Supplementary Material I: RISKIT-CJS Trial Steering Committee (TSC) and Data Monitoring and Ethics Committee (DMEC) Terms of Reference

Overall responsibility is to act as the oversight body for this trial on behalf of the Sponsor and Funder.

The role of the TSC and DMEC is to provide oversight for the trial. It should also provide advice through its independent Chair to the RISKIT-CJS Trial Management Group (TMG), the funder (NIHR) and the sponsor (University of Kent) on all aspects of the trial.

The specific roles include:

- provide expert oversight of the trial
- maintain confidentiality of all trial information that is not already in the public domain
- make decisions as to the future continuation (or otherwise) of the trial
- monitor recruitment rates and encourage the TMG to develop strategies to deal with any recruitment problems
- approve the protocol
- review progress reports of the trial prepared by the RISKIT-CJS Trial Manager (behalf of the TMG)
- assess the impact and relevance of any accumulating external evidence
- monitor completeness of data and comment on strategies from TMG to encourage satisfactory completion in the future
- monitor follow-up rates and review strategies from TMG to deal with problems
- monitoring patients' safety including review of any reported serious adverse events (SAEs)
- censure sites that are deviating from the protocol
- approve any amendments to the protocol, where appropriate
- approve any proposals by the TMG concerning any change to the design of the trial, including additional sub studies
- oversee the timely reporting of trial results
- approve / comment on the publication policy
- approve / comment on the main trial manuscript
- approve external or early internal requests for release of data or subsets of data or samples including clinical data.