Committee (REC) and where appropriate the Medicines and Healthcare products Regulatory Agency (MHRA).
- 4.1.2. The responsibility for receiving informed consent should only be delegated to individuals with the appropriate specialist training, experience and knowledge to enable them to explain fully the implications of participating in the trial or study to the potential participant.
- 4.1.3. All investigators and delegated staff active on a clinical trial or research study being conducted for RCHT must undertake Good Clinical Practice (GCP) training at a level that is commensurate with their role. Refer to the R and D SOP011 Research Training (see Documents folder on EDGE).

- 4.1.4. It is recommended that any staff receiving informed consent also complete dedicated Informed Consent training.

4.2. Delegating Responsibility for Informed Consent

- 4.2.1. The Principal Investigator (PI) is responsible for the local site in a clinical trial or research study and may also be the Chief Investigator for the trial or study. PIs may delegate tasks to appropriately trained and qualified members of their research team; however, they must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibilities. Refer to R and D SOP009 Roles and Responsibilities (see Documents folder in EDGE).
- 4.2.2. The PI should ensure that informed consent is received and documented for all participants in accordance with the relevant protocol, approved study documentation and the ethical approval.
- 4.2.3. The PI can delegate the process of receiving informed consent to other members of the research team. The PI must decide whether a proposed delegate is appropriate. They must supervise delegated tasks and ensure that there are effective lines of communication.
- 4.2.4. For studies which do not involve a Clinical Trial of Investigational Medicinal Product (CTIMP) or medical device, the participant may be identified and informed consent received by a non-medically qualified person, where this has been approved by the REC and sponsor. It is expected that there will be a health professional with the relevant qualification(s) as part of the research team and readily available to refer to, as required.
- 4.2.5. The delegation of the consent process by the PI to an appropriate, suitably qualified member of the research team should be considered for each trial or study, in accordance with the relevant protocol, Good Clinical Practice (GCP) guidelines and with agreement from the sponsor.
- 4.2.6. When accepting the responsibility for receiving informed consent, the designee:
- Accepts the additional responsibility and feels confident to receive informed consent in line with professional organisational guidelines i.e., General Medical Council, Nursing and Midwifery Council, Code of Professional Conduct.
 - Must be qualified by education, training and experience, and ensure that they have a comprehensive understanding of the trial or study, including the potential risks and benefits.
- 4.2.7. It should be noted that receiving informed consent is a separate procedure from checking eligibility, and where it is stated that eligibility must be confirmed by the PI or a registered doctor, this cannot be delegated to a research nurse or practitioner.

- 4.2.8. Any research personnel involved in giving information during the informed consent procedure, should document the discussion in the medical notes.
- 4.2.9. Delegation of duties for informed consent should be documented appropriately, please refer to R and D SOP030 Delegation of Duties (see Documents folder in EDGE).

4.3. Consultation

- 4.3.1. Participants who potentially fulfils the eligibility criteria for a clinical trial or research study will be identified and approached. Generally, members of the clinical care team will identify potential participants and make the first approach. The IRAS application should define the method for approaching potential participants.
- 4.3.2. When receiving consent, it's important to allow participants sufficient time to ask questions and carefully consider their decision to take part. This helps to ensure the quality of informed consent and the participant's understanding of the risks and burden of participating in the trial or study.
- 4.3.3. Clear communication is essential, avoid using jargon or overly technical language (medical or research related). Information should be presented in a way that is accessible and relatable to ensure participants fully understand.
- 4.3.4. The participant must be provided with the Participant Information Sheet (PIS) and given adequate time for consideration and discussion, including discussions with a suitably qualified and trained member of the research team, as required.
- 4.3.5. The participant should be encouraged to read the information and to discuss the trial or study with any family and friends, or other healthcare professional such as a GP (if applicable), to allow them to determine whether to participate.
- 4.3.6. There is no statutory requirement for how long participants should consider their potential participation in a trial or study. This will depend on the need for treatment, for example, if the trial or study is in an emergency setting this could require a very short timeframe. The minimum timeframe will be defined in the Integrated Risk Application System (IRAS) application, if required.
- 4.3.7. The participant should be given the opportunity to ask further questions and must not be coerced or unduly influenced to participate in the study.
- 4.3.8. Whether the informed consent process takes place in person or remotely, the research team member receiving consent should assure themselves of the identity of the participant (or legally acceptable representative) in accordance with applicable regulatory requirements.

4.4. Capacity

4.4.1. Directive 2001/20/EC sets out the principles for individuals who are incapable of giving their informed consent, including; clinical trials for minors (Article 4) and incapacitated adults not able to give informed legal consent (Article 5). [eudr_20010020_adopted_en.pdf](#)

- Consent for minors is covered in [Section 4.5](#) of this document.
- Research involving adults unable to consent for themselves requires specific REC notice of favourable opinion from a recognised Mental Capacity Act flagged REC. The research provisions of the Mental Capacity Act 2005, sections 30-34 apply to the conduct of research. [Mental Capacity Act 2005](#)

4.4.2. Investigators and appropriate staff receiving consent, are responsible for assessing the decision-making capacity of the participant in accordance with the relevant legislation and RCHT policies.

4.4.3. The Mental Capacity Act 2005 states that everyone has the right to make their own decisions if they can, and that they should be supported and involved as much as possible.

4.4.4. There are five principles which underpin the Mental Capacity Act 2005, providing a safeguard for people their capacity to make decisions may be called into question:

- **Presumption of Capacity:** A person must be assumed to have capacity unless it is proved otherwise.
- **Maximising decision-making:** Until all practical steps have been taken to help someone make a decision without success they cannot be treated as lacking capacity.
- **Unwise decisions:** An unwise decision does not in itself indicate a lack of capacity.
- **Best interests:** Any act done or decision for someone lacking capacity must be made in their best interests.
- **Less restrictive option:** When a person lacks capacity any act or decision should aim to be the less restrictive option to the person in terms of their right and freedom of action.

4.4.5. ICH GCP E6 (R3) Section II Paragraph 2.1 states, “Freely given informed consent should be received and documented from every participant prior to clinical trial participation. For potential participants unable to provide informed consent, their legally acceptable representatives, acting in the participants’ best interest, should provide consent prior to clinical trial participation.”

- 4.4.6. If a capable adult refuses informed consent, and subsequently becomes unable to give informed consent, the refusal is legally binding. The individual cannot be entered into that trial or study by seeking consent from the legal representative. Mental Health Act 2005 Part 1 Section 24 <https://www.legislation.gov.uk/ukpga/2005/9/section/24>.
- 4.4.7. If a capable adult gives informed consent to take part in a trial or study but subsequently becomes unable to give informed consent by virtue of physical or mental incapacity, the consent previously given when capable remains legally valid. Mental Health Act 2005 Part 1 Section 26 <https://www.legislation.gov.uk/ukpga/2005/9/section/26>.
- 4.4.8. Where a potential adult participant lacks capacity to provide consent for themselves, in accordance with the Clinical Trials Regulations SI 2004/1031 and amended Clinical Trials Regulations SI 2025/538, a legal representative will be identified and approached to provide consent. The legal representative is someone who 'by virtue of their relationship' with the potential participant, is suitable to act as their legal representative for the purposes of the trial or study and is available and willing to act as a legal representative. This will usually be a relative or friend, who acts as a Personal Legal Representative (PerLR). In the circumstance that no friend or relative can be identified, or there is insufficient opportunity to identify and approach such a person, a doctor or other healthcare professional who is not connected to the trial or study can be approached to act as a Professional Legal Representative (PrLR).
- 4.4.9. The person receiving consent should be satisfied the legal representative is undertaking the consent process on behalf of the participant and not expressing their own views and opinions.
- 4.4.10. Participants who did not have capacity to provide consent for themselves at the point of Informed Consent or at the time a decision or action was taken, who later regain capacity to give consent to the trial or study, should be seen by an appropriately delegated member of the research team.
- The legal representative should be advised from the outset of what processes will be followed in the event of the participant regaining the capacity to consent.
 - The participant should be provided with an appropriate Participant Information Sheet (PIS), that explains what has happened to date, what consent is now sought for and inviting them to continue to take part in the trial or study.
 - The appropriately delegated member of the research team will ask the participant to give their consent for their continued participation in the trial or study.
 - The research team should plan for how a situation will be handled where the participant withdraws consent for their continued participation, and the use of the previously collected data.

4.5. Consent Process for Minors

- 4.5.1. Clinical Trials Regulations SI 2004/1031 and amended Clinical Trials Regulations SI 2025/538, prohibit children under the age of 16 from giving consent to take part in a CTIMP. To involve a minor in a CTIMP, parental or legal representative consent must be received. The process to be followed must be approved by the sponsor, HRA and the MHRA. The process must be given a favourable opinion by the REC. [Research involving children - Health Research Authority](#)
- 4.5.2. In accordance GCP guidelines, where a minor is to be included as a participant in a clinical trial, age-appropriate assent information should be provided and discussed with the minor as part of the consent process, and assent from the minor to enrol in the trial should be obtained as appropriate. A process for consent should be considered if, during the course of the trial, the minor reaches the age of legal consent, in accordance with applicable regulatory requirements. [ICH E6\(R3\) Step4 FinalGuideline 2025 0106.pdf](#)
- 4.5.3. For participants under the age of 16, the legally designated representative (often one of the parents/guardians, see definition [Section 4.5](#), Table 1) would sign the consent form on behalf of the minor, where appropriate. The minor's assent should be recorded on an assent form corresponding to their age range, that has been approved by a REC. The process that has been followed should be documented in the minor's medical notes.
- 4.5.4. Parents or Legal Representatives should understand that they are being asked to give consent on behalf of the child or young person and they should understand the objectives, risks and burden of the trial or study and the conditions under which it is to be conducted and have been informed of the right to withdraw the child or young person from the study or trial at any time.
- 4.5.5. Common law presumes that young people aged between 16 and 18 are usually competent to give consent to treatment. Case law suggests that if a young person has sufficient understanding and intelligence to understand fully what is proposed and can use and weigh this information in reaching a decision, they can give consent to treatment. The process given a favourable decision by the REC will be outlined in the protocol and other trial study documentation, providing details on whether informed consent can be given by young people between 16 and 18.
- 4.5.6. In accordance with the Clinical Trials Regulations SI 2004/1031 and amended Clinical Trials Regulations SI 2025/538, there is a hierarchy for determining who should be approached to give informed consent on behalf of a minor prior to their inclusion in the study (see Table 1 below). The provisions for informed consent by a legal representative only apply in the case of emergency treatment where no person with parental responsibility can be contacted prior to the proposed inclusion of the minor.

- 4.5.7. The explicit wish of a minor who is capable of forming an opinion and assessing the informed consent information, to refuse participation in, or to be withdrawn from, the trial or study any time should always be respected.
- 4.5.8. The process that has been followed should be documented in the minor's medical notes.

Table 1

Hierarchy	Person who may give consent	Definition	Comments
1.	Parent/ Guardian	A parent or person with parental responsibility.	Should always be approached when available. Guidance around who should be regarded as having parental responsibility is available via: Parental rights and responsibilities: Who has parental responsibility - GOV.UK
2.	Personal Legal Representative	A person not connected with the conduct of the trial who is suitable to act as the legal representative by virtue of their relationship with the minor, and available and willing to do so.	May be approached if no person with parental responsibility can be contacted prior to the proposed inclusion of the minor, by reason of the emergency nature of the treatment provided as part of the trial.
3.	Professional Legal Representative	A person nominated by the relevant healthcare provider (e.g., an acute NHS Trust or Health Board) who is not connected with the conduct of the trial.	May be approached if no person suitable to act as a personal legal representative is available. Informed consent must be given before the minor is entered into the trial.

- 4.5.9. During a clinical trial for an investigational product, if the minor reaches the age of majority as detailed in the protocol, their express informed consent should be received before their participation in the trial may continue (see [Section 4.6.1. and 4.6.4.](#)).
- 4.5.10. To involve a minor in other non-CTIMP research, the child may consent for themselves if they are deemed competent. Dependent upon the study, this may be a common-sense decision, assessed clinically and by an appropriate competence tool. It is still advisable to gain parental assent in most cases.

4.6. Assent

- 4.6.1. In some circumstances, such as research in urgent care situations, the process of fully informed consent may not be possible prior to the study related procedures taking place. In these situations, a process of verbal consent (Assent) to a trial or study may be adopted, provided that at a later pre-determined time, fully informed consent follows.
- 4.6.2. Assent is also used for participants who haven't reached the legal age for consent or do not have the capacity to decide for themselves. The assent process allows them to say 'yes' or 'no' to the research, even if they don't understand everything about it.
- 4.6.3. Documentation used in the assent process should be age and capacity appropriate; the documents should be approved by the REC and the sponsor. An appropriate, approved version of the PIS should be used to provide a brief explanation about the essential elements of the study to the participant allowing them to decide whether they wish to participate in the research study. If the participant decides to take part in the trial or study, verbal assent will be taken and documented in the medical notes by the researcher/medic receiving assent.
- 4.6.4. Where assent is given by the participant, as a minimum the following information is recorded:
- Date of the Assent.
 - Time of the Assent.
 - Name of the person receiving Assent.
 - Version number of the PIS used for the Assent.
- 4.6.5. The person receiving the Assent, must be delegated to receive consent.
- 4.6.6. The Assent procedure must be followed up using the approved informed consent process within the timescale stated on the approved documentation. The provision of the Verbal Assent should be discussed fully during the sponsor review or Site Initiation Visit, and where possible, the risk assessment and Green Light process.

4.6.7. If the participant is unable due to capacity or unwilling to complete the informed consent process within the approved timescale, they must be considered to have withdrawn their consent for the study. When a participant withdraws from a trial or study, the data collected to date may be retained and analysed, but this should be considered in a case-by-case basis.

4.6.8. The assent and consent process must be documented in the participant's medical records.

4.7. Emergency Situations

The Clinical Trials Regulations SI 2004/1031 Schedule 1 Part 1 (6) and amended Clinical Trials Regulations SI 2025/538, allows for treatment which needs to be administered urgently to a participant who is a minor or an adult lacking capacity, where time may not allow for written consent to be received from a person with parental responsibility (in the case of minors) or a legal representative. Minors and adults lacking capacity can be entered into a trial or study prior to informed consent, provided that:

- having regard to the nature of the trial or study and the particular circumstances of the case, it is necessary to take action for the purpose of the trial or study as a matter of urgency, but
- it is not reasonably practicable to receive informed consent prior to entering the participant, and
- the action to be taken is carried out in accordance with a procedure approved by the REC.

4.8. Participants who do not speak English

4.8.1. It is important that information is available in a language understandable to eligible research participants.

4.8.2. The study's IRAS Application form should be reviewed for the requirements regarding interpreting services for potential participants who do not speak English or require interpreting assistance. The protocol should also detail whether non-English speaking patients are eligible or ineligible for participation in the trial or study.

4.8.3. It is recommended that if a potential participant who does not speak English is considered for participation in a clinical trial or research study, the research team contacts the sponsor to obtain a translated version of the PIS and ICF which they should submit to REC and HRA for information, as part of the full documentation packages prior to use.

4.8.4. Using family members as interpreters is not appropriate. RCHT independent interpreting services provides a language interpreter for the majority of languages spoken in the UK and should be used for participants who do not speak English. Details on how to access RCHT's interpreting service can be found for the following link: <http://intranet-rcht.cornwall.nhs.uk/brilliant-care/clinical-governance/patient-experience/interpreting-services/>.

- 4.8.5. The interpreter should sign and date the consent form as a witness and it is recommended that the interpreter add their interpreter license number as a reference.
- 4.8.6. The informed consent documentation in the participant's medical notes should state the name of the interpreter used and confirm any discussions that took place during the consenting process, to ensure the participant was fully informed and understood the trial or study requirements prior to completing the ICF.
- 4.8.7. For any questions or concerns relating to the consenting of a potential research participant who does not speak English, the PI or research team should contact the sponsor for further direction and have written documentation from the sponsor clarifying any questions prior to proceeding with receiving consent from the potential research participant. All written correspondence should be saved in the Investigator Site File (ISF).

4.9. Research with Human Tissue

- 4.9.1. All research involving the acquisition of human tissue and samples should be undertaken in accordance with the Human Tissue Authority (HTA) Code of Practice: Guiding Principles and the Fundamental Principle of Consent [Code A: Guiding principles and the fundamental principle of consent | Human Tissue Authority](#). The consent should make it clear to the participant what will happen to their samples and if they are being asked to gift their samples for research other than the trial or study to which they are consenting and if so how long the samples will be held for and that they will be disposed of appropriately at the end of this period of time.
- 4.9.2. It should be made clear when receiving consent from a participant, that consent can be withdrawn at any time. The practical implications of withdrawing consent should be discussed to help participants, or their representatives, understand what is realistic in terms of withdrawal and to manage expectations. Withdrawal of consent cannot be acted upon where tissue and samples have already been used.
- 4.9.3. If someone gives consent for their tissue to be stored or used for more than one scheduled purpose and then withdraws consent for its use in research, this does not necessarily mean that the sample or samples should be removed or destroyed. The samples may no longer be stored or used for the research for which consent has been withdrawn.
- 4.9.4. If a participant withdraws consent for samples to be used in any future research projects, this does not mean that information and research data should be withdrawn from any existing projects.

4.9.5. Access to Tissue from the Deceased

Under the Human Tissue Act 2004, consent is required for the removal of tissue samples from the deceased for the following scheduled purposes (activities):

- Anatomical examination.
- Research in connection with disorders or the functioning of the human body.
- Establishing after a person's death the efficacy of any drug or other treatment administered to them.
- Obtaining scientific or medical information, which may be relevant to any person including a future person.

4.9.6. A full list of scheduled purposes can be found on the Human Tissue Authority website via the following link: <https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice>.

4.9.7. Where tissue is planned to be taken from the deceased, consent can be sought from the following, in order of preference:

- Where an adult has provided consent for a specific scheduled purpose (activity), such as storage or use of tissue, to take place following their death, then that consent is considered sufficient and lawful.
- Nominated representative: Appointment of this person and its associated terms and conditions may be made in writing or verbally.
- Person in a 'qualifying relationship': This is hierarchical in order of preference:
 - Spouse or partner (including civil or same sex partner).
 - Parent or child.
 - Brother or sister.
 - Grandparent or grandchild.
 - Niece or nephew.
 - Stepfather or stepmother.
 - Half-brother or half-sister.
 - Friend of long standing.

4.10. Documenting the consent process

4.10.1. Informed consent to take part in a clinical trial or research study must be obtained before any trial or study related procedures take place. Sometimes there may be a separate consent process for carrying out screening procedures before eligibility is confirmed and consent to participate in the trial or study is sought. If a two-stage process is in place, it must have received a favourable opinion from an REC.

- 4.10.2. The process by which a participant or their legally acceptable representative voluntarily confirms their willingness to participate in a trial or study should be documented in accordance with GCP guidelines and the REC approved documentation for the trial or study.
- 4.10.3. Whatever the decision of the participant the process should be documented in the participant's medical notes as it occurs and in sufficient detail to provide a clear narrative of the events, including any questions from the participant or their legal representative and the answers given in response.
- 4.10.4. For clinical trials and research studies involving a CTIMP or medical device, informed consent must be evidenced, this could be in writing or electronic format, the methodology for receiving informed consent will have received approval from a REC. Refer to [Section 4.12](#) for trials and studies using electronic consent (eConsent).
- 4.10.5. When receiving informed consent in writing, the person receiving informed consent should invite the participant to document their willingness to adhere to research requirements by writing their initials beside each point on the latest REC approved version of the Informed Consent Form (ICF). The participant should then document their willingness to participate in the study by signing and dating the ICF. The ICF must be personally signed and dated by both the participant and the person receiving informed consent and both should print their names beside the signatures.
- 4.10.6. Some trials and studies may have additional optional processes involved in a sub study, such as providing samples for translational research or participating in pharmacokinetic mapping. In such instances the consent of the participant should be freely given following the same processes for each study and sub-study as described above.
- 4.10.7. For the consent to be valid the research participant must always be able to communicate their decision. If the person is unable to sign or to mark the consent form to indicate their consent as defined in the REC approval, then consent may be given orally in the presence of at least one witness, usually a relative or patient advocate. The role of the relative or advocate in the consent process must be documented in the medical records.
- 4.10.8. For participants who lack capacity, the opinion of the participant's representative about the participant's enrolment should be formally documented. Participants should not be enrolled into the study if it is contrary to any form of statement made in advance by the participant whilst competent. This does not have to be in writing and the PI or delegate should take reasonable steps to find out if there are any advance wishes by consulting relatives. A participant's wishes must always be respected throughout.
- 4.10.9. In the case of minors, the parent or legal guardian representative must sign the consent form. In cases where the child has been involved and is judged competent to give consent, they should also sign the ICF. It is

also good practice to document the child's view where they are not judged competent to give consent. This may include a separate 'Assent' form or minor-specific ICF.

- 4.10.10. After the ICF has been signed, the participant should receive a copy of the signed and dated consent form. A copy of the consent form and associated participant information documentation must also be filed in the participant's medical notes and the original signed ICF filed in the Investigator Site File (ISF) for the study.
- 4.10.11. Only after informed consent has been freely given and documented, can the PI or research team undertake any research activity or start the screening process to determine if the participant is eligible through meeting all inclusion and none of the exclusion criteria.
- 4.10.12. The PI or delegate should update the enrolment log which should be filed in the ISF and complete any study specific documentation required by the sponsor. In line with General Data Protection Regulations (GDPR), no information should be shared externally without consent unless it is anonymised.
- 4.10.13. For participants who decline the opportunity to participate in the trial or study, the person receiving informed consent should thank the participant for their time and consideration and proceed with standard care as appropriate. Document the discussion with the potential participant in the medical notes.
- 4.10.14. Consent is an on-going process; it does not end with a signature on a consent form. At each visit the participant should be assessed to determine if they are willing to continue. For example, during the treatment phase of a trial or study the participant could be seen frequently, and the study team should discuss any behaviour or comment that may indicate the participant is not willing to continue. Where visits are less frequent the study team should ask the participant if they are willing to continue. Reaffirm consent with the participant and document the discussion in the medical notes.

4.11. Remote Methods for Receiving Consent

Receiving consent remotely should receive ethical approval from the REC. The PI or delegate should ensure:

- Time and suitable location for the information to be received by the potential participant and confidentiality to be maintained.
- Remote consent is undertaken with a colleague who can verify the process, if required.
- PIS is provided to participants, and sufficient time provided for them to review.
- That the process is clearly documented in the medical notes.

4.12. eConsent

- 4.12.1. Under the principles of the GCP guidelines, the PI or delegate receiving consent should ensure that participants understand what they are consenting to, particularly for trials and studies using complex or digital methods.
- 4.12.2. The MHRA and HRA issued a joint statement in 2018, approving the use of electronic methods for seeking, confirming and documenting informed consent for participation in research. [hra-mhra-econsent-statement-sept-18.pdf](#)
- 4.12.3. eConsent approach can supplement the traditional paper-based approach or replace it, as appropriate.
- 4.12.4. Participants must be provided information about the trial or study through a consultation with the investigator or an appropriately delegated member of the research team. The purpose of the consultation is to provide potential participants with the opportunity to understand the nature, significance, implications, and risks of the trial or study in order that they may make an informed decision about whether or not to take part.
- 4.12.5. Where possible, the consultation should be conducted in person or, where this can be justified and approved by the REC, by electronic methods that allow for two-way communication in real time, such as via telephone or video conferencing. Whichever method is used, it is important that confidentiality is maintained, and that the communication method is secure.
- 4.12.6. The use of electronic methods to provide information may not be appropriate for everyone. Special attention should be paid to the information needs of specific patient populations and those of individual participants. Wherever possible this should include consideration of the resources which the patient population or individual may need to access this information.

4.13. Withdrawal of Consent

- 4.13.1. A participant has the right to withdraw from the trial or study at any time, without penalty and standard of care will not be affected.
- 4.13.2. Investigators may explore ways to resolve issues and encourage participants, without undue influence, to reconsider withdrawal.
- 4.13.3. Following the participant's withdrawal from the trial or study, no further protocol procedures should be undertaken unless the participant agrees for these to be followed up for their own safety. Otherwise, any further treatment should continue outside of the protocol.
- 4.13.4. It should be clearly documented whether the participant has withdrawn from treatment or treatment and follow-up.

- 4.13.5. Data and samples already collected at the point of withdrawal may be used in the trial analysis. The participant may request that no further data is added to the database, that any retained samples be destroyed and that previous data collected are not used. Discussion should be carried out with the sponsor or their representative around the use and destruction of data.
- 4.13.6. It should also be documented whether the participant withdraws consent for their data to be used in the trial or study or future research, as applicable.
- 4.13.7. Refer to [Section 4.9](#) for the use of Human Tissue samples in research.

5. Dissemination and Implementation

- 5.1. Trust-wide Research and Development (R and D) procedural documents will be stored on the Trust's Document Library, and a working copy will be accessible through EDGE providing alternative access for research staff.
- 5.2. The Research Governance Manager or delegate will arrange for documents to be published on the Trust Documents Library and EDGE.
- 5.3. The Research Governance Manager or delegate will ensure that any previous versions of the document are made inaccessible to general EDGE users, in accordance with the EDGE document archiving procedure.
- 5.4. R and D SMT to define any training requirements prior to the implementation of any procedural documentation. There will be appropriate time allowed for such training prior to the publishing of the SOP or WI.
- 5.5. Relevant research staff registered on EDGE will be notified by email of the new or reviewed document. Relevant staff will be identified from the ownership and responsibilities ([Section 3](#)) of this procedural document and the R and D AD19 Training Matrix (see Documents folder in EDGE).
- 5.6. Details of how to access EDGE is available by contacting the Research Systems Officer via rch-tr.edge@nhs.net.
- 5.7. It is the responsibility of all staff to check the website regularly, in order to see if SOPs have been added or amended. R and D will endeavour to notify research staff of any SOP developments that may be relevant to them via staff communications, for example, R and D Newsletters, Leadership Huddle and Workstream Huddles. A list of any new or updated SOPs will be reviewed and ratified at the R and D Senior Management Team Governance and Performance monthly meetings.
- 5.8. Consideration must be given at study set up as to which SOPs will not apply to a specific study, with agreement from the R and D Senior Management Team (SMT). Full details must be included as a written statement in the study site file.
- 5.9. Whilst SOPs may be printed, the electronic version maintained on R and D internet page is the controlled copy. Any printed copies are not controlled documents.

5.10. Chief and Principal Investigators will be notified as per the Trust's process for notifying all staff of new procedural documents.

5.11. Training and Development

5.11.1. When a new SOP is authorised, or when an existing SOP is revised, self-directed training as specified and detailed by the SMT must be carried out by all staff to which the SOP is relevant, and this training documented on EDGE.

5.11.2. Staff should take time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP as required. If clarification is needed, the staff member should approach the Research Governance Manager, or another member of the SMT, who will arrange additional training. All staff are responsible for maintaining their own training logs and copies must be made available to study monitors on request.

5.12. SOP Deviations

5.12.1. If a process deviates from an approved SOP, a risk assessment will be undertaken to determine the consequences and identify any remedial action(s) that needs to be taken. It may also be appropriate to submit an incident report via the Datix system.

5.12.2. The author of the risk assessment must submit the risk assessment to SMT.

6. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Successful implementation of the procedures described in this SOP ensures that there is a clear understanding of the roles and responsibilities for staff conducting research studies and clinical trials at RCHT.
Lead	Research Governance Manager.
Tool	Internal and external monitoring of research studies and clinical trials will monitor the implementation of this SOP and compliance with Good Clinical Practice (GCP).
Frequency	Compliance with this procedural document will be monitored as part of the R and D risk-based, audit and monitoring process directed through the R and D SMT Governance and Performance meetings.
Reporting arrangements	The Research Governance Manager will provide monthly reports at the R and D SMT Governance and Performance meetings.

Information Category	Detail of process and methodology for monitoring compliance
Acting on recommendations and Lead(s)	The Governance and Performance SMT meetings will provide effective oversight and ensure corrective actions are undertaken.
Change in practice and lessons to be shared	The Governance and Performance SMT meetings will identify non-compliance and appoint a member of the SMT to provide support and advice to identify training needs and improve practice. Required changes to practice will be implemented as soon as practically possible.

7. Updating and Review

The R and D procedural documents will be reviewed no less than every three years by the R and D SMT unless an earlier review is required, in accordance with Section 9 of the Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies).

8. Equality and Diversity

8.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the [Equality Diversity And Inclusion Policy](#) or the [Equality and Diversity website](#).

8.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Research and Development SOP029 - Informed Consent Standard Operating Procedure V6.0
This document replaces (exact title of previous version):	Research and Development SOP029 - Informed Consent Standard Operating Procedure V5.0
Date Issued / Approved:	May 2026
Date Valid From:	July 2026
Date Valid To:	July 2029
Author / Owner:	Caroline Phillips, Research Governance Manager.
Contact details:	rcht.researchqualityassurance@nhs.net
Brief summary of contents:	This SOP also outlines the participant informed consent process, including the required documentation and procedures for completing and filing the essential study documentation.
Suggested Keywords:	Standard Operating Procedures (SOP). Good Clinical Practice (GCP). Research and Development (R and D).
Target Audience:	RCHT: Yes CFT: No CIOS ICB: No
Executive Director responsible for Policy:	Chief Strategy Officer
Approval route for consultation and ratification:	R and D Senior Management Team (SMT)
Manager confirming approval processes:	Bianca Mills, Head of Research and Development
Name of Governance Lead confirming consultation and ratification:	Caroline Phillips - Research Governance Manager
Links to key external standards:	Good Clinical Practice for Clinical Trials https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials

Information Category	Detailed Information
Related Documents:	The Medicines for Human Use (Clinical Trials) Regulations 2004 The Medicines for Human Use (Clinical Trials) Regulations 2004 The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 International Council for Harmonisation (ICH) Guideline for Good Clinical Practice E6 (R3), (06 January 2025). https://database.ich.org/sites/default/files/ICH_Step4_FinalGuideline_2025_0106 World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants (October 2024) WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants – WMA – The World Medical Association UK Policy Framework for Health and Social Care Research (2017) https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/ Good Clinical Practice – HRA Guidance https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/good-clinical-practice/ Directive 2001/20/EC of the European Parliament and of the Council https://www.legislation.gov.uk/eudr/2001/20/contents Mental Capacity Act 2005 - https://www.legislation.gov.uk/ukpga/2005/9/section/1 Parental Rights and Responsibilities https://www.gov.uk/parental-rights-responsibilities/who-has-parental-responsibility Human Tissues Act 2004 - https://www.legislation.gov.uk/ukpga/2004/30/contents Joint statement on seeking consent by electronic methods https://s3.eu-west-

Information Category	Detailed Information
	2.amazonaws.com/www.hra.nhs.uk/media/documents/hra-mhra-econsent-statement-sept-18.pdf R and D SOP004 Reporting and Managing Non-compliance and Serious Breaches. R and D SOP009 Roles and Responsibilities. R and D SOP030 Delegation of Duties. R and D AD19 Training Matrix.
Training Need Identified:	Yes – Details provided in Section 5.
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Research and Development

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
01/07/2014	V1.0	Complete revision to reflect current practice.	Dr N Morley, R and D Assistant Research Manager.
27/04/2017	V2.1	'Policy Under review' label added.	Helen Holman, Data Quality and Project Monitoring Officer.
01/08/2017	V3.0	Complete rewrite to align with Trust policies.	Dr N Morley, R and D Assistant Research Manager.
01/06/2021	V4.0	Review and update in accordance with Trust policies.	Dr N Morley, R and D Assistant Research Manager.
25/05/2023	V5.0	Changes from RD and I to R and D. Review of SOP in line with GCP guidance and feedback from external monitoring and audits. Review and update in accordance with Trust policies. Document reformatted in line with the Trust's policy.	Caroline Phillips, Research Governance Manager.

Date	Version Number	Summary of Changes	Changes Made by
		Change of title from Consent to Participate in Research to Informed Consent	
21/05/2026	V6.0	Review to reflect the changes to the Clinical Trials Regulations and ICH GCP guidance. Review of SOP in line with GCP guidance, feedback from external monitoring and audits and changes to R and D procedures. Review and update in accordance with Trust policies.	Caroline Phillips, Research Governance Manager.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus six years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust [The Policy on Policies \(Development and Management of Knowledge Procedural and Web Documents Policy\)](#). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Quality and Equality Impact Assessment (QEIA) Form

The QEIA process allows RCHT to monitor the impact of changes to its policies and services, ensuring that nobody is unduly disadvantaged.

Please ensure you have completed a Quality and Equality Impact Assessment (QEIA) using this link to complete the form:

[E11 QEIA Policy](#).

For guidance, please see the [QEIA Essentials – Quick Reference Guide](#) or contact as required below:

Equality, Diversity and Inclusion guidance, please contact: rcht.inclusion@nhs.net.

Quality Governance guidance, please contact Jillian Tozer: jillian.tozer3@nhs.net.