SOP number	**51.023**	Version	**6.0**
Title	**Sponsor process for an IDMC**		

Prepared by	Liz-Anne Lewsley
Approved by	Melissa Robert
Released by	Jesse Dawson

SOP category	
Staff category	

Staff Category	**R**	**A**	**C**	**I**
Research & Innovation Systems & Operations Manager		X		
Sponsor Research Co-ordinators	X			
R&I Innovation Co-ordinator	X			
Project Managers	X			
University of Glasgow Research Governance Manager & Officer			X	
R&I Sponsor Pharmacy			X	
Chief Investigators			X	
Data Managers			X	
R&I Governance			X	

1. Scope

This procedure applies to Sponsor representatives for clinical trials of investigational medicinal products (CTIMPs), non-CA marked Medical Devices (CIMD), and, where appropriate, other high risk studies, Sponsored by NHS Greater Glasgow & Clyde (NHSGGC) or Co-Sponsored by NHSGGC and the University of Glasgow (UoG)

Set up and management of an Independent Data Monitoring Committee (IDMC) for studies managed by the GO CTU is delegated to the GO CTU and will follow their equivalent SOPs.

2. Purpose

The purpose of this SOP is to describe the process to determine when an IDMC is required and to detail the requirements of the group, timelines and content of IDMC charter. These activities help to ensure Sponsor oversight for this type of trial activity.

3. Procedures

3.1 Determining Whether an IDMC Is Required

The purpose of an IDMC is to plan the ongoing review of the data collected in a clinical trial in order to protect the safety of the participants, and ensure the validity of the results. Not all clinical trials require an IDMC and this decision should be made taking account of the following:

- Study population – whether the trial involves vulnerable groups or patients with life-threatening illnesses
- Potential risk of harm - significant risk of harm or unknown risk, or well characterised drug with good safety record
- Study duration - impractical in very short studies/ appropriate with long term outcomes
- Early assessment of futility/efficacy
- Study design- complex/ adaptive studies, or simple treatment of short-duration

Discussion must involve the Chief Investigator (CI), Sponsor representatives (Governance team/ Pharmacy/ Co-ordinators) as well as, where appropriate, input from Data Management. The need for an IDMC will be discussed at the Sponsor risk assessment of the study (SOP 51.003) and the decision to have an IDMC documented during the risk assessment meeting.

The final decision rests with the Sponsor.

3.2 Setting up an IDMC

This is the responsibility of the Sponsor, with input from the CI and should be set up before, or as close to the date of first patient recruitment as possible. If it is an early phase trial the IDMC should be set up before RGL. Early phase trials may also require a Safety Review Committee ,please refer to Sponsor SOP on the Mangement of Dose Escalation in Early Phase IMP/ATIMP Clinical Trials (SOP 21.025) for guidance.

Identifying members:

IDMCs vary in size but should consist of a minimum of 3 members - a chairperson who is an experienced trialist, a statistician, and at least one other member expert in the area of medicine and/or device being studied. When members have been identified by the CI they will be approached officially by the Sponsor, with the assistance of the Project Manager, with a request to take part using Form 51.023C and 51.023D for trials sponsored by NHSGGC alone, and Co-Sponsored with the University of Glasgow, respectively. It is the requirement of some funders (e.g. NIHR) that they have to approve the Chair of the IDMC therefore this should be actioned if applicable.

They will also be sent a draft Charter based on the MRC template (https://www.mrcctu.ucl.ac.uk/our-research/other-research-policy/regulatory-information-toolkits-templates/), including a Competing Interests statement, and the current version of the protocol. The IDMC may, with prior approval from Sponsor(s), contact and involve consultants to provide additional expertise as and when this is required.

The Study Project Manager will normally act as the Committee co-ordinator.

3.3 IDMC Charter/Meetings

The IDMC will review and agree the IDMC Charter at their first meeting, and once signed by all committee members this will be stored in the Trial Master File.

The IDMC charter will specify the minimum number of members required for meetings to be considered quorate, along with attendance expectations. While this may vary depending on the specific trial, a meeting is typically quorate when it includes a formally appointed Chairperson (an experienced trialist), a Statistician, and at least one additional expert in the relevant medical or device field.

The IDMC charter will be reviewed as required, and if updates are needed, a revised version will be prepared and re-signed by all committee members.

3.3.1 IDMC meetings:

The minimum frequency and data requirement of the IDMC will be included in the Charter. The Project Manager or designee will act as the committee co-ordinator, and the data provided by an unblinded Statistician (where appropriate and according to Data Management centre SOPs). Attendance will be taken and the meeting confirmed quorate prior to commencement. If the meeting is not quorate, it may be that this will need to be re-scheduled however details should be included in the Charter. Open sessions of the meetings will involve the committee, CI (or representative), and Consultants as required, whereas closed sessions will involve only the IDMC members.

3.3.2 IDMC minutes/reports and recommendations:

Minutes of open sessions of the meeting will be taken by the Project Manager (or delegate) as committee co-ordinator, and for closed sessions by a nominated member of the committee. These will be stored securely by the Chair and provided to the Sponsor after completion of the study analysis.

The committee Chair will provide a completed report to the Sponsor and the Chair of the Trial Steering Committee (TSC) after each meeting on the report template (based on Annexe 3 of the MRC IDMC template) indicating whether they consider that the study should continue as is, be amended, or halted. Recommendations made by the IDMC over the course of a trial should be given full consideration by the Sponsor, TSC and research team. The outcome of these considerations may results in amendments being made to the study protocol and associated study documents.

4. Referenced documents

- Form 51.023C - Letter of Invitation to IDMC member GG&C sole Sponsor
- Form 51.023D - Letter of Invitation to IDMC member GG&C/UoG co-sponsor
- SOP 51.003 - Risk Assessment
- SOP 21.025 – Management of Dose Escalation in Early Phase IMP/ATIMP Clinical Trials
- MRC CTU Template Independent Data Monitoring Committee Charter and Annexes (https://www.mrcctu.ucl.ac.uk/our-research/other-research-policy/regulatory-information-toolkits-templates/)

5. Related documents

- SOP 51.036 - Trial Steering Committee for Trials Involving an Investigative Medicinal Product (CTIMP) Sponsored by NHS GG&C or Co-sponsored by NHS GG&C and the University of Glasgow

6. Document History

Version	Date	Description	Retrospective Implementation
1.0	28/01/2016	New SOP release	No
2.0	14/07/2016	SOP renumbering	No
3.0	17/12/2018	Staff category, Author & Approver updated	No
4.0	02/03/2020	Contractual nature of the committee invite/acceptance added. Clarification of processes and procedures added SOP version updated IDMC recommendation form number updated	No
5.0	25/08/2022	Staff Categories expanded Inclusion of Clinical Trials of non-CA marked Medical Devices (CIMD) Added reference to CRUK CTU equivalent SOPs Included additional statements re make up of TSC Added information on approaching potential member Added Forms 51.023C and 51.023D and made Form 51.023A and 51.023B obsolete. Updated link to MRC IDMC Charter	No
6.0	21/10/2025	Amend references from CRUK CTU to GO CTU Removal of text regarding honorary contracts Update to link for MRC IDMC Charter Template Clarification of when IDMC should be set up in relation to RGL and patient recruitment Reference to Safety Review Committee (dose escalation SOP 21.025) Updates regarding IDMC being quorate	No