SOP-QA-17 V5

Title: Project committees	
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Document History

Version	Description of update	Date Effective
1	Addition of other NHS areas to scope. Change of number for Q-Pulse.	2-10-15
2	Reformatted Removal of reference to DMC Charter template at 3.8	1-4-17
3	Addition of link to DMC Charter template at 5	19-6-17
4	Reference to TSC informing Sponsor if trial is to be stopped at 3.13 Reference to UK Policy Framework for Health & Social Care Research at 1.1, 1.2 and 1.5	1-6-18
5	Updated reference to MRC TSC charter template at 3.5 and 5 Minor update to wording at 3.6, 3.13 and 3.25 True signatures changed to simple signatures at 3.9	21-6-21

1. Scope

1.1 This SOP applies to any Chief Investigators (CI), Sponsor staff and researchers involved in creating the necessary management and oversight committees for research projects sponsored or co-sponsored by University of Aberdeen (UoA) and/or NHS Grampian (NHSG), which fall under the remit of the UK Policy Framework for Health and Social Care Research and/or the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended.

1.2 The expectation of the Sponsor is that all research projects falling under the UK Policy Framework for Health & Social Care Research shall have a **Project Management Group** (PMG). For small scale non interventional projects, this may simply comprise the researcher(s) and their line-manager or supervisor(s).

1.3 The expectation of the Sponsor is that every Clinical Trial of Investigational Medicinal Product (CTIMP) falling under the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended and other interventional projects (eg surgical projects, device projects, non-CTIMP drug projects and any other project deemed to be 'interventional' by the Sponsor), shall have a **Trial/Project Steering Committee** (TSC).

1.4 The funder of a research project may also require certain committees to be set up as a condition of providing funding.

1.5 Studies which fall under the UK Policy Framework for Health & Social Care Research and/or the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, may also require an independent **Data Monitoring Committee** (DMC) to be established depending on indication, trial endpoint(s), trial duration, available knowledge of the drug, device or procedure. During Sponsor risk

assessment the requirement for a DMC shall be identified if not already included within the protocol.

2. Responsibilities

Chief Investigator (CI)	Ensuring a PMG, TSC and/or DMC are set up for research projects.

3. Procedure

Project set-up

3.1 Project set up refers to the time period following confirmation of funding, when the protocol is being developed.

3.2 At the project set up stage, the CI shall define the PMG and consider the requirement for a TSC and/or an independent DMC. The research protocol shall stipulate the requirement for each committee and membership. If a Clinical Trials Unit (CTU) is involved, they may provide support in setting up the required committees.

3.3 The **PMG** should consist at least of the researcher(s) and their supervisor(s). Larger projects should have a PMG consisting of the CI, grant-holders, those responsible for the day-to-day management of the project and line managers, if appropriate. The PMG may also include a lay representative. The PMG has responsibility for writing the research protocol and any associated documentation, and obtaining the necessary approvals for the research to commence.

3.4 The **TSC** should consist of an independent chair, together with at least two other independent members and usually the CI as a minimum. At least one independent member should be an experienced research physician, with expertise in the relevant therapeutic area. The TSC may also involve a lay representative. For pilot projects, the Sponsor may agree to a TSC with less than three independent members, but this should be clarified on a case-by-case basis.

3.5 The role of the TSC at this stage is to review the research protocol and associated documentation and to agree the **TSC Charter** with Terms of Reference. A template for the TSC Charter, including a Competing Interests statement is available on the Medical Research Council's website. It is expected that the TSC will meet and the TSC Charter be signed before enrolment to the research project commences.

3.6 The **DMC** should consist of three independent members (minimum); at least one physician with expertise in the relevant therapeutic area; at least one experienced statistician and at least one other independent member. Further guidance on the qualifications and experience of DMC members is provided in the European Medicines Agency (EMA) Guideline on Data Monitoring Committees. For some projects the Sponsor may agree that no DMC is required, or a DMC with less than three independent members can be convened, but this should be clarified on a case-by-case basis. In such cases the TSC would be required to take on the role of the DMC. Members of the DMC shall be completely independent of the research project and not be the same individuals as the TSC.

3.7 Where there is no TSC and/or DMC, the PMG has the responsibilities normally assigned to these committees (if applicable) but there shall be no requirement for Charters to be completed.

3.8 A DMC should be fully constituted and established prior to enrolment of participants into a research project to enable it to respond to any arising safety issues. The DMC Charter shall be

signed before enrolment to the research project commences. At this stage, the DMC shall agree any stopping rules for the research, which may be incorporated into the DMC Charter.

3.9 All relevant signed Charters shall be stored as original hard copies in the Trial/Project Master File (TMF). Simple electronic signatures may be used and such versions may be stored electronically.

Project conduct

3.10 Project conduct refers to the time period after project approvals are in place.

3.11 The role of the **PMG** at this stage is to ensure that the research protocol is fully implemented by the research site(s) and to monitor progress and conduct of the research and any sub studies, in line with applicable Sponsor SOPs.

3.12 The role of the **TSC** at this stage is to convene at least annually to review progress and conduct of the research and any sub studies. They should be provided with any relevant literature, which may impact on the scope and/or validity of the project by the CI, or delegate, in advance.

3.13 ⚠ If the TSC recommend that a trial be stopped, the Sponsor shall be informed immediately.

3.14 The role of the **DMC** at this stage is to monitor accumulating unblinded research data and to make recommendations to the Sponsor and TSC as to whether there are any ethical or safety issues with the primary aim of protecting patient safety. The DMC shall be supported by an unblinded statistician associated with the PMG, who will generate unblinded data for the DMC's review; generated as close as possible to the scheduled DMC meeting to ensure the current status of the trial data. Validated programming and statistical code (ie code which has been verified against known results) should be used in the preparation of DMC reports.

3.15 ⚠ The unblinded report shall not be shared with any other members of the PMG, including the CI. The CI may be invited to attend an 'open session' of the DMC meeting; to provide an overview of progress. The unblinded report shall be discussed by the DMC in a '**closed session**' with only the independent members and the unblinded statistician present. After each meeting, the DMC provides the CI and the TSC with written recommendations regarding research modification, continuation or termination.

3.16 Documentation and minutes of all oversight committee meetings, indicating actions taken by the CI to address recommendation made by the TSC or DMC, shall be generated and held in the TMF. ! Minutes from DMC 'closed sessions' shall be held separately by the unblinded statistician.

3.17 The CI shall send open minutes from all oversight committee meetings and documentation of actions taken to the Sponsor (researchgovernance@abdn.ac.uk).

Project close-out (or early termination)

3.18 Project close-out refers to the time period when recruitment is completed (according to the protocol) and end of study notifications are being submitted. Any closure prior to this is considered an early termination (see SOP-QA-31 – Research project closure).

3.19 The role of the **PMG** at project close out is to ensure that the research is properly reported and closed out, in line with the protocol and applicable sponsor SOPs.

3.20 The role of the **PMG** at early termination is to reach a consensus on the reasons for early termination to ensure that the research is properly reported and closed out, in line with the protocol (as appropriate) and applicable Sponsor SOPs.

3.21 The role of the **TSC** at project close out is to review the research outputs ie final report and/or any papers prior to publication.

3.22 The role of the **TSC** at **early termination** is to reach a consensus on any amendment required to the research outputs now to be generated.

3.23 The role of the CI at project close out is to ensure that the TSC and DMC are informed when recruitment and follow up have been completed. Also, the contribution of the TSC and the DMC are appropriately acknowledged in the final report and/or any papers.

3.24 The role of the CI at early termination is to ensure that the TSC and DMC are approached for their opinion and confirmation that early termination is acceptable for the research project. Also, the contribution of the TSC and the DMC are appropriately acknowledged in the final report and/or any papers.

3.25 The role of the DMC is to confirm when there is no requirement for further meetings.

3.26 Following project closure, all confidential reports submitted to the DMC and/or TSC and the data and programs used to produce the reports, and minutes from 'closed DMC sessions' shall be retained and securely archived in the TMF.

4. Abbreviations and definitions

CTIMP	Clinical Trial of Investigational Medicinal Product
CTU	Clinical Trials Unit
DMC	Data Monitoring Committee
EMA	European Medicines Agency
MHRA	Medicines and Healthcare products Regulatory Agency
PMG	Project Management Group
TMF	Trial Master File
TSC	Trial Steering Committee

5. Related documentation and references

SOP-QA-3	Protocol guidance for high risk trials and CTIMPs
SOP-QA-5	Sponsorship review and risk assessment
SOP-QA-7	Trial Master File
SOP-QA-31	Research project closure

Medical Research Council Tool Kits