University Hospitals Bristol NHS
NHS Foundation Trust

Research Guidance Sheet No.5
Applications for Study Wide Approval

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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/. On creating a new study within IRAS you will be asked a number of 'filter' questions. Depending on your responses a suite of project specific application forms will be created.

When any of the individual forms are selected a tab titled 'Submission' will be visible. The 'Submission' tab will detail the submission process to each of the relevant agencies, additional more detailed guidance can be found in the FAQs within IRAS. NB in most cases the form will not be submitted directly from the system and it will be necessary to post or email the form and accompanying documents to the relevant agency.

As well as a submission tab, each form will also have a 'Checklist' tab. Here you will be able to complete a project specific checklist of the documents which should accompany the application form.

There is a lot of help available within the IRAS system with a section of FAQs, guidance notes for the completion of each question, prompts when responses to filter questions appear inconsistent as well as an online tutorial on how to use the system.

Clinical Trials of Investigational Medicinal Products (CTIMPs)

Applications to the Medicines and Healthcare products Regulatory Agency (MHRA) for a Clinical Trials Authorisation (CTA) can now be completed within IRAS. However, it is still necessary to gain a EudraCT number before applying for a CTA or other approvals. A EudraCT number is a unique identifying number allocated to your trial. It is mandatory for all studies starting in the European Community, involving the use of an Investigational Medicinal Product (IMP), to have a EudraCT number and to be registered on this database.

Applying for EudraCT number is a two stage process whereby on online request is made for a security number to gain access to the EudraCT database. The security number is emailed and can then be used to apply for a EudraCT number; this must be done within 24 hours of applying for the security number. In all other respects the process is quick and straightforward. Applications can be made at https://eudract.emea.europa.eu/eudract/index.do

International Randomised Control Trial Number (ISRCTN)

Not reporting trials is seen as ethical and scientific misconduct and the pressure to register trials is increasing. The ISRCTN register is a database conceived for the registration of Randomised Controlled Trials (RCTs) and to address the difficulty of differentiating between and identifying publications arising from RCTs. It provides a unique number for each RCT and provides a means of tracking a trial throughout its life cycle. It is the responsibility of the Chief Investigator to ensure a trial is registered and whilst it is not mandatory for non IMP trials to be registered many journals will not publish from studies that are not registered prior to commencement.

Details on the purpose of the ISRCTN and when and how it should be used can be found at http://www.controlled-trials.com/isrctn/isrctn_faqs.

There are several routes to gaining ISRCTN registration; the most convenient is through the NIHR Portfolio for studies eligible for inclusion in it. Chief Investigators of RCTs will be asked by representatives of the Portfolio if they would like the study to be registered by them

If the study is not eligible for inclusion on the NIHR portfolio the preferred option is using the UK based **Controlled Trials Registry** http://www.controlled-trials.com/ ; however registration costs £160. The final alternative for ISRCTN registration is **ClinicalTrials.gov** http://www.clinicaltrials.gov/ which is an American based site that registers studies free of charge. The Trust has an organisational account with ClinicalTrials.gov for studies it sponsors.