International Studies

The aim of this guidance is to ensure that sponsorship of a proposed international study is feasible and to fully inform all relevant parties of the processes to be followed:-

a) when an interventional study sponsored in the UK, solely by the Trust, is proposed to be conducted at sites outside the UK,

OR

b) the study involves a Trust employee and is taking place only outside the UK.

Due to the complexity of the legal and regulatory issues arising out of international studies, the R&D Manager or their Deputy (R&D Office contracts team) must be fully informed and involved in the process at an early stage.

We will aim to move as fast as possible but a researcher should allow a minimum of six months from beginning the process to starting the study.

As soon as the R&D Manager has been informed of a potential study a meeting will be convened with all relevant parties to consider the nature of the study and liabilities that need to be covered, the number and location of the sites, and the proposed arrangements for obtaining regulatory and ethics approvals.

Governance measures

As well as the normal governance checks that would be carried out by the Trust the following things need to be considered

a) A lead site will need to be identified by the Chief Investigator for each country. The Trust will delegate the responsibility for applying for and maintaining local regulatory and ethical approvals to the lead site. These approvals may vary from country to country and it is important that the lead site is able to help and advise on the local requirements at an early stage.

b) In some international studies the individual countries take on all the sponsorship duties including insurance. In all other cases the Chief Investigator will need to liaise with the Trust R&D Office to arrange applicable insurance cover for the relevant aspects for the international study. This is likely to involve a cost to the research project which the Chief Investigator must ensure can be met.

c) The Chief Investigator needs to be able to provide relevant documentation for all ethical, regulatory requirements needed to commence the study in each country. These should be in English so any translation required will be charged as a cost to the research project which the Chief Investigator must ensure can be met.

d) Ethics approval from the appropriate Research Ethics Committee (REC) should also be received for work carried out overseas – the Research Governance Officer will assist with identifying internal steps required.

e) the R&D Office contracts team will need to decide what contracts need to be put in place and review all contracts used in the study. This may involve the input from

Legal Services and external lawyers. If external legal advice is required this is a cost to the research project which the Chief Investigator must ensure can be met.

No research activity shall commence at any non-UK site until copies of the following documents have been received and approved by the R&D Manager and R&D Office

- Confirmation that funding is in place
- Ethical and regulatory approvals both in the UK and overseas and any site approvals required are in place
- Ethically approved Participant Information Sheet and Consent Form are in place
- Relevant insurance documents
- Participating Site Contracts

Monitoring

The researcher will need to consider how any monitoring required under legislation is to be done before starting the study. It may be necessary to require the sites with which you are dealing to undertake this and this will need to be included in any site contracts which are negotiated.

Summary

The legal, ethical and insurance requirements for the undertaking of interventional research overseas are complex and vary significantly from country to country. It is vital that you liaise with the trust R&D Office at the outset to ensure that all the necessary requirements which are to be met are identified at the outset.