Clinical Trial Commencement Form

University Department	
Project Reference	
Chief Investigator for University	
Title of Trial	

Brief Description of Study

SECTION ONE

Please read the attached Guidance Notes and then tick one of the following which best describes this trial

Drug Trial	☐	Excluded Trial	☐
Non Hazardous Trial	☐	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 contractually required to provide cover 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 an 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 an ABPI indemnity or equivalent being provided by the trial Sponsor? Yes ☐ No ☐

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.

Signed	
Role in Trial	
Date	

Please return the completed form to: Name : Department :

Guidance Notes

How is a Clinical Trial defined?

The Policy definition of a Clinical Trial is as follows:-

"Any trial which requires ethical approval"

A Clinical Trial is an investigation or series of investigations conducted on any person for a medicinal purpose, meaning:

- treating or preventing disease
- diagnosing disease or ascertaining the existence, degree or extent of a physiological or psychological condition
- assisting with or altering in any way the process of conception or participating in methods of contraception (**BUT** see "Which Trials Are Excluded From Cover?" below)
- inducing anaesthesia
- otherwise preventing or interfering with the normal operation of a physiological or psychological condition.

What is a Non-Hazardous Clinical Trial?

Very low hazard clinical trials are exempt from some of the medical exclusions in the policy. They are defined within the policy as Non-Hazardous Clinical Trials and involve one or more of the following only.

- the insertion of needles into patients' veins for the purpose of withdrawing blood samples
- the measurement of physiological processes using non-invasive methods
- the administration by mouth of foods or variation of diet other than the administration of drugs or food supplements
- the collection of body secretions and excretions by non-invasive methods for analysis
- the use of tissue samples which would otherwise be disposed of subject to
  i) informed consent being obtained in all cases
  ii) disposal of such tissue material in an approved manner
  iii) such tissue material not having been obtained in connection with any other Clinical Trial covered by the Policy

Although Non-Hazardous Clinical Trials are considered to be clinical trials for insurance purposes, they are automatically insured and we do not require any information about them.

What is a Drug Trial?

We consider a drug trial to be any investigation involving a medicinal substance that requires a Clinical Trial Authorisation from the MHRA under the **Medicines for Human Use (Clinical Trials) Regulations 2004.**

Which Trials Are Excluded From Cover?

Our aim is to provide automatic protection for your Clinical Trials work. However, we do exclude certain trials which require special consideration:

- large scale Trials involving more than 1000 Research Subjects;
- trials involving children under 5 years of age;
- genetic trials for non-medical purposes;
- trials involving conception or contraception;
- trials involving pregnant women;
- trials involving Research Subjects who are resident outside Great Britain, Northern Ireland, the Channel Islands or the Isle of Man;
- trials where the substance under investigation has been designed and/or manufactured by the Insured.

Sometimes we can provide cover for such trials at additional cost, but we will always require individual notification in advance with full details (e.g. trial protocol / ethics application and patient information sheet) and cover is not provided unless we specifically agree in writing.

Trials which we generally regard as being **unacceptable** are:

- any trial where the University designs, manufactures or makes up the drug used in the trial.

All other Trials

These are all other clinical trials which do not fall into any of the above categories.