

Treasury Management Standard Operating Procedures for

Clinical Trials - Research Involving Human Participants (Overseas Trials)

Background

The University of Birmingham has increasing exposure to International Trials.

The monitoring process of the proposed international work is covered within Research and Commercial Services to enable compliance with the Department of Health's Research Governance Framework (2nd ed.2005) and whereby identification of the Sponsor of a proposed research study and the roles and responsibilities attached to that duty is established.

Details for this can be found on the Research and Commercial Services website at www.rcs.bham.ac.uk/staff/researchers/sponsorship.shtml

1. As with UK based applications these are received from various sources:-
Notification is made usually by email occasionally by phone call and hard copy via the internal mail system by:-
 - Chief Investigator (CI)
 - Trial Co-ordinator
 - Research Accounting Finance
 - Research and Commercial Services(RCS)
2. Once paperwork is received an examination of it made to ensure we have:-
 - Clinical Trial Application/Protocol
 - Completed Clinical Trial Questionnaire (CT09) highlighting where overseas work is being proposed
3. Details need to be supplied to the insurance office of the proposed countries for the Trial to establish what issues may need to be addressed.
4. Establish who the Sponsor of the Trial is by:-
 - Liaison with CI
 - Liaison with RCS and copies of their paperwork/emails may be forwarded to the insurance office. RCS will be looking at the implications of overseas work from the Governance point of view
5. After examination of the CT09 further referral will be required for insurance approval to be given by UM Association Ltd (UMAL) because of the planned overseas work. The insurers need to see if there are any legislative issues for

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whichever country is being proposed and so they will require specific details of what is being planned. How will the work be monitored? and who will be doing the work?

6. Referral to UMAL with electronic versions of all the paperwork will expedite the whole process and these can be emailed to:-
 - Terry Crow Liability Underwriter at UMAL at terry.crow@umal.ac.uk
 - Susan Wilkinson Chief Executive at UMAL at susan.wilkinson@umal.co.uk

7. UMAL will ask further questions if necessary as part of the insurance proposal process and then they will confirm by email if approval has been given and will ask for the proposed trial start and end dates and if specific confirmatory letters are requested these will be produced.

8. Confirmation of acceptance of a trial is made from the insurance office usually by email to:-
 - CI and/or Trial Co-ordinator
 - RCS
 - Research Accounting Finance

9. If UMAL are to issue a confirmation letter this will be forwarded on to those mentioned in 8 above

10. Within the Insurance Office our papers are held on individual files, referenced and we have both hard copy and electronic records (Excel Spreadsheet and Access Database)

11. If a trial is to be extended beyond the original proposed dates the trigger for this should be the trial co-ordinator or the CI, this would still apply with overseas trials.

12. Notification should be made to the insurance office to be able to advise UMAL accordingly

13. Questions asked by UMAL for an extension of insurance cover to be considered will take the form of:-
 - Has there been any significant change to the original trial protocol?
 - Have there been any Serious Unexpected Adverse Reactions (SUSARS)?
 - Have there been any significant increases in the number of participants onto the trial?Once they have answers to these questions then consideration can be given to an extension./

14. Notification will be made back to those mentioned in 8. above once an extension of the insurance approval has been made(usually by email)
15. The insurance office records will be amended accordingly to reflect these changes.
16. Insurers may charge additional premium for the cover for higher risk trials and therefore an invoice would be produced and this is processed through our normal Payments system

In case of query please contact:

Mrs G Kelsall, Insurance Officer on 0121.414.6111 email at g.l.kelsall@bham.ac.uk

Mrs Hazel Bradford, Assistant Insurance Officer on 0121.414.6628 email at h.p.bradford@bham.ac.uk