SOP number	**51.001**	Version	**7.0**
Title	**Protocol Development for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow**		

Prepared by Signature	Louise Ner	Date
Approved by Signature	Melissa Robert	Date
Released by Signature	Jesse Dawson	Date

SOP category	NHSGGC Sponsor R&I

Staff category

Staff Category	**R**	**A**	**C**	**I**
Research & Innovation Systems Manager		X		
Chief Investigator	X			
Project Management	X			
Sponsor Research Co-ordinators	X			
Sponsor Research Facilitator	X			
Innovation Project Manager	X			
Innovation Contracts Manager			X	
R&I Sponsor Pharmacy			X	
R&I Pharmacovigilance			X	
University of Glasgow Research Regulation and Compliance team			X	
Data Management			X	
R&I Monitors			X	
Senior Research Administrators			X	

1. Scope

This SOP applies to R&I staff listed above and specific experts as required during the development of the protocol for Clinical Trial of Investigational Medicinal Products (CTIMPs), Clinical Investigation of Medical Device (CIMD) and all other research studies involving humans, their tissues and/or data (together referred to as 'research studies').

2. Purpose

The purpose of this SOP is to describe how a clinical research protocol must be written to Good Clinical Practice (GCP) standards to comply with The Medicines for Human Use (Clinical Trials) Regulations 2004 (and amendments) and other relevant legislation.

3. Procedures

3.1. Background

A clinical research protocol is a full description of the research study and will act as a 'manual' for members of the research team to ensure everyone adheres to the methods outlined. It is a controlled document which describes a range of activities including the background, rationale, design, population, oversight, data collection, analysis and archiving of a study. The protocol must be carefully designed to ensure the health and safety of the participants, as well as answer specific research questions.

3.2. Responsibilities

The Chief Investigator (CI) of the study is responsible for developing the clinical research protocol. The Sponsor Research Co-ordinator (SRC), Sponsor Research Facilitator (SRF) or Innovation Project Manager (IPM) (together referred to as R&I Co-ordinators) will direct the CI to an appropriate template, review the clinical research protocol in collaboration with relevant stakeholders and advise mandatory inclusions before providing Sponsor approval in advance of any NHS Research Ethics Committee (REC) or regulatory submissions.

3.3. Preparing a Clinical Research Protocol

Upon the initial approach to R&I, the R&I Co-ordinator will direct the CI to the appropriate protocol guidance and template on the Health Research Authority (HRA) website depending on the type of clinical study (e.g. CTIMP, CIMD or other research study): Protocol - Health Research Authority. The R&I Co-ordinator will advise the CI to include the Sponsor(s) logo(s), protocol version number (starting at v0.1) and date of last change during the drafting process.

Where appropriate, the CI will develop the protocol in liaison with the Trial Management Group (TMG), independent experts and Principal Investigators (PIs) for multi-site studies. The R&I Co-ordinator will facilitate this process and provide advice as required.

3.3.1. CTIMP Sub-Studies

Sub-Studies will be separated from the main trial protocol in agreement with the CI and relevant stakeholders. This will allow Sponsor to demonstrate appropriate oversight for the type of study. Approval for a CTIMP sub-study must be obtained by Sponsor before inclusion. This will be discussed with all relevant Sponsor stakeholders and if required, escalated to the R&I Director for confirmation of approval. If approved, details of the sub-study and requirements for participation in the sub-study, must be clearly defined within the main study protocol.

3.4. Review of Clinical Research Protocol

When the CI has a completed draft of the protocol, this will be sent to the R&I Co-ordinator for review. The R&I Co-ordinator or CI may seek independent expert advice to ensure that the clinical protocol:

- contains the appropriate information
- makes full appraisal of the safety and wellbeing of study participants
- is designed appropriately to answer the research questions

Advice may be sought from a number of different professionals which may include, but is not limited to, an Independent Medical Advisor, a Statistician, a Sponsor Pharmacist, a Study Co-ordinator, Clinical Trial Monitor, Radiation Expert or Pharmaco-/ device vigilance expert. The R&I co-ordinator must ensure input has been sought from a Sponsor Pharmacist for any protocol involving a medicine and an appropriately qualified Statistician for any randomised studies, except for pilot studies.

The R&I Co-ordinator will ensure, in collaboration with the relevant Sponsor representative(s), the protocol clearly describes the background, risks and benefits associated with the study; the rationale behind the study; the aims of the study; who the participants are in the study; inclusion and exclusion criteria; detailed information on recruitment and informed consent; the schedule of events (screening, baseline, treatment, follow-up), procedures, imaging pathway if relevant (as per SOP 51.033), sample pathway if relevant (as per SOP 51.028), details of and requirements for participation in approved sub-studies, medications and doses (if relevant); the duration of the study; procedures for reporting adverse events; and statistical methods that will be used to answer the research questions; the data management plan (including source data management); monitoring of the trial (required for CTIMPs/CIMDs); archiving procedures as per SOP 51.024/51.025 and plans for dissemination of the results.

3.5. Approval of Clinical Research Protocol for REC/Regulatory Submission

The final version of the protocol must be approved by Sponsor(s) before submission to the REC and/or any regulatory bodies (e.g. MHRA) or trial activity commences as per SOP 51.014. When all comments have been addressed and any issues have been resolved, the SRC or SRF will confirm to CI, on behalf of relevant Sponsor stakeholders, that the protocol complies with Sponsor standards. The final protocol will be named version 1.0 (V1.0), signed and dated as the day of Sponsor approval. All appropriate staff must sign the protocol e.g. Chief Investigator, Sponsor Representative (normally R&I Co-ordinator), Statistician (if appropriate). Each amended protocol version must be re-signed. Sponsor approval for REC/Regulatory submission is dependent upon review and approval of all other required documents (as per SOP 51.014). The SRA will save V1.0 of the protocol and any relevant correspondence in the TMF and e-folder (as per SOP 51.016).

3.6. Peer Review of Clinical Research Protocols

It is the responsibility of the study Sponsor(s) to ensure that the study is of high quality, has an acceptable risk/benefit profile, is relevant and is appropriately designed to answer the specific research questions. Therefore all clinical research studies must undergo independent peer review as per SOP 51.003.

4. Referenced documents

- SOP 51.003 - Peer review
- SOP 51.014 - Preparation and Submission of IRAS Forms
- SOP 51.016 - Preparation and Maintenance of a Trial Master File
- SOP 51.024 - Archiving Essential Documents from Clinical Research – Process for a GGC Sponsored/Co –Sponsored Clinical Trial of an Investigational Medicinal Product (CTIMP) and/or Clinical Investigation of a Medical Device (CIMD)
- SOP 51.025 - Archiving Essential Documents from Clinical Research – Process for a Sponsored Non CTIMP
- SOP 51.028 - NHS Laboratory samples for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow or hosted by NHSGGC
- SOP 51.033 - Research Imaging for Trials involving an Investigative Medicinal Compound (CTIMP) Sponsored by NHS GG&C or Co-sponsored by NHS GG&C and the University of Glasgow (UoG)

5. Related documents

- SOP 55.001 - Pharmacovigilance in Clinical Trials of Investigational Medicinal Products (Glasgow Clinical Trials Unit).
- HRA Protocol guidance and template for use in a Clinical Trial of an Investigational Medicinal Product (CTIMP)
- HRA Protocol guidance and template for use in qualitative research

6. Document History

Version	Date	Description
1.0	27/07/2012	Release of Version 1
2.0	14/07/2016	Updated to template v1.4. Change of author. Minor update to text.
3.0	30/05/18	Change of author. Minor update to text and formatting. Update to Form 51.001A and Form 51.001B. to reflect categorisation of laboratory tests.
4.0	17/12/2018	Staff category updated & author changed
5.0	02/03/2020	Additional detail of procedures and participation in sub-studies. Addition of source data management Staff Category updated Remove reference to regulation. Reference to HRA Protocol templates included Procedure and process updated Clarity added in relation to Protocol sign off.
6.0	11/02/2022	Updated to change R&D to R&I, include innovation staff and detail clinical Investigations of non-CA marked devices
7.0	21/08/2025	Updated to reflect current regulations and clarify process