

# Research Guidance sheet No.2<sup>a</sup> Process for gaining University Hospitals Bristol (UH Bristol) Sponsorship

v4.2 01.10.2010

Where the funder of a study is not intending to take the responsibility for sponsorship the sponsor will usually be the employing organisation of the Chief Investigator.

#### 1. Develop a protocol

There are many sources of assistance available and the Research Design Service (RDS) may be able to help you with this stage. Details of what should be included in a protocol can be found in the Protocol guidance sheets (IS1a – IS1d) available from the Research <u>website</u>. Where a study will require the assistance of support departments, discussions on feasibility and appropriateness should be held at the protocol development stage. Pro-formas are available from the Research website to assist with this. The Support Department Research Leads may well be able to advise on a better way of facilitating the requirements of your study and be able to assist in the development of the Protocol. Contact details for the Research Leads for the Support Departments are available on our website.

Before submitting the protocol for review ensure that specific information related to UH Bristol sponsorship is included. Standard wording is available on Research Guidance Sheets 3a and 3b and requirements for some headings can be copied directly from these.

#### 1.1 Grant applications

Occasionally research funders will require a commitment from another party that, if the applicant is successful, they are prepared to accept sponsorship of the study. In this instance UH Bristol will be able to offer a letter of support indicating that it will be able to take the role of sponsor in the event of funds being awarded on provision of a copy of the grant application. However, if successful a full protocol will still be required before confirming sponsorship arrangements.

#### 2. Sponsorship request

Departmental staff should be contacted as early as possible so that an indication can be given as to whether the Trust is an appropriate sponsor. Where it expected that UH Bristol is to be the sponsor, a <u>Sponsorship Request Form</u> may be downloaded from the website. An electronic copy of the protocol, support department pro-formas and, where it has already taken place, evidence of scientific review should be sent to the Research Management Office with the request form. Documents should be sent to <u>researchapprovals@uhbristol.nhs.uk</u>.

# 3. UH Bristol reviews appropriateness of request

On receipt of a sponsorship request staff in the Research Management Office will assess whether it is appropriate for UH Bristol to act as sponsor for the study. Where it is inappropriate for the Trust to be the sponsor advice will be given on more suitable organisations to approach.

# 4. Scientific review

Scientific review should be carried out by at least two individuals independent of the project, and evidence of this review will be required prior to the Trust agreeing to accept the role of sponsor. In most instances the Research Management Office will arrange these reviews however, where a funding body has/will be conducting an independent scientific review, this may count as one of the reviews; sponsorship will then be dependent on funding being awarded. Where another external review can be provided this may also count as one of the reviews.

# 5. Decision on whether UH Bristol will Sponsor the Study

Where UH Bristol agrees to act as sponsor a formal letter will be issued; agreement by the Trust to act in this capacity is conditional on gaining full Trust approval.

### 6. Study Approval Processes

Once provisional sponsorship agreements are in place standard study approval processes can be undertaken.

For more information see Research Guidance Sheets 5 – 'Applications for Study Wide Approval' and 6 'Applications for Local R&D Approval'