Standard Operating Procedure			**51.001**
Protocol Development			
Version	6.0		
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Released by	Julie Brittenden	Signature	Date

1. SOP Category

NHS GG&C Sponsor R&I

2. Staff Category

R&I Co-ordinators (research and innovation)
Chief Investigators
Clinical Trial Monitors
Sponsor Pharmacovigilance
Sponsor Pharmacy
Project Management
Research Governance for University of Glasgow (Manager & Officer)
Innovation Contracts Manager (Innovation Co-ordinator)
Innovation Project Manager

3. Scope

This SOP applies to Co-ordinators during the set-up phase of clinical research and innovation studies and provides a guide for developing clinical research protocols. For Clinical Investigations of non-CA marked Medical Devices the term protocol means Clinical Investigation Plan.

4. Purpose

The purpose of this SOP is to describe the format for writing a clinical research protocol that complies with standards required by Good Clinical Practice (GCP) as outlined in the relevant legislation.

This document outlines the minimum information required to prepare a protocol for clinical research studies. In addition, this SOP describes the role of the R&I Co-ordinator in assisting investigators develop a high quality research protocol for each clinical study.

Background

A clinical research protocol is the document that outlines, in detail, the study plan. The plan should be carefully designed to ensure the health and safety of the participants, as well as answer specific research questions.

All research studies involving humans, their tissues and/or data are required to have a protocol written to the standards of GCP. For investigational studies involving medicinal products (CTIMPS) or medical devices it is a regulatory requirement.

Whom
This SOP applies to staff working across GG&C when developing non-commercial clinical research protocols for studies either Sponsored or Co-Sponsored by NHS Greater Glasgow & Clyde.

Responsibility for the clinical research protocol lies with the Chief Investigator (CI) of the study. The R&I Co-ordinator should assist and advise on the development of clinical research protocols and mandatory inclusions before providing Sponsor approval in advance of any regulatory submissions.

How
Clinical research protocols should be developed by the CI in liaison with the Trial Steering Committee and Principal Investigators (for multi-site studies) (if appropriate). The Research Co-ordinator should facilitate this process and provide advice as required.

Upon the initial approach to R&I the R&I Co-ordinator should direct the CI to protocol template(s) appropriate to the type of clinical study (e.g. CTIMP, Clinical Investigation of a non-CA marked device, other study). The protocol should be completed and approved by Sponsor before any submission to regulatory bodies (competent authority or Research Ethics Committee) or trial activity commences.

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. For example, input from a Sponsor Pharmacist must be sought for a CTIMP protocol or a non-CTIMP protocol involving medicines; and for any randomised studies then an appropriately qualified Statistician must be consulted, except for pilot projects.

5. Procedures

Preparing a Clinical Research Protocol
Initially, the R&I office should direct researchers to the appropriate protocol guidance and template on the Health Research Authority (HRA) website.

The protocol should clearly describe 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, requirements for participation in 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) and plans for dissemination of the results.

CTIMP Sub-Studies
Approval for the inclusion of a CTIMP sub-study must be obtained. The approval of a Sub-study must be considered by Sponsor representative and if required escalated to the R&I Director for confirmation of approval. Details of, and requirements for participation in, any sub-study must be clearly defined within the main study protocol.

The Sponsor and/or co-sponsor's logo(s), protocol version number (starting at V0.1) and date of last amendment should be added to protocols during the drafting process. The final version of the protocol approved by Sponsor(s) for submission to regulatory bodies should be named version 1.0 (v1.0), signed and dated as the day of Sponsor approval. All appropriate staff should sign the protocol e.g. Chief Investigator, Sponsor Representative, Statistician (if protocol template cover sheet dictates). Each amended protocol version should be re-signed.

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. Studies funded by a recognised eligible funder will not require further peer review as these studies are reviewed extensively by the funding body when assessing the grant for funding support. Further independent peer review is, also, not required for student studies as they will have undergone review as part of the educational process and responsibility for the study designs is with the Academic Supervisor and their substantive employer.

If required, the R&I Co-ordinator is responsible for arranging independent peer review in accordance with the Peer Review SOP 51.003.

6. Referenced documents

SOP 51.003: 'Peer review'

7. Related documents

SOP 55.001: Pharmacovigilance in Clinical Trials of Investigational Medicinal Products (Glasgow Clinical Trials Unit).

8. 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 non0CA marked devices