Treasury Management Standard Operating Procedures for

Clinical Trials - Research Involving Human Participants (UK based)

Background

The University of Birmingham procedures enable compliance with the Department of Health's Research Governance Framework (2nd ed.2005) whereby identification of the role of 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
The RCS website highlights-

- The Role of the Sponsor
- The University as Sponsor
- Applying for University Sponsorship
- Applying for NHS REC Ethics approval
- Insurance Cover
- R&D approval

The Clinical Trial process is part of the whole Governance and Sponsorship process and those standard operating procedures carried out in Treasury Management for insurance approval to be gained are shown below.

1. Clinical Trial Applications are received from various sources:-
   Notifications are made usually by email occasionally by phone call and hard copy via the internal mail system to either the Insurance Officer or the Assistant Insurance Officer by:-

   - Chief Investigator (CI)
   - Principal Investigator (PI)
   - 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-previously CT2006)
   - Patient Information Sheet
   - Patient Consent Form
   - Evidence of any indemnity being offered by a third party e.g. NHS or Drug Co.

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3. Establish who the Sponsor of the Trial is by:-

- Liaison with PI
- Liaison with RCS (Sean Jennings, Research Governance Officer on 0121.415.8011 email s.jennings@bham.ac.uk)

Copies of RCS's paperwork may be forwarded to the insurance office to link with our papers for further information

4. After examination of the CT09 further referral may be required for insurance approval to be given by the University Insurers UM Association Ltd (UMAL) who are based in London if:-

- Trials involve drugs and surgery or nutrients
- Research Subjects are known to be pregnant at the time of a trial
- Research Subjects are under 5 years old
- Trials are assisting with or altering in any way the process of conception
- Trials are investigating or participating in methods of contraception
- Trials involve genetic engineering other than for the prevention and diagnosis of disease
- Trials involve products manufactured by the University

5. If referral to UMAL is necessary then 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

6. UMAL will ask further questions if necessary as part of the insurance proposal process and then they will confirm by email that 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.

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

8. If UMAL are to issue a confirmation letter this will be forwarded to the Insurance Officer and then on to those mentioned in 7 above

9. Within the Insurance Office trial papers are held on individual files, referenced and there are both hard copy and electronic records (Excel Spreadsheet and Access Database)

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10. If a trial is to be extended beyond the original proposed dates, the trigger for this should be the trial co-ordinator or the PI

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

12. Questions asked by UMAL before an extension of insurance cover is granted 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.

13. Notification will be made back to those mentioned in 7. above once an extension of the insurance approval has been made (usually by email)

14. The insurance office records will be amended accordingly to reflect these changes.

15. 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