**Clinical Trial Insurance Checklist**

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|---|
| School/Institute : |
| Project Reference : |
| Chief Investigator for University : |
| Title of Trial : |
| Sponsor(s) : |

Please tick the appropriate box

1) Will the trial involve the use of research subjects outside Great Britain, Northern Ireland, the Channel Islands or the Isle of Man? Yes ☐ No ☐

2) Will the trial involve assisting with or altering in any way the process of conception or investigating or participating in methods of contraception? Yes ☐ No ☐

3) Will the trial involve the use of a drug or medical device designed or manufactured by the University? Yes ☐ No ☐

4) Will the trial involve research subjects known to be pregnant at the time of the trial? Yes ☐ No ☐

5) Will the trial involve research subjects who will be under the age of 5 years at the time of the trial? Yes ☐ No ☐

6) Will the trial involve genetic engineering where the purpose of such genetic engineering is NOT preventing or diagnosing disease? Yes ☐ No ☐

7) Will the total number of research subjects exceed 1,000? Yes ☐ No ☐

8) Will written informed consent be obtained either from the research subject or their legal guardian? Yes ☐ No ☐

9) Is the trial being sponsored by a pharmaceutical manufacturer or similar commercial organisation? Yes ☐ No ☐

10) If the answer to Q 9) is Yes, is an ABPI indemnity or equivalent indemnity being obtained? Yes ☐ No ☐

If any of the answers to Q 1) – 7) are Yes, or the answers to Q 8) or 10) are No, the Trial may need to be submitted to Insurers for further consideration. To allow the Trial to be referred, please supply the following:

A) Full copy of the Trial Protocol and Ethics Committee approval, or other documentation describing the study
B) A copy of any indemnity agreement from the commercial organisation sponsoring the trial where applicable
C) Full details of all trial centre locations and numbers of triallists where such centres are outside the UK
D) Details of the procedure and parties from whom consent will be obtained if the answer to Q 8) is No
E) Any other information you consider will assist the Insurers' understanding of the Trial and the contractual relationships

Please return to :