University Hospitals Bristol NHS
NHS Foundation Trust

Research Guidance Sheet No.14
Early Closure of Studies

V3.1_01.11.2010

Introduction

If your study has already gained R&D approval at University Hospitals Bristol, Research Ethics Committee (REC) approval and/or a Notice of Acceptance from the MHRA (Medicines and Healthcare products Regulatory Agency) for a Clinical Trial using an Investigational Medicinal Products (IMP), and is then terminated early, the following steps should be taken by the Chief/Principal Investigator.

If the study is NOT a clinical trial using an IMP

Step 1:

The REC which gave a favourable ethical opinion of the research should be notified in writing of the early termination of a study using the following form – http://www.nres.npsa.nhs.uk/applications/after-ethical-review/endofstudy/. The form should be sent within 15 days of the study terminating and reasons should be given for its termination. The REC office will acknowledge receipt of the end of study declaration form.

Step 2:

The Research Management Office and Sponsor should also be notified in writing explaining the reason why the study was abandoned and the date on which this took place. Letters, and a copy of the form sent in Step 1, should be e-mailed to 'researchapprovalsl@uhbristol.nhs.uk'.

If the study is a clinical trial using an IMP

Step 1:

Inform the Sponsor of the study.

Step 2:

The Sponsor or delegated individual should notify the REC which gave a favourable ethical opinion of the research using the following form:
http://ec.europa.eu/health/files/eudralex/vol-10/declaration_end_trial_form.doc
The same form should be sent by the Sponsor or delegated individual to the Clinical Trials Unit, 151 Buckingham Palace Road, Victoria, London, SW1W 9SZ. Both forms should be sent within 15 days of the study terminating and reasons should be given for its termination. The REC office and MHRA will acknowledge receipt of the end of study declaration form.

Step 3:

Participating R&D offices should also be notified in writing explaining the reason why the study was terminated early and the date on which this took place. To notify UH Bristol a cover letter and copy of the form sent in Step 2 should be e-mailed to 'researchapprovals@uhbristol.nhs.uk'

Further reading

The following websites may be useful:

From the National Research Ethics Service
http://www.nres.npsa.nhs.uk/applications/after-ethical-review/

From the Medicines and Healthcare products Regulatory Agency
http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=983

From the European Clinical Trials Database
https://eudract.emea.europa.eu/eudract/index.do