University Hospitals Bristol NHS
NHS Foundation Trust

# Research Guidance Sheet No.6
# Applications for Local R&D Approval

V9 30.09.2010

## Integrated Research Application System (IRAS)

Applications for the approval of Research in the NHS are now conducted through the Integrated Research Application System (IRAS) https://www.myresearchproject.org.uk/.

With the exception of sites that have been designated as Participant Identification Centres (PICs); a Site Specific Information (SSI) form must be completed for each participating NHS Trust, including the lead site. The central team use the IRAS system to transfer an SSI form to the Principal Investigator/Local Collaborator at the site. The Principal Investigator/Local Collaborator has responsibility for completion of the SSI, whilst other members of the study team may assist with the completion of the SSI it is ultimately the responsibility of the Principal Investigator and s/he who must sign the form.

## Research Staff

The Principal Investigator must have a full or honorary clinical contract with the Trust. All researchers coming on Trust premises or having contact with Trust patients must hold a full or honorary research contract or have obtained a letter of access with the Trust. For external researchers information on research passports and letters of access can be found at: http://www.uhbristol.nhs.uk/research-passports.

All researchers taking informed consent should:

- Hold relevant professional qualifications.
- Have undertaken Good Clinical Practice (GCP) in Research/ICH GCP training within the last three years.
- Have undertaken training in, and be sufficiently conversant with, the study protocol.

Professional qualifications and GCP training should be demonstrated on research CVs submitted as supporting documents. For preference CVs should follow the format provided within IRAS.

## Participant Identification Centres (PICs)

Participant Identification Centres are those sites that are carrying out no study related procedures but may, for example, be sending out letters on behalf of a central study team or participating in a staff survey. PICs should be identified as such in section C of the main R&D Form. To review an application for a study as a PIC the main application must be being processed through the NIHR Co-ordinated System for gaining NHS Permissions (CSP). Where a site is considered to be a PIC it is not necessary for an SSI to be submitted or a Principal Investigator in place (a local collaborator will still be necessary) participant related documents should be on the headed paper of the central research unit.

## Supporting Documents

Supporting documents for the local application include:

- Scanned or electronically signed signature page of the SSI.
- Summary CVs for all local investigators mentioned on the SSI form.
- Local versions of Participant related documents. These should be on the headed paper of the clinic or department through which participants are being recruited. Contact details for the local research team and complaints procedures should be included.
- Local Authorisations – Local authorisations for support departments. These should include the pro-formas for any supporting departments. Acceptance should be indicated either by a signed hard copy of the pro-forma or inclusion of the acceptance email. Signatures are not required on the SSI form
- Contract, Site Agreement or document outlining a clear delegation of responsibilities.
- ARSAC licence, if relevant.

## Local Information

Contact details for the Trust Research and Innovation:

Mary Perkins
Deputy Director of Research
Research and Innovation
Level 3, Education Centre
Upper Maudlin Street, Bristol, BS2 8AE

Tel: 0117 342 0233
Fax: 0117 324 0239
Email: ResearchApprovals@uhbristol.nhs.uk

Information for participants can be found in the leaflet 'Patient Information – Research and Development' this can be downloaded from http://www.uhbristol.nhs.uk/files/nhs-ubht/ResearchandDevelopment.pdf.

Additional advice can be gained from:

The Patient Advice and Liaison Service
Information Desk
Level 2, Queens Building
Marlborough Street
Bristol BS2 8HW

Complaints should be addressed to:
The Chief Executive
Trust Headquarters
Marlborough Street
Bristol BS1 3NU

## Submission

Studies being processed through the NIHR Co-ordinated System for gaining NHS Permissions (CSP) should follow the process outlined on the submission tabs for the R&D form and SSI forms.

Studies not being processed through the NIHR CSP should submit both local and study wide documents (including signed R&D and SSI forms) to ResearchApprovals@uhbristol.nhs.uk.