Standard Operating Procedure			**51.023**
Sponsor process for an IDMC			
Version	**5.0**		
Prepared by	Maureen Travers	Signature	Date
Approved by	Melissa Robert	Signature	Date
Released by	Julie Brittenden	Signature	Date

1. SOP Category
NHS GG&C Sponsor R&I

2. Staff Category
- Chief Investigators
- University of Glasgow Research Governance Manager & Officer
- Sponsor Research Co-ordinators
- R&I Innovation Contracts Manager
- R&I Innovation Co-ordinator
- NHS GG&C Sponsor Project Management Unit,
- Innovation Project Managers
- GU Project Managers
- R&I Sponsor Pharmacy

3. 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 (NHS GG&C) or co-sponsored by NHS GG&C and the University of Glasgow (UoG)

Set up and management of an IDMC for studies managed by the CRUK CTU is delegated to the CRUK CTU and will follow their equivalent SOPs.

4. 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.

5. Procedures
5.1 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 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..

The final decision rests with the Sponsor.

5.2 Setting up an IDMC

This is the responsibility of the Sponsor, with input from the Chief Investigator (CI) and should be set up before, or as close to the date of first patient recruitment as possible.

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 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 forms 51.023C and 51.023D for trials sponsored by NHS GG&C alone, and Co-Sponsored with the University of Glasgow, respectively.

They will also be sent a draft Charter based on the MRC template (https://www.ctu.mrc.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.

5.3 IDMC Charter/meetings

The IDMC will review and agree the IDMC Charter and Terms of Reference, and once signed by all committee members this will be stored in the Trial Master File.

5.3.1 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 (according to Data Management centre SOPs). 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.

5.3.2 IDMC minutes/reports and recommendations:

Minutes of open sessions of the meeting will be taken by the Project Manager (or delegate) as committee coordinator, 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.

6. 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
- MRC CTU Template Independent Data Monitoring Committee Charter and Annexes (https://www.ctu.mrc.ac.uk/our-research/other-research-policy/regulatory-information-toolkits-templates)

7. 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

8. Document History

Version	Date	Description
1.0	28/01/2016	New SOP release
2.0	14/07/2016	SOP renumbering
3.0	17/12/2018	Staff category, Author & Approver updated
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
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