

JOINT RESEARCH OFFICE

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Newsletter—Version 1 July 2009 New Developments in NHS R&D

This last year has seen many changes in R&D within Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH FT) with the merger of Trust R&D with Newcastle University Medical Faculty Grants and Contracts department to form the Joint Research Office. We are working towards joint processes and procedures to help streamline applications and approvals for collaborative projects between the University and the Trust and future newsletters will keep researchers updated with these developments. However, this newsletter focuses entirely on new developments within NHS R&D to take account of the many changes in this area with the implementation of the Integrated Research Application System (IRAS), the move of Site Specific Assessment (SSA) to Trust R&D Departments and the introduction of the Co-ordinated System for Gaining NHS Permissions (CSP). There is a lot of new information for everyone to process and we hope this provides some clarification and guidance.

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Applying for R&D Approval at Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH FT)

To keep pace with the recent changes over the past year, further changes are required to the Trust R&D approval system. Most of the forms required to apply for Trust R&D approval are now produced via the Integrated Research Application System (IRAS) - see below for further details. The combined dataset that is produced when data is entered into IRAS populates the applications necessary for an NHS Research Ethics Committee (REC) and for Trust R&D departments (NHS R&D Form and the Site Specific Information form).

The application for Trust R&D approval should be made at the same time as applications to REC and any other applications required. The following forms are required to apply for Trust R&D approval:

Essential documents for a valid application:

- NHS R&D form created in IRAS – this is required as an XML file AND as a PDF file
- SSI form created in each case for NUTH FT – this is required as a PDF file
- CVs of the main investigator at this site and any other key staff at this site (eg, any co-investigator, lead research nurse—do not require CVs of staff that do not have patient contact)
- A local additional information form (V3.0 July 2009)—this is a short form which provides vital information required to do local assessments
- Evidence of Funding and a breakdown of costs at this site as well as any costings spreadsheet you might have (eg, Research Platform, Industry costing template etc)
- Latest study protocol which clearly shows the version number and date.
- Latest Participant Information Sheet and Informed Consent form which clearly shows the version number and date.
- For ALL commercial projects – study agreement/contract (at least in draft)
- ALL ctIMP studies where the Trust is **not** Sponsor (both commercial and non-commercial studies) - study agreement/contract with the sponsor (at least in draft)

Documents that can follow if not available at time of application:

- Favourable opinion from NHS REC
- Approval letter from MHRA
- Caldicott approval
- Any other required approvals

Please note: If your study is being processed through CSP (see below for details) then all of the documents listed above may not be required as they could already be in the central document repository in CSP. Please contact R&D to confirm which documents are needed.

With immediate effect all documents should be submitted via email to Trust.R&D@nuth.nhs.uk. This email is now to be used exclusively for R&D submissions and R&D staff personal emails should be used for queries.

Please DO NOT copy in members of the R&D staff to your application email. You will be sent an email acknowledging your application, requesting additional information if necessary, providing you with a Trust R&D reference number and, if the application is valid, confirming that your project will go to the next Trust R&D Approval Committee meeting (see website for R&D committee dates at http://www.newcastle-hospitals.org.uk/about-us/staff-information_research-development.aspx)

Remaining dates for the Trust R&D Approvals Committee for 2009 are as follows:

- | | | |
|-------------|-----------------------------------|---------------------------------|
| • AUGUST | Deadline: 12 th by 5pm | Meeting: 26 th 9-1PM |
| • SEPTEMBER | Deadline: 11 th by 5pm | Meeting: 25 th 9-1PM |
| • OCTOBER | Deadline: 13 th by 5pm | Meeting: 27 th 1-5PM |
| • NOVEMBER | Deadline: 11 th by 5pm | Meeting: 25 th 9-1PM |
| • DECEMBER | Deadline: 4 th by 5pm | Meeting: 18 th 1-5PM |

The Integrated Research Applications System (IRAS)

IRAS is a single system for applying for the permissions and approvals required for health and social care/community care research in the UK. It is not a form but a set of information that is used to create the various forms needed to apply for the approvals required for your research. IRAS captures the information needed for applications to the following review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Gene Therapy Advisory Committee (GTAC)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Ministry of Justice
- NHS/HSC R&D Offices
- NRES/NHS/HSC Research Ethics Committee
- National Information Governance Board (NIGB)
- Social Care Research Ethics Committee

The filter form in IRAS is key to the success of your application as this ensures that the correct forms are generated for your requirements from the list above.

A full explanation of how to submit each form generated in IRAS is available by highlighting the form for submission and clicking on the 'submission' tab. This section will also explain how to save files as XML.

IRAS is accessed at <https://www.myresearchproject.org.uk> and has a fully comprehensive help module at <https://www.myresearchproject.org.uk/Help/UsingIRAS.aspx>

The NIHR Clinical Research Network Portfolio

The NIHR Clinical Research Network Portfolio (NIHR Portfolio) is a database of studies that have met certain eligibility criteria (See http://www.ukcrn.org.uk/index/clinical/portfolio_new/P_eligibility.html)

For non-commercial studies these criteria are:

- The funding for the study was awarded as a result of open competition throughout England
- The study has been subjected to a high quality peer review as part of the funding process
- The research is of clear value to the NHS
- The funder takes account of Department of Health and NHS priorities and needs in their research funding strategies

For commercial studies, the criteria are:

- There is a genuine and testable hypothesis or a valid research question with a possible future benefit for patients as its objective
- There is a statistically valid trial design which is reasonable for the stated main objective and main hypothesis of the trial
- The trial and its design been subjected to an adequate peer review process
- The NIHR CRN CC network infrastructure has the current capacity to deliver the trial data reliably and on time

Studies that are on the NIHR Portfolio are able to access infrastructure support through the CLRN (Comprehensive Local Research Networks). The local CLRN for our Trust is Northumberland, Tyne & Wear (NTW) CLRN (<http://www.crnc.nihr.ac.uk/index/networks/comprehensive/clrns/northumberland.html>)

The infrastructure support has been provided in the form of PA clinic sessions for investigators and additional staff in support departments, e.g. pharmacy and radiology, and in research teams, e.g. research nurses and data managers. To be considered for the NIHR Portfolio, new studies should apply using the Portfolio Adoption Form generated through the IRAS filter page and portfolio projects are processed through the Coordinated System for Gaining NHS Permission (CSP) - see below.

The NIHR Coordinated System for Gaining NHS Permission (CSP)

CSP was introduced in England on the 18th November 2008 and is the R&D approval system for all studies adopted to the NIHR Portfolio. It is centrally coordinated through the NIHR CSP Unit and locally co-ordinated through the 25 Comprehensive Local Research Networks (CLRNs).

The aims of NIHR CSP are:

- Reduce the duplication in the NHS review process
- The central document repository accessible to all sites included in the study, means that documents should only have to be submitted once for any study.
- Provide a single point to which sponsors and investigator need to apply for NHS permission to start multi-site and single site studies
- Ensure clarity regarding the roles and responsibilities of sponsors, investigators, Clinical Research Networks and NHS Trusts

To apply for adoption to the NIHR Portfolio:

- Complete the project registration form in IRAS. The answer to question 3 'In which countries of the UK will the research sites be located?' must contain England and the lead R&D Office must be within England (question 3a)
- This will activate question 5a 'Do you want your application processed through CSP?'. 'Yes' must be selected here which will bring up the Portfolio Adoption Form (PAF) in the Project Forms section of the IRAS navigation page
- Complete the PAF and submit to the CLRN via the submissions tab in the IRAS navigation page
- Once the form has been validated, submit the NHS R&D Form and SSI Form to the CLRN
- The CLRN will then contact R&D to inform us of the study
- We will then contact the local Principal Investigator to request the necessary documentation required to complete the governance checks within CSP
- Once all of the governance checks have been completed, the study can then go for approval by the Chief Executive

Site Specific Assessment (SSA)

As of the 1st April, Trust R&D Offices are now responsible for performing the SSA for sites as part of the project review process.

- The SSI form should now be submitted directly to the relevant NHS R&D office where site approval is required. When submitting a project for Trust approval, please remember to include signed and dated copies of relevant CVs.
- RECs will rely on the checks undertaken by R&D departments as the checks that form the SSA are already part of standard R&D review. The favourable opinion from REC will be conditional upon permission at each of the relevant NHS organisations.
- There is no longer a need to inform REC about the addition of new sites EXCEPT for clinical trials of Investigational Medicinal Products (ctIMPs). For ctIMPs it is still necessary to submit a substantial amendment to MHRA and REC with the main details of the new site and investigator in order to comply with the Clinical Trials regulations.
- There will no longer be a list of approved sites produced (as was previously produced by REC as form SF1).

You can download the combined bulletin from National Patient Safety Agency and the NHS Research & Development Forum which provides full details about this change at: <http://www.nres.npsa.nhs.uk/news-and-publications/news/bulletin-on-the-site-specific-assessment-transfer/>

Caldicott

Approval from the Newcastle upon Tyne Hospitals NHS Foundation Trust Caldicott Guardian is required for research where data is used for any living patient (this also includes images, videos, charts etc). An application should be made to the Caldicott Guardian for **all** access to NHS patient data even if you consider the data being held to be non-identifiable data. It is the responsibility of the Caldicott Guardian to review the use of all data and determine if it is appropriately anonymised to ensure that it is non-identifiable.

Applications for Caldicott approval and to register a database can now be made using a single on-line application form for those that have access to NUTH FT intranet. To access the form and guidance notes, go to the alphabetical site index on the intranet site and click 'C' for Caldicott. On the Caldicott/Data Protection page click on the 'Data Protection Notification' button. On the next page click 'Data Protection and Caldicott Guidance' document and read these notes before completing the application form. To complete the on-line form click on 'the 'Data Protection and Caldicott Form' button. Using the 'Send for Approval' button at the bottom of the form, this is sent directly to the Caldicott and Data Protection team for consideration.

For those who do not have access to the Trust intranet site, the Caldicott application can be obtained from Trust R&D as a word document.

Once you have received approval for use of the data, you should inform R&D as this approval forms part of your overall Trust R&D approval. In addition, if the study is being processed through CSP, please forward a copy of your Caldicott approval to Jill Peacock within the JRO for uploading to the document repository in CSP.

Audit Feedback

As part of the requirements of The Research Governance Framework, R&D performs formal audits of a proportion of the research projects being undertaken within the Trust. Currently, we audit 10% of the projects that received R&D approval in the previous year and all clinical trials of Investigational Medicinal Products (ctIMPs) approved in the previous year where the Trust is acting as Research Sponsor.

During the recent audits for 2008-2009, there were several findings that were common to a number of the projects audited. Therefore, we have decided to publicise these findings to help researchers avoid these common pitfalls in the future.

Informed Consent

- The Patient Information Sheet (PIS) and Informed Consent Form (ICF) should always be on Trust letterhead or at least feature the Trust's logo. It is acceptable to keep one master copy on letterhead paper and photocopy this for use.
- The ICF should always clearly cross-reference the most up-to-date PIS to ensure that the patient is fully informed of what they are consenting to. This is normally the first statement that the participant initials against.
- The initials box at the end of each statement must be initialled and not ticked. This provides the only evidence that the participant has read and agreed to each term.
- The participant has to sign AND date the ICF themselves. This is important to provide evidence of the exact date that the ICF was signed by the participant.

Informed Consent (cont'd)

- The person taking consent must sign and date the ICF at the time consent is taken while the participant is present.
- A copy of the original consent form must be filed in the Investigator Site File (ISF) with a copy given to the participant and a copy stored with their clinical patient notes. These additional copies can be photocopies as long as the one with original signatures is held on the ISF.
- For situations where a third person needs to be present, e.g. if the participant is visually impaired or does not speak English, then this third person must also sign the ICF as a witness.

Version Control

- Ensure that all documents being used, e.g. protocol, PIS, GP letter etc, are the most up-to-date REC/MHRA approved versions. All essential documents should have a version number and date.
- When a document is updated, the previous version must have a line drawn through it and the word 'SUPERSEDED by Version ...' written on the document. One copy of the previous versions of each document should be stored within the ISF to provide a version history but all other copies should be destroyed immediately and replaced with the new version.
- If a participant is still involved in the study when there is a change to the PIS and/or ICF then the participant must be re-consented to the updated version, ideally at their next study visit.

Evidence of Training

- A training log should be kept in the ISF to provide documentary evidence that each member of the research team is fully trained to take part in the study.
- The ISF should also include a CV for each member of the research team. The CV should provide evidence of the suitability of the staff member to be involved in the study and give details of any GCP training undertaken.

Missing Documentation

- Frequently missing or incomplete signature/delegation log. A signature/delegation log should be present for all studies and should include every member of the research team and detail their role within the study. This delegation of duties must be signed off by the main investigator at this site for the study as it is their responsibility to ensure that those delegated these tasks are appropriately trained and qualified to perform them.
- As well as the main investigator, there should always be at least one back-up co-investigator who can prescribe on a study and this person should be clearly identified on the delegation log. This is important for pharmacy staff as they cannot process a prescription unless it is signed by a named person on the delegation log.
- There was inconsistency regarding the reporting of amendments to the R&D department.
- General lack of files notes to explain discrepancies in documentation.
- Lack of evidence of research team meetings/Data Monitoring Committee (DMC) meetings. This is important evidence for ctIMP studies to show that Serious Adverse Events (SAEs) are regularly discussed and reviewed. Safety monitoring is a delegated responsibility to the main investigators and meetings where SAEs are discussed should have minutes prepared documenting decisions.

Audit feedback (cont'd)

Recording of Information in Clinical Notes

The participant's clinical notes normally contain the primary source data for a research study.

- Notes should include details of a person's participation with a photocopy of the participant information sheet and signed informed consent form.
- The notes should also include information about eligibility for the study and this must be signed or countersigned by the Principal Investigator or a Co-Investigator to eligibility.
- Details of all assessments undertaken as part of the study and information regarding the participants withdrawal from a study should be reported in the notes.

SOP Update

There are already a number of Standard Operating Procedures (SOPs) and Working Instructions (WIs) for research which are hosted by the Clinical Platform website at: <http://www.ncl.ac.uk/crp/collaboration/standardop/library/>

There is currently a SOP working group reviewing these SOPs and developing additional SOPs for use in research through the Trust and University. All SOPs will be put up on the R&D section of the Trust internet: http://www.newcastle-hospitals.org.uk/about-us/staff-information_research-development.aspx

Events/Training

There are numerous Good Clinical Practice training courses available through different organisations. GCP is a regulatory requirement for those researchers undertaking clinical trials of Investigational Medicinal Products (ctIMPs). There are several courses for new staff and updates for those needing to refresh their knowledge.

Training courses are provided by Newcastle Biomedicine Clinical Research Platforms at the Clinical Research Facility within the RVI. Further information can be found at: <http://www.ncl.ac.uk/crp/training>

Courses are also available through NTW CLRN for those working on NIHR Portfolio studies. Further information can be obtained from Mark Ryan-Daly at Mark.Ryan-Daly@nuth.nhs.uk and a booking form is available at: http://www.crnc.nihr.ac.uk/index/networks/comprehensive/clrns/northumberland/latest_news/mainColumnParagraphs/09/document/GCP%20Booking%20Form%202009.pdf

NTW CLRN is organising a number of roadshows across the region. For further information again, please contact Mark Ryan-Daly, Project Manager for NTW CLRN, by email at Mark.Ryan-Daly@nuth.nhs.uk or by telephone on 0191 241 8808.

Useful Contact Details

Local REC details: <http://www.nres.npsa.nhs.uk/contacts/find-your-local-rec>

Newcastle & North Tyneside 1 REC: 0191 222 3581
Sunderland REC: 0191 428 3545
Co Durham & Tees Valley REC: 0164 262 4164

Newcastle & North Tyneside 2 REC: 0191 222 3581
Northern & Yorkshire REC: 0191 428 3545

NTW CLRN: <http://www.ukcrn.org.uk/index/networks/comprehensive/clrns/northumberland.html>

Lestryne Clift, Information Manager: 0191 241 8843
Karen Hutchinson, Industry Manager: 0191 241 8845
Mark Ryan-Daly, Project Manager: 0191 241 8808
Justine Smith, Lead RM&G Manager: 0191 241 8841

Meet the Team

Amanda Tortice- Research Operations Manager for the JRO

Email: Amanda.Tortice@ncl.ac.uk

Tel: 0191 2825959

Contacts for Trust R&D

Webpage: http://www.newcastle-hospitals.org.uk/about-us/staff-information_research-development.aspx

Lesley Hall- Research Governance Manger

Research Governance Issues/Audit Queries/Honorary Contracts

Email: Lesley.Hall@nuth.nhs.uk

Tel: 0191 2824823

Jill Peacock – Research Management & Governance Manager with NTW CLRN

Research Governance Issues/NCRN Portfolio Applications/Amendments

Email: Jillian.Peacock@nuth.nhs.uk

Tel: 0191 2824523

Sean Scott—PA to Research Operations Manager

Advice on How to Apply for R&D Approval/Progress on R&D Applications/General Queries

Email: Sean.scott@nuth.nhs.uk

Tel: 0191 2825959

Marie Wright – Data Entry Clerk and Receptionist

General Enquiries/Registering a Study

Email: Marie.Wright@nuth.nhs.uk

Tel: 0191 2824522

Contacts for University Grants and Contracts (Medical Sciences)

Webpages: internal page: <http://www.ncl.ac.uk/business-directorate/joint> external page:
<http://www.ncl.ac.uk/research/>

Carole Greenwood– Clerical/Secretarial Assistant

General Queries/Variation to award queries

Email: Carole.Greenwood@ncl.ac.uk

Tel: 0191 2824518

Dorothy McGuiness– Grants Administrator

Research Agreements for Staff and Application Queries (NICR and ICM)

Email: Dorothy.McGuiness@ncl.ac.uk

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Leanne Woolmer– Grants Administrator

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Helen Gallon– Grants and Contracts Manager

Commercial Agreements and Clinical Trial Agreements (NICR and ICM)

Email: Helen.Gallon@ncl.ac.uk

Tel: 0191 2824513

Amanda Gregory- Grants and Contracts Manager

Commercial Agreements and Clinical Trial Agreements (All other Institutes) & Material Transfer Agreements

Email: Amanda.Gregory@ncl.ac.uk

Tel: 0191 2824514

Gwen Averley– Research Funding Development Manager (Medical Sciences)

Assistance in preparing proposals or advice on which call/funder is suitable for your research

Email: Gwen.averley@ncl.ac.uk

Sadly, Helen Andrew and Ed Boal have left us for a new challenge in Bristol. We wish them well in their new venture and all the best for the future