Guidance Notes

How is a Clinical Trial defined?

Definition of a clinical trial is "any activity which requires ethical approval"

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

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.