CLINICAL TRIAL COMMENCEMENT FORM

University Department:
Insurance Reference : 609/M/C/
Chief Investigator for University:
Title of Trial:
Commencement Date:

Brief Description of Study (including age range of the participants)

SECTION ONE

Please tick one of the following which best describes this trial

Drug Trial [ ] Referral Trial [ ]
Non Hazardous Trial [ ] Standard (all other Trials) [ ]

In what capacity is the University acting in respect of this trial? Please read all of the options below and then select by ticking the most appropriate box.

(A) Sponsor of the trial where the University is the only participating centre and all Research Subjects will be recruited by the University to the trial.

(B) Sponsor of a multi-centre trial involving both the University as a trial centre and other trial centres/sites.

(C) As a participating centre in a multi centre trial where others are acting as Sponsor of the trial.

(D) As a participating centre in a single site trial where others are acting as Sponsor of the trial.

PLEASE NOW PROCEED TO SECTIONS AS DETAILED BELOW

If you have ticked answer (A) proceed to Section Two
(B) proceed to Section Three
(C) proceed to Section Four
(D) proceed to Section Five
SECTION TWO – Sponsor of Single Site University Study

Please advise

(A) Total number of Research Subjects to be recruited to the trial ...........

SECTION THREE – Sponsor of Multi Centre Study

Please advise

(A) Total number of Research Subjects to be recruited by the University to the trial. ...........

(B) Total number of Research Subjects to be recruited to the trial by other participating centres/sites. ...........

(C) Are all other participating centres/sites providing Clinical Trials insurance for Injury to their own Research Subjects? Yes □ No □

(D) If Yes, is this (i) Legal Liability Only cover? Yes □ No □

(ii) Legal Liability and No Fault cover? Yes □ No □

SECTION FOUR – Participating Centre in Multi Centre Trial where others are acting as Sponsor of the Trial

Please advise

(A) Total number of Research Subjects to be recruited by the University to the trial. ...........

(B) Is Clinical Trials insurance (ABPI indemnity or equivalent) being provided by the trial Sponsor? Yes □ No □

SECTION FIVE – Participating Centre in Single Site Trial where others are acting as Sponsor of the Trial

Please advise

(A) Total number of Research Subjects to be recruited by the University to the trial. ...........

(B) Is Clinical Trials insurance (ABPI indemnity or equivalent) being provided by the trial Sponsor? Yes □ No □
SECTION SIX – to be Completed in all Cases

Please advise any other information regarding the University’s role in the study you consider may be of importance or would assist the Insurers’ understanding of the trial.

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<th>Role in Trial:</th>
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Please now return this form with a copy of the LREC approval letter and the current Information Sheet to the Insurance Manager, University of Cambridge, Finance Division, Greenwich House, Madingley Road, Cambridge CB3 0TX.