The main features of the TSC are as follows:

- The role of the TSC is to provide overall supervision for a trial on behalf of the Trial Sponsor and Trial Funder and to ensure that the trial is conducted to the rigorous standards set out in the Medical Research Council's (MRC) Guidelines for Good Clinical Practice. It should be noted that the day-to-day management of the trial is the responsibility of the Investigators and the Chief Investigator may wish to set up a separate Trial Management Group (TMG) to assist with this function.

- In particular, the TSC should concentrate on progress of the trial, adherence to the protocol, patient safety and the consideration of new information of relevance to the research question.

- The safety and well-being of the trial participants are the most important considerations and should prevail over the interests of science and society

- The TSC should provide advice, through its chair, to the Chief Investigator(s), the Trial Sponsor, the Trial Funder, the Host Institution and the Contractor on all appropriate aspects of the trial.

- Membership of the TSC should be limited and include an independent Chair[1], at least two other independent members, one or two Principal Investigators and, where possible, a consumer representative. Involvement of independent members provides protection for both Trial Participants and the Principal Investigator(s).

- Representatives of the Trial Sponsor and the Trial Funder should be invited to all TSC meetings.

- Responsibility for calling and organising TSC meetings lies with the Chief Investigator. The TSC should meet at least annually, although there may be periods when more frequent meetings are necessary.

- There may be occasions when the Trial Sponsor or the Trial Funder will wish to organise and administer these meetings for particular trials. In the HTA Programme's case this is unlikely, but it reserves the right to convene a meeting of the TSC in exceptional circumstances.

- The TSC will provide evidence to support any requests for extensions, indicating that all practicable steps have been taken to achieve targets.

Now that your project has been approved for funding you are required to submit to the HTA Programme a suggested membership, including a chair, for the TSC. You should contact your nominees, prior to submission, to ascertain their availability and willingness to be appointed. The HTA programme, will formally appoint the Chair and Members by means of a formal appointment letter.

N.B. *An indication of any proposed overseas members should have been given at the full application stage and feedback on such proposals supplied to you following the Commissioning Board's consideration of your application.*

[1] The Good Clinical Practice (GCP) guidelines define independence as: 'not involved directly in the trial other than as a member of the TSC'.