Appendix 4: Risk Assessment Decision Flow Chart

*In cases where for organisational reasons it is appropriate to risk assess a study (e.g. new research teams, facilities etc.), the Sponsor may make the decision to undertake a risk assessment.

1. Is the study a CTIMP or a Device Study or both?*
   - Yes
   - No

2. Does the study involve participants?
   - Yes
   - No

3. Is it a non-intervention study (i.e. questionnaire, interview or sample collection study?)
   - Yes
   - No

4. Will participants receive an intervention or treatment that is standard care?
   - Yes
   - No

5. Is it a multicentre study?
   - Yes
   - No

- Perform Risk Assessment and sponsor review
- Risk Assessment not required. Perform sponsor review.