

Document Title			
Standard Operating Procedures for Computed Tomography (CT) Imaging investigation in Research			
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1.0	10/09/2026	01/09/2029	First version developed in consultation and published to QMS.

1.0 Introduction

Computed Tomography (CT) uses ionising radiation to produce detailed cross-sectional images and may be undertaken as part of biomedical or medical research.

QS Enterprises Ltd (QSE) may be approached by NHS, academic, charitable or commercial research organisations to undertake CT examinations as part of approved research studies. Research CT exposures are subject to the Ionising Radiation (Medical Exposure) Regulations 2017 [IR(ME)R], as amended, in addition to applicable research governance, radiation protection and local QSE requirements.

Where another organisation is involved in the referral, justification, organisation or delivery of an exposure undertaken at QSE, there may be more than one IR(ME)R employer involved in the pathway. Regulation 6A of IR(ME)R requires such employers to co-operate to the extent necessary to ensure that each has access to information concerning the exposure or potential exposure and is able to fulfil its responsibilities under the Regulations.

QSE has therefore established a formal process for the appraisal and authorisation of research CT studies. This includes completion of an **IR(ME)R Process Agreement** between QSE and the relevant external employer and formal review of the study documentation by QSE's Medical Physics Expert (MPE) and nominated IR(ME)R Practitioner before any research CT exposures commence.

2.0 Purpose

The purpose of this SOP is to:

- define the process for appraisal, approval and implementation of research studies involving CT at QSE;
- ensure that research CT exposures are undertaken in accordance with IR(ME)R;
- describe QSE's arrangements for compliance with Regulation 6A concerning co-operation between employers;
- ensure that the respective IR(ME)R responsibilities of QSE and any external employer are clearly defined before participant exposures commence;
- ensure appropriate Practitioner and MPE review of research CT studies;
- ensure that approved research protocols, dose constraints and study-specific requirements are correctly implemented; and
- provide a clear governance framework for subsequent protocol amendments, incidents and study closure.

2.0 Definitions/Abbreviations

Research CT	A CT examination undertaken wholly or partly as part of a biomedical or medical research programme.
IR(ME)R	The Ionising Radiation (Medical Exposure) Regulations 2017, as amended.
IR(ME)R Employer	A person or organisation which, in the course of a trade, business or other undertaking, carries out or engages others to carry out medical exposures or practical aspects of medical exposures within the meaning of IR(ME)R.
External Employer / Research Partner	The external organisation which holds IR(ME)R employer responsibilities for one or more elements of the research exposure pathway.
IR(ME)R Process Agreement	The study-specific written agreement between QSE and the external IR(ME)R employer defining respective responsibilities and arrangements for co-operation between employers.
IR(ME)R Practitioner	A registered healthcare professional entitled by the relevant IR(ME)R employer to take responsibility for justification of an individual exposure.
Operator	An individual entitled by the IR(ME)R employer to undertake practical aspects of an exposure.
Medical Physics Expert (MPE)	An individual meeting the requirements of IR(ME)R and recognised by the employer to provide specialist advice on radiation physics in relation to medical exposures.
Principle Investigator	The individual with overall responsibility for conduct of the research study at the relevant research site.
IRAS	Integrated Research Application System.
Sponsor	The organisation taking responsibility for the initiation, management and financing of the research.
PIS	Participant Information Sheet.

4.0 Scope

This SOP applies to all research studies involving CT exposures undertaken using CT equipment owned and managed by QSE.

It applies to research involving healthy volunteers and patients and includes studies where:

- the CT exposure is additional to normal clinical care;
- a clinically indicated CT examination is modified for research purposes;
- research-specific acquisitions or repeat acquisitions are required; or
- QSE provides CT imaging as a service to another research organisation.

This SOP applies in addition to QSE's normal IR(ME)R Employer's Procedures, CT operating procedures, radiation safety policies, referral and vetting procedures, incident reporting procedures and research governance requirements.

No research CT exposure may be undertaken outside the process described within this SOP.

5.0 Equipment

Research CT examinations may only be undertaken using CT equipment owned and managed by QSE and included within QSE's current IR(ME)R equipment inventory.

All equipment used for research CT must remain subject to QSE's normal quality assurance, maintenance and radiation protection arrangements.

Study-specific reconstruction software or other software which falls within the IR(ME)R definition of equipment must be appropriately assessed before use.

6.0 Specific Procedures

6.1 Appraisal of proposed studies

QSE may receive enquiries from academic, NHS, charitable and commercial research organisations seeking CT data acquisition services.

All new research proposals must be reviewed through a consistent appraisal process to ensure that they are technically feasible, appropriately governed, adequately resourced, commercially agreed and safe for participants and staff. A robust and clearly defined process for handling new enquiries is required to ensure that:

- Communication with investigators/research teams is efficient and timely,
- New proposals are considered with an appropriate and equitable attention to detail,
- Study protocols are accepted and implemented in a way that protects company assets, including the protection of valuable scanner capacity.
- Protects QSE employees from exposure to research studies for which they have not received appropriate training, or do not have the appropriate equipment available to perform their role safely and efficiently.
- Research CT continues to complement QSE's clinical scanning services, and does not in any way interfere with, or form a barrier to new clinical scanning pathways.

Before QSE agrees to participate in a study, sufficient information must be obtained to allow an initial assessment of:

- the study sponsor and Principal Investigator;
- the proposed participant population;

- the purpose of the CT examination;
- the number and frequency of CT examinations;
- the anatomical area to be examined;
- whether examinations represent additional radiation exposure for research purposes;
- anticipated study duration and participant numbers;
- contrast or other medicinal product requirements;
- proposed CT acquisition protocol;
- reporting or clinical evaluation requirements;
- operational feasibility and scanner capacity;
- research governance and approval status; and
- the organisations and individuals undertaking the relevant IR(ME)R functions.

An initial assessment of technical feasibility does **not** constitute IR(ME)R authorisation or permission to commence scanning.

No research CT participants may be scheduled or exposed until the approval process described below has been completed.

Enquiries made to any other employee or department should be redirected to the Operations Manager or CEO before any response is given.

6.2 Research Governance Documentation

Before final study approval, the research partner must provide QSE with the study documentation required for local review.

As a minimum, this will normally include:

- the current approved study protocol;
- the IRAS radiation exposure documentation/form;
- the current approved Participant Information Sheet;
- evidence of the relevant HRA/REC approval where applicable;
- details of the study sponsor and Principal Investigator;

- confirmation of completion of the applicable HRA Radiation Assurance process;
- details of the proposed CT exposure and frequency of exposure;
- details of any applicable research dose constraint;
- relevant imaging or technical manuals; and
- any additional documentation requested by the QSE Practitioner, MPE, Superintendent Radiographer or Operations Manager.

The version number and date of all documents submitted for IR(ME)R review must be identifiable.

6.3 Co-operations of Employers – IR(ME)R Regulation 6A

Where QSE and another organisation both hold IR(ME)R responsibilities in relation to the same research exposure pathway, the organisations must co-operate in accordance with Regulation 6A.

Before the study commences, a study-specific **Process Agreement for IR(ME)R Research CT Scanning** must be completed and agreed between QSE and the external IR(ME)R employer.

The Process Agreement must identify, as applicable:

- the organisations acting as IR(ME)R employers;
- the duration and scope of the agreement;
- modality and any restrictions relating to examination or participant type;
- relevant operational and radiation protection contacts;
- which employer's IR(ME)R Employer's Procedures apply to each aspect of the pathway;
- who may act as Referrer;
- which employer is responsible for Practitioner justification;
- arrangements for authorisation of exposures;
- who arranges the examinations;
- responsibility for establishing and approving CT protocols;
- Operator responsibilities;
- image transfer and PACS arrangements;
- MPE responsibilities;
- clinical evaluation/reporting arrangements;
- recording and monitoring of radiation doses;
- access to relevant previous imaging or exposure information;

- responsibility for ensuring compliance with research dose constraints and the permitted number of study exposures; and
- arrangements for investigation and communication of radiation incidents.

The completed Process Agreement must enable both employers to obtain the information required to discharge their respective responsibilities under IR(ME)R.

The legal responsibilities of either employer are not transferred merely by completion of the agreement. The agreement records how the respective responsibilities will operate in practice and how the employers will co-operate.

The final Process Agreement must be retained within the study-specific QSE research record.

6.4 HRA Radiation Assurance and MPE Review

Research studies involving ionising radiation should have undergone the applicable HRA Radiation Assurance process.

The external employer/research partner is responsible for supplying QSE with the final documentation resulting from the research radiation review process.

Regardless of any national or lead MPE review, **local MPE review by the MPE supporting QSE must take place before CT scanning commences.**

The research partner must provide the QSE MPE with the relevant study documentation, including as a minimum:

- study protocol;
- Participant Information Sheet; and
- IRAS radiation exposure documentation.

The QSE MPE will review the proposed study to confirm, as applicable, that:

- the proposed CT protocol can be performed locally within the estimated dose range established for the research;
- the proposed acquisition is appropriately optimised;
- relevant study dose constraints have been identified;
- the radiation dose and associated risk described within the Participant Information Sheet are appropriate;
- appropriate arrangements exist for local dose monitoring; and
- any study-specific radiation protection considerations have been addressed.

Any concerns or required amendments identified by the MPE must be resolved before the study proceeds.

6.5 IR(ME)R Practitioner Review

In addition to MPE review, the study must be reviewed by a radiologist who is appropriately entitled by QSE to act as an IR(ME)R Practitioner for the relevant exposures.

The Practitioner will review the study protocol, research application/IRAS radiation documentation and Participant Information Sheet.

The Practitioner must be satisfied that:

- any additional ionising radiation exposure arising from participation in the research has been appropriately identified within the research application;
- the proposed research exposures are capable of justification under IR(ME)R;
- sufficient information is available to support subsequent individual justification of participant exposures;
- the proposed referral and justification arrangements are appropriate; and
- the responsibilities defined within the IR(ME)R Process Agreement are compatible with QSE's Employer's Procedures.

Study-level approval does not replace the requirement for each individual exposure to be appropriately referred, justified and authorised in accordance with IR(ME)R.

6.6 Final IR(ME)R Authorisation of the Study

Completion of the local review will be documented using the approved **Post-IRAS CRE & MPE / IR(ME)R Authorisation Form**.

The form must identify the versions of the following documents reviewed:

- study protocol;
- Participant Information Sheet; and
- IRAS radiation exposure form/documentation.

The QSE IR(ME)R Practitioner and QSE MPE must complete their respective declarations and record their name, signature and date.

The study must not proceed to participant scanning until:

1. the IR(ME)R Process Agreement has been agreed;
2. required research governance documentation is available;
3. local MPE review has been satisfactorily completed;
4. local Practitioner review has been satisfactorily completed;
5. the Post-IRAS/IR(ME)R Authorisation Form has been completed;

6. operational feasibility has been confirmed;
7. the approved protocol has been implemented on the relevant CT scanner;
8. relevant staff training has been completed; and
9. the appropriate contractual/work-order arrangements are in place.

Evidence of completion must be retained in the study-specific research folder.

6.7 CT Protocol Implementation

Only the CT protocol approved through the research radiation review process may be implemented for participant scanning.

The local protocol must be reviewed by the Superintendent Radiographer/research lead and MPE as appropriate before use.

The protocol must be clearly identifiable on the CT scanner and, wherever practicable, distinguishable from routine clinical protocols.

Relevant parameters must be checked against the approved study documentation before the first participant is scanned.

Test or phantom acquisitions may be undertaken where required for protocol development or validation. Human research exposures must not be undertaken for protocol testing unless specifically permitted by the approved research protocol and IR(ME)R arrangements.

6.8 Referral, Justification and Authorisation of the Individual Exposures

Every research CT exposure must be individually referred, justified and authorised in accordance with the responsibilities established in the IR(ME)R Process Agreement and applicable Employer's Procedures.

A research protocol, REC approval or study-level IR(ME)R review does not itself constitute justification of an individual participant exposure.

The Referrer must provide sufficient information to allow the Practitioner to undertake justification, including relevant clinical and research information and, where necessary, information concerning previous exposures.

The Practitioner must determine that the individual research exposure shows sufficient net benefit having regard to the requirements of IR(ME)R and the specific circumstances of the research programme.

Operators must not undertake an exposure where the required referral, justification or authorisation cannot be demonstrated.

6.9 Participant Identification and Study Eligibility

All research participants must undergo QSE's standard positive patient identification procedure before exposure.

Study identifiers must not replace QSE's required patient identification process for the purposes of confirming the identity of the participant attending for examination. QSE staff must use the identifiers required by local clinical procedures to ensure that the correct participant receives the correct exposure.

The research partner remains responsible for confirming research eligibility and consent unless another arrangement is explicitly documented.

Before exposure, QSE staff must confirm that the participant presented for scanning corresponds with the research referral and that the requested examination is consistent with the approved study.

Where the study sponsor, protocol, data management plan or contractual arrangements require the use of a study-specific identifier, pseudonymised identifier or subject number for research purposes, this requirement must be clearly identified during study implementation and communicated to all relevant QSE staff.

Clinical patient identifiers required for safe local identification and delivery of the examination must not automatically be used in external research communications, study documentation, image transfers or other research-related correspondence.

6.10 Pregnancy

All applicable research CT exposures must follow QSE's current IR(ME)R Employer's Procedure relating to pregnancy enquiries.

The fact that a participant has already undergone research screening or completed study consent documentation does not remove QSE's obligation to follow its local pregnancy enquiry procedure before exposure.

Any uncertainty must be resolved before the CT exposure takes place.

6.11 Dose Constraints and Number of Research Exposures

Where a research dose constraint has been established, the external employer/research sponsor must ensure that the participant does not undergo more research exposures than permitted by the approved study and that the cumulative exposure remains within the applicable research dose constraint.

This responsibility must be documented within the IR(ME)R Process Agreement.

QSE Operators remain responsible for ensuring that the CT examination delivered locally is consistent with the approved protocol and for recording the radiation dose arising from the exposure.

Where there is uncertainty regarding the participant's previous research exposures, permitted number of examinations or applicable dose constraint, scanning must not proceed until the necessary information has been obtained from the research partner.

6.12 Optimisation and Dose Monitoring

Research CT exposures must be optimised in accordance with IR(ME)R.

Operators must ensure that exposures are performed using the approved research protocol and that radiation doses are kept as low as reasonably practicable while achieving the intended research purpose.

Patient/participant dose information will be recorded and monitored through QSE's established dose monitoring arrangements.

The MPE should be consulted where:

- observed doses differ unexpectedly from the approved or anticipated range;
- protocol changes are proposed;
- dose constraints may be approached or exceeded;
- repeated exposures are being considered; or
- there are other concerns regarding optimisation.

6.13 Training Requirements

All QSE staff undertaking practical aspects of research CT exposures must be appropriately entitled and adequately trained for the functions they perform under IR(ME)R.

Staff must additionally receive study-specific training where required.

This may include:

- approved research CT protocol;
- participant preparation;
- study-specific inclusion or exclusion information relevant to scanning;
- contrast administration;
- image reconstruction requirements;
- research documentation;
- image transfer or upload requirements;
- study-specific participant identification and pseudonymisation requirements;
- approved identifiers to be used in external research communications;
- dose recording requirements; and
- escalation procedures.

Where a sponsor requires study-specific identifiers to be used in preference to clinical identifiers for research communications or data transfer, this requirement must form part of the study-specific training and implementation information available to relevant staff.

Completion of study-specific training must be documented where required.

6.14 Information Provided to Participants

The research organisation/Principal Investigator is responsible for providing study-specific information and obtaining research consent in accordance with the approved research protocol.

The Participant Information Sheet must accurately describe additional ionising radiation exposure and associated risk. This forms part of the documentation reviewed by the local QSE MPE and Practitioner.

QSE may provide additional operational information necessary to attend and safely undergo the CT examination.

Study-specific questions regarding research participation or consent should normally be referred to the research team.

6.15 Clinical Evaluation and Incidental Findings

The arrangements for clinical evaluation of research CT images must be agreed before study commencement and documented within the IR(ME)R Process Agreement and/or study contract.

Where a diagnostic report is required, the relevant QSE Imaging Reporting Policy and reporting procedures will apply.

Where images are being acquired solely for research analysis, responsibility for clinical evaluation and management of incidental findings must nevertheless be explicitly established within the study arrangements.

If a QSE radiographer, radiologist or other member of staff identifies a potentially significant unexpected abnormality, this must be escalated in accordance with QSE's applicable clinical governance arrangements and the agreed study process.

6.16 Contrast and Medicines

Where a research CT study involves administration of iodinated contrast or another medicine, all administrations undertaken by QSE must comply with QSE's existing medicines policies, PGDs, PSDs, protocols and professional scope-of-practice requirements.

Any research-specific variation from QSE's normal contrast practice must be identified during study appraisal and reviewed before approval.

No medicine may be administered outside QSE's approved governance arrangements solely because its use is specified within a research protocol.

6.17 Protocol Amendments and Changes to Study Documentation

Research CT protocols must not be changed informally.

The research partner must inform QSE of any amendment which may affect:

- radiation exposure;
- number or frequency of CT examinations;
- CT acquisition parameters;
- participant population;
- anatomical coverage;
- use of contrast;
- Participant Information Sheet;

- IRAS radiation information;
- dose estimates or dose constraints;
- referral, justification or authorisation arrangements;
- participant identification, pseudonymisation or data-transfer requirements; or
- responsibilities assigned to either IR(ME)R employer.

Revised documentation must be submitted to QSE before the amendment is implemented.

The Operations Manager, Superintendent Radiographer/research lead, Practitioner and/or MPE will determine whether renewed review and authorisation are required.

Where an amendment affects information previously considered by the Practitioner or MPE, the amended documents must normally be formally reviewed and an updated authorisation recorded before implementation.

Staff must be informed of approved amendments and obsolete protocol/document versions must be removed from operational use.

6.18 Incidents and Accidental or Unintended Exposures

Any incident, near miss, protocol deviation or potential accidental or unintended exposure occurring at QSE must be reported through QSE's incident reporting process and managed in accordance with QSE's IR(ME)R Employer's Procedures.

Where more than one IR(ME)R employer is involved, both employers must communicate and co-operate during investigation as required by Regulation 6A.

Each organisation must make any required entry within its own incident reporting system.

The organisations must exchange sufficient information to:

- establish the circumstances of the event;
- assess the radiation exposure involved;
- identify contributing factors;
- determine required corrective action;
- establish whether external notification is required; and
- share relevant learning and changes to the agreed process.

The MPE must be involved where dose assessment is required.

Responsibility for notification to the relevant enforcing authority must be determined in accordance with IR(ME)R and the responsibilities of the respective employers. Where appropriate, this should be established within the Process Agreement.

Duty of candour requirements must be considered and applied where applicable.

6.19 Data Sharing, Study Identifiers and Research Communications

Study-specific data handling arrangements must be agreed before commencement and documented within the relevant contract, work order, protocol, data management plan and/or data-sharing agreement.

The agreed arrangements must clearly identify:

- what participant identifiers may be used;
- whether study numbers, pseudonymised identifiers or other sponsor-defined identifiers are mandatory;
- what information may be shared with the sponsor, CRO or another research partner;
- authorised recipients;
- approved transfer methods; and
- any circumstances in which identifiable clinical information may legitimately be disclosed.

QSE's routine clinical identifiers may continue to be used internally where required for safe patient identification, clinical record keeping, PACS/RIS operation and delivery of the examination.

However, where a research study requires external communications or transferred data to use only a study-specific or pseudonymised identifier, **patient-identifiable information must not be included in external research emails, documentation, file names, image-transfer communications or other correspondence unless explicitly authorised by the agreed study arrangements.**

Before sending participant-related information externally, staff must undertake a pre-send confidentiality check to confirm that:

- the recipient is authorised;
- the communication relates to the correct participant;
- only information necessary for the stated purpose is included;
- the correct study identifier has been used; and
- patient-identifiable information has been removed where the study requires pseudonymised or study-specific communication.

Where there is uncertainty about which identifier may be used, information must not be sent until the requirement has been confirmed with the Superintendent Radiographer, research lead, Operations Manager or designated study contact.

Imaging data must only be transferred to authorised recipients using approved secure transfer mechanisms.

Staff must not transfer identifiable research data using unapproved email accounts, portable media, personal cloud storage or informal file-sharing routes.

Any inadvertent disclosure of patient-identifiable information or failure to follow agreed study-identification requirements must be reported through QSE's incident reporting process and managed in accordance with QSE's information governance procedures.

6.20 Contracts, Indemnity and Finance

No research CT activity may commence until the appropriate contract, work order or equivalent written agreement has been approved by QSE.

The contractual arrangement must define the services to be delivered and, where applicable:

- scan fees;
- cancellation arrangements;
- participant scheduling;
- image transfer;
- reporting/clinical evaluation;
- consumables and contrast;
- indemnity and insurance;
- data processing responsibilities;
- participant identification and pseudonymisation requirements;
- protocol amendments; and
- study-specific training or setup costs.

Completion of a commercial contract does not replace the requirement for the IR(ME)R Process Agreement or local Practitioner/MPE approval.

7.0 Study Records

A dedicated electronic study record/folder must be maintained for each research CT study.

As applicable, this should contain:

- study protocol;
- Participant Information Sheet;
- IRAS radiation documentation;
- HRA/REC approval documentation;
- IR(ME)R Process Agreement;
- completed Post-IRAS CRE & MPE / IR(ME)R Authorisation Form;
- approved CT protocol;

- relevant MPE correspondence;
- Practitioner correspondence;
- contract/work order;
- study-specific instructions;
- training records;
- approved amendments and superseded-document record;
- relevant correspondence; and
- incident or deviation documentation where applicable.

Staff must be able to identify the current approved versions of the documents governing the study.

9.0 Monitoring and Audit

QSE's research governance arrangements will include periodic review of active CT research studies.

Compliance with this SOP may be audited, including review of:

- presence of a completed IR(ME)R Process Agreement;
- Practitioner and MPE approval before commencement;
- use of correct approved document versions;
- staff training;
- CT protocol compliance;
- dose monitoring;
- protocol amendments;
- incidents and deviations; and
- study record completeness.

Where deficiencies are identified, appropriate corrective action must be taken and documented.

9.0 References

- The Ionising Radiation (Medical Exposure) Regulations 2017.
- The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2024.
- Department of Health and Social Care: Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017.
- Health Research Authority: Radiation Assurance guidance.

- UK Policy Framework for Health and Social Care Research.
- QSE IR(ME)R Employer's Procedures.
- QSE CT Local Procedures and Protocols.
- QSE Incident Reporting Policy.
- QSE Imaging Reporting Policy.
- QSE Consent Policy.
- QSE Information Governance/Data Protection Policies.
- Process Agreement for IR(ME)R Research CT Scanning.
- Post-IRAS CRE & MPE / IR(ME)R Authorisation Form.

Appendix A

Research CT – New enquiry.

Study Name:	
PI Name:	
Sponsor organisation:	
REC/HRA approval status and reference number (<i>where applicable</i>):	
Type of scan required:	
Facilitator name and email:	
Protocol specification (incl. requirement for contrast etc) (<i>please attached acquisition manual if available</i>)	
Is a diagnostic report required?	
Anticipated start date:	
Number of subjects:	
Frequency of scan visits per subject / Number of CT Exposures per participant:	
Anticipated study duration:	

Appendix B

Research CT Approval Checklist

Governance documentation

- ☐ Current study protocol received
- ☐ Current Participant Information Sheet received
- ☐ IRAS radiation exposure documentation received
- ☐ REC/HRA approval confirmed where applicable
- ☐ HRA Radiation Assurance completed where applicable
- ☐ Contract/work order completed

IR(ME)R governance

- ☐ External IR(ME)R employer identified
- ☐ QSE IR(ME)R employer responsibilities identified
- ☐ IR(ME)R Process Agreement completed and signed
- ☐ Referral arrangements confirmed
- ☐ Practitioner/justification arrangements confirmed
- ☐ Operator responsibilities confirmed
- ☐ Clinical evaluation arrangements confirmed
- ☐ Responsibility for monitoring number of research exposures confirmed
- ☐ Research dose constraint identified where applicable

Local review

- ☐ QSE MPE review completed
- ☐ QSE IR(ME)R Practitioner review completed
- ☐ Post-IRAS CRE & MPE / IR(ME)R Authorisation Form completed
- ☐ CT protocol built and checked
- ☐ Dose expectations confirmed
- ☐ Contrast arrangements reviewed where applicable
- ☐ Study-specific staff training completed

Equality Impact Assessment (EIA)

This Equality Impact Assessment provides evidence for meeting the Company's commitment to equality and the responsibilities outlined above, for more information about QSE's commitment to equality, please refer to the Diversity, Equality, Inclusion and Human Rights Policy and Equal Opportunities Policy.

For each protected characteristics, answer the questions below by indicating Yes (Y) or No (N)	Sex (male / female / transgender)	Age	Race/Ethnicity	Disability	Religion/Belief	Sexual Orientation	Marriage/Civil Partnership	Pregnancy and Maternity	Carers	Other Group	List Negative/Positive Impacts below
Does the policy have the potential to affect individuals or communities differently in a negative way?	No	No	No	No	No	No	No	No	No	No	
Is there potential for the policy to promote equality of opportunity for all / promote good relations with different groups (a positive impact)?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	This policy supports general principles in place to protect subjects who enrol in clinical research.
For each protected characteristic, are there any areas where you are unsure about the impact and more information is needed?	No	No	No	No	No	No	No	No	No	No	

Assessor Name:	Peter Sutton	Role:	Operations manager	Signed:	P. Sutton	Assessment date:	10/09/2026
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