Steps in the process of applying for NHS ethical and NHS R&D approval

Warwick staff and students

Chief Investigators, students and student supervisors should be aware of the time required to gain ethical approval and permissions from the NHS Trusts involved in their studies. This guidance aims to flag up the key stages along the way.

1. **Identify the Lead NHS organisation involved in the study**

   The Lead NHS R&D contact could be the R&D office of the Chief Investigator’s (CI) employing NHS organisation; a partner NHS organisation of the HEI employing the CI; the R&D office where the sponsoring organisation is based; the R&D office of a main NHS collaborator; the site where the study is first initiated; or a combination of these.

2. **Contact NHS Trust R&D office of the Lead NHS Organisation** before submitting any forms through IRAS and discuss:
   - whether an honorary contract or letter of access is required for any University person involved in the study
   - whether the study has been adopted by the CLRN portfolio. This is important as it will determine whether the R&D process will be handled by the CLRN – read the guidance on [http://www.crncc.nihr.ac.uk/about_us/processes/csp](http://www.crncc.nihr.ac.uk/about_us/processes/csp)
   - If the study is not adopted by the CLRN the University CI must seek approval from the R&D Department in each NHS Trust in which data is being collected. Further guidance is on the IRAS website [https://www.myresearchproject.org.uk/Help/Information.aspx](https://www.myresearchproject.org.uk/Help/Information.aspx)

   - Allow plenty of time for approvals for a regional or national study.

3. **Criminal Records Bureau and Occupational Health checks**

   Visit HR to organise a CRB and occupational health check for researchers who require an honorary contract (can take up to 12 weeks in summer holidays). A fee will be charged to studies funded by external grants and should be costed into the bid.

4. **Sponsorship, liability and insurance**

   Discuss study with a WMS RSS Officer (Debbie Greer, Maria Ovens, Navdeep Bains) to ensure there are no liability, insurance or sponsorship issues. The University will normally sponsor studies led by a Chief Investigator who has a substantive University contract, depending on the nature of the research. Where the Chief Investigator is employed by the lead NHS organisation, the NHS organisation will normally sponsor the study. Sometimes there will be a co-sponsorship agreement between the two organisations and time should be planned for these agreements to be put in place.

   For authorised Sponsorship of your study, all project documentation should be submitted to one of the RSS officers named above prior to booking your slot with a REC. The documents will be reviewed and amendments requested where relevant. The University has suggested responses to some of the IRAS form questions, such as Insurance / Indemnity and contact details for complaints. Once the application is finalised, your slot with a committee should be booked, and the application submitted for electronic authorisation by the Sponsor, which for Warwick is Dr Peter Hedges. Once electronic authorisations are complete the form is then routed through to the REC, and hard copies should be
submitted within the four working days allocated from the date of booking with the REC. Once the documents have been received and validated by the REC, they will also confirm if you need to complete and submit a Site Specific Involvement (SSI) form. Approval from all sites involved is mandatory prior to any research being carried out at that site.

5. **Sponsorship Declaration**
Where the University is the sponsor, agree a date on which you will submit your IRAS application electronically to the RSS officer for the sponsorship declaration to be signed.

6. **Preparing the application form**
Complete the IRAS application form – including the site-specific information form (SSIF) required for obtaining NHS R&D Permissions. If you have not completed an IRAS application form you should:
   a) Register for an account [https://www.myresearchproject.org.uk/SignIn.aspx](https://www.myresearchproject.org.uk/SignIn.aspx)
   b) Familiarise yourself with the process by following the e-learning module [https://www.myresearchproject.org.uk/ELearning/IRAS_E_learning.htm](https://www.myresearchproject.org.uk/ELearning/IRAS_E_learning.htm)

   Complete all study related documentation e.g.
   
   c) Research protocol including a brief summary of the project (in lay terms), including the scientific benefit
   d) Evidence of Peer Review
   e) Letters of invitation to participants and/or appropriate others
   f) Participant information sheet(s) (PIS)
   h) Interview schedules or topic guides for participants
   i) Questionnaire(s)
   j) Copies of advertisement material for research participants, e.g. posters, newspaper adverts, website. For video or audio cassettes, please also provide the printed script
   k) CVs for
      - Chief Investigators (for submission with main REC application)
      - Local Principal Investigators (for submission with the Site-Specific Information Form to RECs and NHS R&D offices)
      - Academic supervisors (for submission with student applications).

7. **How to submit an application to an NHS Research Ethics Committee (REC)**
Applicants must ensure that the application is ready to submit when you telephone to book it in for ethical review.

In order to be ready to submit:
   - the REC application form must have been completed and ready to be signed by the chief investigator
   - you must also have all of the supporting documentation together, as outlined in the REC application form checklist.

All documents:
   - must bear version numbers and dates (except where indicated on checklist);
   - marked as mandatory on the checklist must be submitted in all cases for the application to be valid;
   - should be printed on one side of the paper only;
when collated, they should not be stapled as they will need to be photocopied.

**Booking the application**
Once you are ready to submit, you should telephone either:
- your local REC, or
- the Local Allocation System (LAS), or
- the Central Allocation System (CAS).


a) NHS R&D Permissions - General guidance on the SSI form

- The Site-Specific Information Form (SSI) Form is a form used to apply for NHS permission for research. NHS permission is always required for a research site. For NHS research sites, NHS permission must be sought from the relevant NHS care organisation before the project starts at the NHS site.

- The SSI Form should only be completed after Parts A–D of the REC application form have been completed by the Chief Investigator and validated for ethical review by the main REC. The CI will then transfer Parts A-D of the R&D application to the PI to assist in completion of the SSI Form.

- Some of the answers in the SSI Form will appear automatically and will be identical to the answers the Chief Investigator gave to questions in Parts A and B.

- For information on the documents to submit in an R&D application, please select the checklist and submission tabs. There are different arrangements developing in different parts of the UK for R&D applications and the tabs will provide the appropriate information for your study and site.

b) After submission
When the REC co-ordinator receives your application they will check that it is valid. If you have completed your IRAS form correctly and you have submitted it with all the relevant supporting documents in time for the submission deadline, you will be issued with a validation letter within five working days, confirming that your application is valid.

If possible, you should attend the meeting at which the REC will consider your application. Please check directly with the REC co-ordinator whether this will be in person or by phone.

c) After the REC Meeting
The REC’s decision will be notified to you in writing within 10 working days after the meeting. The letter will contain details of any revisions and clarification the REC requires and sometimes the REC may make some suggestions about your research.

If you have any queries or wish to discuss the content of your letter, you should contact the REC co-ordinator or the named person in your decision letter. Your response to that letter would normally be dealt with by the REC chair by way of delegated power (or a sub-committee).

A REC is required to give an ethical opinion on an application within 60 calendar days of the receipt of a valid application. Where the REC considers that further information is required in order to give an opinion, it may make one request in writing for further information. The period of 60 days will be suspended pending receipt of this information.
10. *After Ethical Review*

The researcher’s relationship with the Research Ethics Committee does not end with a Favourable opinion. Researchers are required to keep the REC informed of progress, changes to the protocol, certain types of event and the end of the study.

- **Annual progress reports**
  You will need to provide a progress report to the main REC each year of the study’s duration.

- **Notification of substantial amendments**
  When and how you should notify the main REC of any changes to your study.

- **Safety reports**
  Requirements for periodic and expedited safety reports, and how to nominate a main REC.

- **End of study and final report**

- Further details on all of the above: [http://www.nres.npsa.nhs.uk/applications/after-ethical-review/](http://www.nres.npsa.nhs.uk/applications/after-ethical-review/)

**List of Abbreviations used:**

- CI  Chief Investigator
- HEI  Higher Education Institute
- IRAS  Integrated Research Application System
- NHS  National Health Service
- PI  Principal Investigator
- R&D  Research and Development
- SSIF  Site Specific Information Form