RESEARCH GOVERNANCE GUIDELINES

STUDY STEERING COMMITTEE (SSC) or TRIAL STEERING COMMITTEE (TSC)

This document is designed to provide information and guidance relating to Steering Committees and Data Monitoring and Ethics Committees. The key aspects include:

- Whether a programme appointed Study Steering Committee is required or recommended for your particular project
- The role of the Study Steering Committee
- Standard constitution terms for a Study Steering Committee
- Composition of a Study Steering Committee
- The role of the Chair of a Study Steering Committee
- Definition of independence

It is expected that all Primary Research projects will have a steering committee and/or a management advisory group in place – details of which should be included at the full proposal stage.

For evidence synthesis projects (literature review/ systematic review), scoping studies or other study design, it is proposed that if the project meets any one of the criteria listed below then a committee should be formed.

In addition some projects may require a Data Monitoring and Ethics Committee DM(E)C as this is the only body involved in a trial which has access to the unblinded comparative data. The role of the members of this committee is to monitor these data and make recommendations to the Study Steering Committee. Further details of when a DM(E)C is required are available towards the end of this document.

Once your project has been approved for funding and your project either meets the criteria or you have been advised during the commissioning phase you are required to put in place a programme appointed Study Steering Committee, you will need to nominate to the NIHR HS&DR an independent Chair and members for your SSC. You should contact your nominees, before you give us their names, to ascertain their availability and willingness to be appointed. The NIHR HS&DR Programme Director, will formally appoint the Chair and members by letter.
Does the SSC* need to be appointed by the HS&DR programme?
The following criteria are factors which make it likely that a research study will benefit from having a SSC:

1. Randomised controlled trial
2. Resource Consumption
   a. Financial - Research costs of £400,000 or above
   b. Time - Duration of project 30 months or more
3. Study Complexity or as recommended by the Commissioning Board including, but not limited to:
   a. If CI is working less than 10%FTE on project
   b. multi-site recruitment
   c. large recruitment target
   d. vulnerable sample group (including children, people with disabilities, adults unable to consent for themselves, prisoners, and any other group of people that may be considered to be at a higher risk of harm than the general population) or
   e. where potential conflicts of interest exist

The role of the SSC

The role of the SSC is to provide overall supervision for a project on behalf of the Project Sponsor and Project Funder and to ensure that the project is conducted to the rigorous standards set out in the Department of Health’s Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. It should be noted that the day-to-day management of the project is the responsibility of the Chief Investigator, and as such the Chief Investigator may wish to set up a separate Project Management Group (PMG) to assist with this function.

The main features of the SSC are as follows:
• To provide advice, through its Chair, to the Chief Investigator, the Project Sponsor, the Project Funder, the Host Institution and the Contractor on all appropriate aspects of the project
• To concentrate on progress of the project, adherence to the protocol, patient safety (where appropriate) and the consideration of new information of relevance to the research question
• The rights, safety and well-being of the participants are the most important considerations and should prevail over the interests of science and society
• To ensure appropriate ethical and other approvals are obtained in line with the project plan
• To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments
• To provide advice to the investigators on all aspects of the project
Standard Constitution of an SSC

The following list identifies the minimum constitution requirements, a set of outline terms of reference, and the primary reporting line for SSC’s. If the project consists of at least one of the criteria identified above, we would expect the following:

• The NIHR HS&DR Programme Director will review the nominees and appoint the Chair and members
• All SSC’s are to have an independent Chair
• Only appointed members will be entitled to vote and the Chair will have a casting vote. The Chair and members to sign and maintain a log of potential conflicts and/or interests
• Attendance at SSC meetings by non-members is at the discretion of the Chair
• The primary SSC reporting line is via the Chair to the NIHR HS&DR Programme Director however communication is likely to be between the Chair and the Programme Manager who has day to day responsibility for the project

Where the project is an RCT or complex project
• SSC’s are to have a minimum of 75% majority of independent members
• The minimum quoracy for a meeting to conduct business is 67% of appointed members

Composition of the SSC

• An independent Chair (UK based and/or holding a substantive UK based appointment)
• Independent statistician, health economist and clinician(s) along with others relevant to the project with relevant expertise (where appropriate)
• At least one individual who is able to contribute a patient and/or wider public perspective.
• Ideally, the SSC should invite observers, including a representative of the sponsor and a representative from the research network to meetings
• An indication of any proposed overseas members should have been given at the full application stage and feedback on such proposals supplied following the Commissioning Board’s consideration of the application
• Although there may be periods when more frequent meetings are necessary, the SSC should meet at least annually
• Where a DM(E)C is required, SSC meetings should be scheduled to follow shortly after DM(E)C meetings so that reports from that group can be considered if appropriate
• Minutes of meetings should be sent to all members, the sponsor, the funder and the study master file

The responsibility for calling and organising SSC meetings lies with the Chief Investigator, in association with the Chair.
There may be occasions when the Project Sponsor or the Project Funder will wish to organise and administer these meetings for particular projects. In the NIHR HS&DR programme’s case this is unlikely, but it reserves the right to attend any meeting and the right to convene a meeting of the SSC in exceptional circumstances.

**The Role of the Chair of SSC**

The Chair of the SSC is directly answerable to the NIHR HS&DR programme, as funder. The Chair’s responsibilities include:

- Liaising with the Chief Investigator to arrange a meeting to finalise the protocol and to set up a schedule of meetings to align with the project plan
- Establishing clear reporting lines – to the Funder, Sponsor, etc.
- Being familiar with relevant guidance documents and with the role of the DM(E)C if appropriate
- Providing an independent, experienced opinion if conflicts arise between the needs of the research team, the funder, the sponsor, the participating organisations and/or any other agencies
- Leading the SSC to provide regular, impartial oversight of the study, especially to identify and pre-empt problems
- Ensuring that changes to the protocol are debated and endorsed by the SSC; letters of endorsement should be made available to the project team when requesting approval from the funder and sponsor for matters such as changes to protocol
- Being available to provide independent advice as required, not just when SSC meetings are scheduled
- Commenting on any extension requests and, where appropriate, providing a letter of recommendation to accompany such a request
- Commenting in detail (when appropriate) regarding the continuation or termination of the project

**Independence**

The definition of independent is as follows:

- Not part of the same institution as any of the applicants or members of the project team
- Not part of the same institution that is acting as a recruitment or investigative centre
- Not related to any of the applicants or members of the project team
- For the Chair only – not an applicant on a rival proposal

DATA MONITORING (AND ETHICS) COMMITTEE – DM(E)C

Data Monitoring (and Ethics) Committees
The formation of a Data Monitoring and Ethics Committee (DM(E)C) is needed when there are particular risk factors involved in a study. A DM(E)C generally consists of 3 to 4 completely independent members and would have access to all necessary study data. Independence in this respect includes being independent from the Chief Investigator, project advisory group and host institution.

If a project meets any one of the following criteria then a DM(E)C should be formed:

1. The use of an investigational medicinal product (IMP) or medical device
2. The study is potentially open to ethical challenge
3. The requirement for analysis of data, the detail of which should not be made available to the project advisory group or Chief Investigator.

The role of the DM(E)C
The DM(E)Cs main role is as follows:

- It is the only body involved in a trial that has access to the unblinded comparative data
- The role of its members is to monitor these data and make recommendations to the SSC on whether there are any ethical or safety reasons why the trial should not continue
- The safety, rights and well-being of the trial participants are paramount
- The DM(E)C considers the need for any interim analysis advising the SSC regarding the release of data and/or information
- The DM(E)C may be asked by the SSC, Project Sponsor or Project Funder to consider data emerging from other related studies
- If funding is required above the level originally requested, the DM(E)C may be asked by the Chief Investigator, SSC, Project Sponsor or Project Funder to provide advice and, where appropriate, information on the data gathered to date in a way that will not compromise the trial
- Membership of the DM(E)C should be completely independent, small (3-4 members) and comprise experts in the field, e.g. a clinician with experience in the relevant area and expert trial statistician
- Responsibility for calling and organising DM(E)C meetings lies with the Chief Investigator, in association with the Chair of the DM(E)C. The project team should provide the DM(E)C with a comprehensive report, the content of which should be agreed in advance by the Chair of the DM(E)C
- The DM(E)C should meet at least annually, or more often as appropriate, and meetings should be timed so that reports can be fed into the SSC
- Minutes of meeting should be sent to all members, the sponsor, the funder, the SSC and the study master file. It should be noted that the minutes may have ‘in camera’ items redacted from some copies
Standard Constitution DM(E)C

The following list identifies the minimum constitution requirements, a set of outline terms of reference and the primary reporting line for DM(E)C:

- Some primary research projects are required to establish a DM(E)C
- The NIHR HS&DR Programme Director will review the nominees and appoint the Chair and members
- All DM(E)C members are to be independent (with at least one member being UK based and/or holding a substantive UK based appointment)
- Only appointed members will be entitled to vote and the Chair will have a casting vote
- The minimum quoracy for a meeting to conduct business is 67% of appointed members
- The Chair and members to sign and maintain a log of potential conflicts and/or interests
- Attendance at DM(E)C meetings by non-members is at the discretion of the Chair
- The primary DM(E)C reporting line is via the Chair to the SSC

Independence

The definition of independent is as follows:

- Membership of the DM(E)C should be completely independent of the CI, SSC and Host Institution
- Not part of the same institution as any of the applicants or members of the project team
- Not part of the same institution that is acting as a recruitment or investigative centre
- Not related to any of the applicants or members of the project team
- For the Chair only: not an applicant on a rival proposal