Research within the NHS- Guidance for UWE researchers

This guidance will provide a summary for those researchers planning to conduct health research within the NHS. Much of the detail highlighted below originates from the guidance published by the Health research Authority (HRA) and can be found at http://www.hra.nhs.uk/research-community/

1. Is your study research?

For research governance purposes the term “research” means the generation of generalisable new knowledge in answer to a clearly defined research question. Whilst some research projects may contain elements of evaluation, those projects that are deemed to be audits or service evaluations do not require review through the NHS system but may require registration with the local NHS clinical governance department. UWE also requires that their staff or researchers should gain ethical approval from their faculty research ethics committee (FREC).

To help you decide whether your project could be classified as “research” you should refer to the Health Research Authority (HRA) Decision tool which can be located at: http://www.hra-decisiontools.org.uk/research/

Guidance regarding the application process for gaining UWE ethical approval can be found at: http://www1.uwe.ac.uk/research/researchethics

2. Which review body approvals does the project require?

The UK has a range of bodies that have roles in regulating different aspects of health research this including the NHS and the National Offender Management Service. Details can be found at http://www.hra.nhs.uk/research-community/before-you-apply/determine-which-review-body-approvals-are-required/

3. How should I apply for approval?

All applications should be submitted via the Integrated Research Application System (IRAS). This is a single online system for applying for permissions and approvals for health and social care/community research in the UK. - See more at: http://www.hra.nhs.uk/research-community/applying-for-approvals/#sthash.QbWhQ4l1.dpuf

Researchers will need to set up an IRAS account where project documentation can be uploaded. Transfer of projects between registered users is also possible within this system and this may be utilised during the sponsorship sign off process.

4. Research Passports for academic staff

The Research passport provides a mechanism for pre-engagement information about a researcher to be shared with relevant NHS organisations in which the

applicant will be conducting research. It includes an occupational health assessment, employment/student screening and DBS check.
Details can be found at:
http://www1.uwe.ac.uk/research/researchethics/guidance.aspx

5. Who should sponsor the project?

The guidance on the roles and responsibilities of the research sponsor can be found at : **http://www1.uwe.ac.uk/research/researchethics/guidance.aspx**

6. Guidance on constructing a study protocol

As part of the application process researchers are required to produce a study protocol which outlines the rationale and key stages in the research. An accompanying flowchart which outlines the recruitment phase and summarises the research process may also be required. Guidance can be found at:
http://www.hra.nhs.uk/research-community/before-you-apply/protocol/

7. Guidance on information sheets and consent forms

Information sheets and consent forms should be written in plain English and should be appropriate for the participant group that the researchers are hoping to recruit. It is advisable that these documents are reviewed by appropriate patients groups prior to submission if at all possible. Guidance and templates can be found at:
http://www.hra.nhs.uk/research-community/before-you-apply/participant-information-sheets-and-informed-consent/

8. Data protection and data management

As part of the review process researchers will need to construct a data management plan which adheres to the data protection policies of both their employers and the NHS site where the research is conducted. The plan should include details regarding data storage, management, disposal and achieving.

Details of UWE's data management and data security policy can be found at:
http://www1.uwe.ac.uk/research/researchgovernance/resourcesforresearchers/researchdatasecurity.aspx

9. Preparing other study documentation

Researchers may also be required to submit copies of contacts, intellectual copyright agreements, evidence of scientific review and evidence of legal indemnity etc. Guidance and templates can be found at**: http://www.hra.nhs.uk/research-community/before-you-apply/prepare-other-study-documentation/**

The ethics administration team will also be able to provide researchers with standard indemnity documents but it is advisable to check if the proposed research activity falls within the remit of this document**.**

10. Trust registration/ permissions from NHS sites

All research that is conducted upon NHS sites will also need to be registered with each study site. Appropriate permissions and accepted research costings also need to be in place before the research can proceed. Details can be found at : **http://www.hra.nhs.uk/research-community/before-you-apply/plan-your-sites/**

This process can be undertaken using the IRAS system which automatically populates some sections of the registration form from the application for ethics approval documentation. Multi-centred sites may require a site specific assessment for each site involved in the research however the HRA are at present trialling a system whereby this process is streamlined. In order to ascertain whether the study is suitable for this HRA approval. Please consult the following guidance for further detail: http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/

11. Booking your review

Once all the completed forms and associated project documentation have been uploaded, researchers are then required to book their study in for review. This booking is managed by the central booking service, details of which can be found at**: http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-central-booking-service-cbs/**

Each Reviewing committee only has a finite number of spaces at each meeting and the central booking service will advise you of the next available opportunity for review. You can specify that you would like your study to be reviewed (if appropriate) by a specific local committee but there may be spaces available sooner if you are prepare to request a review from a committee outside your locality. It is however strongly recommended that researchers attend the review meeting as this often allows for clarification of minor points. Some committees offer telephone/ Skype facilities if this is more convenient.

Further details of this process can be found at: http://www.hra.nhs.uk/research-community/booking-submission-changes-spring-2014/

12. Notification of approvals

Once the study has obtained the appropriate approvals you should inform the relevant review bodies of the study progress and any alterations that may become necessary. Details can be found at : **http://www.hra.nhs.uk/research-community/during-your-research-project/**

Researchers should also provide a copy of the approval letter to the faculty research ethics committee and enter details of the research onto the faculty research governance system which can be found at:
https://teams.uwe.ac.uk/sites/HASgovernance

13. Amendments

During the course of your study it may be necessary to make amendments to the protocol or supporting documentation. These can either be classified minor or substantial amendments. Details of the process can be found at :
http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/

14. End of study reports

At the end of the study researchers will be required to:

- Notify review bodies that the study has ended and provide final reports
- Make arrangements for future use of research data and samples
- Fulfil commitments to study participants, such as providing information about the outcome(s) of the research and care after research
- Publish the results of your research. - See more at: **http://www.hra.nhs.uk/research-community/end-of-study-and-beyond/#sthash.4wMPy0ZG.dpuf**

15. Research registration, research project identifiers and plans for dissemination of research findings

The HRA is committed to increasing transparency in health research. Researchers will be required to register projects on appropriate research sites, publicise their research and, if possible, make their data available to other researchers.

See more at: http://www.hra.nhs.uk/research-community/before-you-apply/project-registration-project-identifiers-and-plans-for-dissemination-of-research-findings/#sthash.sWzMtvhi.dpuf