UNIVERSITY OF BIRMINGHAM

Clinical Trials Activities and Insurance cover

The University of Birmingham sponsors and manages clinical trials, alongside undertaking peripheral activities related to clinical trials.

For clinical trial activities carried out by the University which could result in harm to a patient (and hence a claim against the University and/or its staff), the University carries Clinical Trials cover for its protection against such financial loss, both for legal defence costs and compensation to the patient where the University is held to be liable.

Whilst many trials are automatically covered, there are others that require referral to the University's cover provider, UMAL, (via the University's agreed internal procedures), in order to confirm cover is in place. UMAL's "Research Involving Human Participants Questionnaire" determines which trials are subject to confirmation of cover; this Questionnaire is kept on the Insurance Office webpage.

As peripheral activities are not always brought to the attention of the Insurance Office, UMAL have investigated to what extent peripheral activities may be automatically covered notwithstanding the existing referral categories, in order to smoothen the process of ensuring cover is in place. Below is a list of activities that may be conducted by UoB staff for a clinical trial <u>without the UoB managing and/or sponsoring that clinical trial</u> that will be automatically covered:

- ☐ Acting as a co-investigator on a clinical trial, contributing research advice and guidance. This may be via membership of the Trial Steering Committee or Trial Management Group, and it may include contributing to:
  - ○ Trial design
  - ○ Grant application
  - ○ Protocol and other trial essential document development
  - ○ Publications

  Note that in line with the Research Governance Framework, the Chief Investigator takes on personal responsibility for the design, management and reporting of the study; this is echoed in the Medicines for Human Use (Clinical Trials) regulations where it is stated that the CI takes primary responsibility for the conduct of the trial.
- ☐ Statistical power size calculations at the time of trial design
- ☐ Acting as a member of trial management and oversight groups e.g.:
  - ○ Trial Management Group
  - ○ Data Monitoring Committee
  - ○ Trial Steering Committee
- ☐ Providing clinical advice e.g. responding to clinical queries, assessing Serious Adverse Events
- ☐ Statistical analysis as used for interim reports, planned analyses and publications
- ☐ Health economics advice and analysis
- ☐ Quality of life (or other sub-study) advice and analysis
- ☐ Providing advice relating to trial related activity and any applicable (inter)national guidance/regulations:
  - ○ Investigators
  - ○ Clinical Trials Units
- ☐ Laboratory research where outcome will feed back into the final trial report
- ☐ Providing Registration/Randomisation service
- ☐ Providing Programming or IT service
- ☐ Contributing to the preparation of national guidance
- ☐ Providing costings for clinical trials