

Expressing an interest and setting up new studies: Guidance for Researchers and Research Teams

**IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT
THE CORRECT VERSION IS BEING USED**

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	10 th January 2018	
2.0	23 rd May 2018	Updated version (1.1, 09April2018) of the Commercial EOI Form (Appendix 3). Radiology related additions.

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1. Introduction, Background and Purpose

HRA Approval is the new process for the NHS in England that comprises a review by a NHS Research Ethics Committee (REC) (where required) as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA Staff. In England, it replaces the need for local checks of legal compliance and related matters previously known as Local Governance Review.

This allows NHS organisations to focus their resources on assessing, arranging and confirming their Capacity and Capability to deliver a study.

NB; HRA Approval applies only to the NHS in England. The HRA has compatibility arrangements in place with the national NHS Permission coordinating function in Northern Ireland, Scotland and Wales that mean that the HRA will share information with those national coordinating functions to benefit study set up in participating NHS/HSC organisation across the UK where applicable. Further information about this can be found at <http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/>

The HRA expects local research management staff (such as the Research Delivery Facilitators (RDFs)) to work alongside Researchers and Research Teams when they wish to express an interest in new studies as well as setting up and delivering these. Therefore, research management staff should proactively support Researchers and Research Teams and these individuals should involve local research management staff in discussions with Sponsors, PIs, and Study Coordinators.

This document provides guidance to Researchers and Research Teams about what points to consider when submitting an Expression of Interest (EOI) and setting up a new research study in the Trust. This information is provided under the appropriate study set up stages as defined by the HRA; Identify, Assess, Arrange, Confirm, Site Initiation.

2. Who Should Use This SOP

This SOP should be used by:

- Researchers and Research Teams
- Members of York Teaching Hospital NHS Foundation Trust R&D Unit

3. When this SOP Should be Used

This SOP should be used by a Researcher or Research Team when they wish to submit an EOI to run a research study at a site within York Teaching Hospital NHS Foundation Trust.

This SOP should also be used by Researchers and Research Teams when a Sponsor representative applies for Confirmation of Capacity and Capability to undertake a research study in the Trust.

4. Making an EOI and completing Study Set up activities

1) Identify: Site Identification

- The Researcher or Research Team may be approached by the RDF, Sponsor, CI or Clinical Research Network about a new research study.
- They indicate their interest in the study by completing an EOI Form.

Guidance for Researchers and Research Teams

When you would like to express an interest in running a study in the Trust please inform your allocated RDF. If you are a Researcher who does not sit within an established Research Team please contact the R&D Unit who will put you in contact with one of the Units RDFs. The RDFs are there to help with the completion of EOI Forms and can be contacted for assistance via telephone or email.

The Clinical Research Network generally provides a standardised EOI form to use for Commercial studies. Please refer to Appendix 3 when completing one of these for guidance as to what to put for each question. At times a Sponsor specific EOI form may be provided and this will also be the case if the study is non-commercial. Whilst the EOI forms provided may differ, the general principles of completing these are similar.

The Trust will be competing nationally and potentially internationally against other Organisations to be selected as a site for a study. It is helpful to present ourselves in the best possible light to Sponsors and develop good reputations with these to encourage current and future site selection. The EOI form is an opportunity to present and show off your achievements, facilities and abilities.

Points to consider when completing an EOI;

- Submitting a completed EOI Form does not tie yourselves or the Trust to doing the study. If you are unsure about whether to submit an EOI because the information provided is limited for example it is far better to submit one than miss the opportunity. You can change your mind when further information comes to light or if a problem is identified. As a Trust we are not committed to doing a study until a contract is signed as part of the Confirmation of Capacity and Capability process.
- Be very aware of the deadline for submitting the EOI. Studies are becoming more and more competitive and chances are that if we miss the submission deadline our EOI will not be considered. To place yourself or your team in the best position and in order to develop a good reputation with the Sponsors it is important to submit an EOI on time.
- Upon reviewing the basic study information provided assess whether you have any competing studies, that you have this patient group accessible to you, and that the inclusion/exclusion criteria doesn't present any major challenges.

NB; if provided with more extensive study information (i.e. a protocol, schedule of assessments) at the EOI stage also review whether the content and timings of the visits are reasonable to both yourselves and the patient.

- A key part of completing an EOI is gathering patient population figures to specify a recruitment target. In doing this it is important to utilise MDTs and IT databases as well as potential PIs, Consultants and other members of the Clinical team to advise on the required patient population.

NB; remember to keep your recruitment target realistic and base it on sound evidence and judgment. It is far better to be conservative in recruitment target predictions than to overestimate and not achieve these.

- Check in the study information provided whether any support departments are required and if so include relevant contact details on the EOI Form.
- If the study presents any challenges and you note these on the EOI Form also state how you would try your best to overcome these to successfully reach your recruitment target.
- Once the EOI Form has been complete return this to your allocated RDF who will then forward it onto the relevant organisation. This may be the Clinical Research Network or a Sponsor. If you would like to send the completed EOI Form yourself please do always copy in your allocated RDF so that they are aware.

NB; When your EOI form has been sent off to the relevant organisation your allocated RDF will forward on your completed EOI to the applicable support departments (Pharmacy and Laboratory Research) and request a Stage 1; Feasibility assessment. The relevant person in Radiology will also be provided with the EOI Form and requested to make an initial feasibility decision. The RDF will inform you of the feasibility decisions.

- It may be helpful to create an electronic and/or hard copy folder for EOIs completed to keep a record of these and to draw from when completing future EOIs.

2) **Assess: Assessing Capacity and Capability**

- The Research Team, Support Departments and the RDFs will receive the final protocol.
- The purpose of this stage is Site Selection. The RDFs in collaboration with the Researcher, Research Team, Support Departments and the Sponsor representative assess whether there is the appropriate patient populations and the necessary staff and resources to deliver the study. Some Sponsors may choose to undertake a Site Selection Visit as part of assessing capacity and capability (feasibility).

Guidance for Researchers and Research Teams

Site Selection Visits (SSVs), Pre-Site Selection Visit (PSSV)/ Site Evaluation Visits (SEV) are largely conducted by commercial Sponsors with it being unusual for these to take place for non-commercial studies. If you are notified by the

Sponsor representative that they would like to perform a SSV/PSSV/SEV let your allocated RDF know as well as those relevant support departments.

In order to have the most people in attendance as possible it is important that all relevant parties are liaised with to arrange a suitable date and time to perform the visit. Once arranged it is helpful to send an Outlook invite to all with applicable information contained within it.

NB; where possible, the full protocol and any other relevant documents should at this stage be provided to all parties so that everyone can complete a review of these and collate their questions in preparation for the visit.

Points to consider in preparation for the SSV/PSSV/SEV

- Read through the protocol as much as you can and review the schedule of assessments. Make a list of any questions that you may have that you would like answering during the visit.

NB; remember that a SSV/PSSV/SEV is not only the Sponsor assessing our site and whether it is suitable but it is for you to also further assess the suitability of the study and the Sponsor.

- Every SSV/PSSV/SEV may be different in format but usually they will include a presentation about the protocol overview, discussion with the PI and a visit to Pharmacy and Laboratory Medicine/or other support departments, as required.

NB; check with the Sponsor whether they require IT equipment to ensure a suitable room is booked.

- Many of the questions that the Sponsor representative may ask usually are an extension to those asked on the EOI Form but request more detail. Therefore, it is helpful to know;
 - I. Your current portfolio and previous studies as you may be asked about these in relation to competing studies, experience in particular techniques, success at recruitment...etc.
 - II. Your patient population and your recruitment strategy as you may be asked how you are going to identify suitable patients and reach your target.
 - III. Your relevant clinical areas, pathways and procedures.

3) Arrange: Practical Arranging

- The RDFs, Researcher, Research Team and Support Departments are informed by the Sponsor representative that they have been selected as a site.
- The RDFs will process the new study using the “Local Study Set Up Checklist” (R&D/F12) and the support departments will process the new study in line with their own SOPs and Forms.

- The RDFs will receive the Local Information Pack and confirm receipt of this with the Sponsor which will then trigger the 70 day clock and set the benchmark for recruiting the first participant into the research study. Please refer to Appendix 2 for details of the NIHR 70 day Benchmark Metric.

Guidance for Researchers and Research Team

Once you have been notified by the Sponsor representative that the site has been successfully selected it is important to inform all relevant parties involved of this in case they have not been directly notified.

The Valid Research Application (VRA) /Local Information Pack (LIP) will be received by the RDF either via the Sponsor representative or the Researcher/Research Team (*For details of the content of this please see Appendix1*).

NB often the VRA/LIP will not come through as a complete set of documents and further information may be requested by the RDF in order for a thorough capacity and capability assessment to be complete.

The RDF will share relevant documents with all parties involved and liaise with them to put any practical arrangements in place to enable the delivery of the study at site and provide Confirmation of Capacity and Capability.

Points to consider when setting a new study up

- Communicate regularly with the RDF, the Sponsor representative, Laboratory Research and Pharmacy Clinical Trials to ensure the progression of set up.

NB; notify the RDF when you are happy to start the 70 day clock as they will work with you the best they can to trigger this at a suitable time if circumstances allow for it once they have received all of the documents they require

- RDFs will ask Research Nurses and the relevant support departments to review the Industry Costings Template (commercial studies only) or the Schedule of Events (non- commercial studies only) against the current protocol to check whether they are happy with the activities noted, the timings provided for these and that they relate to the protocol accurately.
- Every study has an Investigator Site File (ISF) and this may be provided to you by the Sponsor representative fully made up or they may only provide you with electronic copies of the documents to go in an ISF that you will need to make up. If you receive one that has been provided by the Sponsor thoroughly check through the documents enclosed and ensure they are the current versions. Your allocated RDF will be able to tell you the current versions in line with the approval documents they have received if you are in doubt.

NB; if you have to make your own ISF up from scratch please do refer to the R&D Unit SOPs, Forms and Templates available to help you with this.

- Create an electronic site file on your x-drive that is accessible to all of the study team.

- You will be required to localise relevant study documents such as the Patient Information Sheet and Consent Form with information such as the Trust header.

NB; if you do not have access to the Trust header or you are unsure as to what to put in relation to reporting complaints or providing advice please do contact your allocated RDF who will be able to provide you with the requested information.

- Depending on the type of study and the Sponsor you may be asked to organise the completion and sign off of important documents such as protocol signature pages, financial disclosures, confidentiality agreements...etc.
- Commercial Sponsors will ask for their own type of source data location checklist to be completed which may include IT related questions. If you would like assistance in completing this please do contact your RDF who will be able to help you.
- You may be asked to provide the Sponsor representative with laboratory equipment calibration certificates and reference ranges. Laboratory Research Team will be able to provide you with these upon request. They will also liaise with you throughout set up if they have any questions in relation to sampling and processing.
- Check whether samples will be processed in the local laboratory or whether these will be couriered/ shipped to a central laboratory. If local laboratory results required, please make sure these tests are available as per standard care/or whether any additional set up is required. If a central laboratory is going to be involved ensure you are aware of the process for booking the courier, including ordering dry ice, sample pick up times for York site, and the courier service cover for weekends/bank holidays Please check and agree with the Labs Research Team all details regarding clinic times and times for sample delivery to Labs, also check if there is a specific time frame for sample prep/processing/storage and/or shipping.
- If a study involves Ionising Radiation or exposure to Radioactive Substances then an IRMER (Ionising Radiation) or ARSAC (Radioactive Substances) will be required. The RDF will work with Leeds Radiation Protection Unit and the radiology leads at sites to complete these for the study where required. The RDF may request your assistance in obtaining signatures on these from the PI.
- If the study involves RECIST reporting then approach appropriate colleagues in the radiology department who may be able to perform this activity for you. Provide them with a good overview to the study and any necessary documents or protocol specific training required by the sponsor. If you are unsure of who to ask to perform this activity please liaise with the core clinical team who may be able to offer suggestion.
- Check whether any central reading of results is required for the study. Some commercial Sponsors require ECG results and imaging results to be read off site by a member of the central study team or their associates. This will be specified in the protocol if this is a requirement. If this is the case then ensure

you are aware of the method for sending these off and who in the research team or radiology department will be responsible for completing this activity. Liaise with them closely ensuring they have completed any specific training required and answer any questions they may have.

- If the study is a CTIMP the pharmacy clinical trials team will liaise with you throughout set up period in relation to things such as prescription format, drug dosing and dispensing.
- Check all CV's and GCP's are up to date at the earliest opportunity and are sent through to the RDF when requested. In line with Trust policy GCP should be updated every 3 years and CVs should be updated, signed and dated within one year.

NB; if you have a new member of staff in the team or a new investigator who is yet to complete a research CV and you do not have a template available please do contact you allocated RDF as they will be able to send you one.

- Check with the Sponsor representative whether there is any study specific training involved and if there is request access to this for relevant individuals at the earliest opportunity to prevent delays.

NB; if the study involves ward staff for example completing study activities you need to ensure that they have received the recommended level of training to comfortably complete their activity.

- If the study involves electronic data capture and/or IVRS/IWRS randomisation systems request logins to these and ensure that all relevant parties have access ready for study opening.
- Receive any supplies being provided to the site for the study e.g. lab kits, site pads...etc and check through these. If you are being provided with any electronic equipment for a study e.g. ECG machine, iPad...etc please contact EME in relation to testing these once they arrive.

NB; liaise with Laboratory Research Team once lab kits have arrived so that they can go through them if they wish.

- If the study requires home visits review the "Lone Working" SOP (R&D/S98) and complete the associated Forms (R&D F113 & R&D F114).
- Organise any practical arrangements such as ensuring there is adequate room space to see patients, any ordering has taken place for specific materials, clinic files or study aids have been created.
- If the study is one that requires safety reporting ensure you know what information to place on a patients CPD alert including out of hours contact information.

4) Confirm: Exchange Agreements

- All preparations to efficiently run the study at site should now be in place and the Support Departments will have issued their Authorisations (if required).

- RDFs should now be at a point of exchanging the agreement with the Sponsor representative.

NB; if the Sponsor is using the Statement of Activities as the agreement this will be completed and issued to the Sponsor by the RDF when they provide Confirmation of Capacity and Capability after the Site Initiation Visit/teleconference. If the Sponsor is using the Contract Model Agreement this may be returned before Confirmation of Capacity and Capability is issued if the Sponsor requires it back in order to complete a Site Initiation.

5) **Site Initiation: Sponsor Initiates Site**

- The Researcher, Research Team, Support Departments and the RDF will participate in the Site Initiation Visit (SIV)/ Teleconference if required.
- The RDFs will issue Confirmation of Capacity and Capability using template email R&D/T04.
- The Sponsor will issue their “Green Light” to begin (*if required*).
- The RDFs will issue the Local Research Team and Support Departments with the go ahead to commence recruitment at site using template email R&D/T05.

Guidance for Researchers and Research Team

Once the Site Initiation has taken place the support departments will issue their Stage 3 - “Readiness” if they have not done so already. The RDF will then issue Confirmation of Capacity and Capability via email to the Sponsor representative. If the study is a CTIMP then Pharmacy will also issue their Stage 4 - “Green Light” once they have received the IMP at site. They may do this at the same time as issuing Stage 3 - “Readiness” if it has arrived at that point. The Sponsor will also issue their “Green Light” (*if applicable- not all Sponsors do this*) once they have received the Confirmation of Capacity and Capability email. The RDF will then open the site to recruitment.

Points to consider when the study opens

- Ensure fully completed Study Delegation Log (signed off by the site PI) is in place. Study specific training, CVs and GCP training records (as required) must be documented in the study ISF for all staff member listed on the Delegation Log.
- Ensure all relevant parties are aware of the study opening particularly those members of the clinical team that may not be included in the above notification.
- Check that all members of the Research Team have access to the project on EDGE so that patient recruits can be uploaded in a timely manner.
- Put into practice any recruitment strategies including pre-screening activity.

NB; IT can assist with pre-screening activities by providing a list of potentially eligible patients from CPD records if suitable criteria are provided to them to complete their search. However, this is not something IT are required to do as part of their jobs and they will be doing this to help so please consider

carefully which studies would require their assistance. Please see Appendix 4 for further details.

- Notify the RDF once you have successfully recruited your first patient into the study and upload onto EDGE.

5. Related SOPs

R&D/F12	Confirmation of Capacity and Capability Checklist
R&D/S64	Setting-up Research Studies Involving Imaging (including studies using Ionising Radiation)
R&D/S94	Laboratory Procedures for Research Studies
R&D/S25	Providing and Documenting Training for Researchers
Pharm/S45	Setting up a Clinical Trial

Appendix 1: Local Information Pack

The Sponsor/third party working on behalf of the Sponsor should provide the following information to the site:

- Copy of the HRA Initial Assessment letter
- HRA Approval Letter for the study (*to be provided once available*)
- Copy of IRAS application form (*R&D form if pre HRA Approval study (April 2016)*)
- Regulatory Approvals (*MHRA-where applicable, Ethics*)
- Protocol
- Any amendments (*including the amendment adding the Trust as a site if not done so with the original application*)
- Participant Information and Consent documents
- Relevant model agreement (*where applicable*)
- NIHR Industry Costing Template (*validated by the Clinical Research Networks – check front page*) – commercial studies
- Schedule of Events – non-commercial studies
- Statement of Activities – non-commercial studies
- Pharmacy, Laboratory, and Radiology Manuals (*where applicable*)
- Any other documentation deemed required by the site in order to complete the capacity and capability assessment
- Confirmation of NIHR portfolio adoption

Appendix 2: The NIHR 70 Day Benchmark Metric

The NIHR 70 Day Benchmark performance metric for initiating new studies (as outlined here: : <http://www.nihr.ac.uk/research-and-impact/nhs-research-performance/hra-approvals-and-nihr-metrics.htm>) is triggered at the point at which the RDF acknowledges, by email receipt, the Full Local Information Pack from the Sponsor following a request by the RDF. Should the documents contained within the pack be sent in separate emails or should a document not be available until a later date, the RDF will not consider this pack complete or trigger the 70 day benchmark clock until the final document needed to complete the Local Information Pack has been received and acknowledged. Please see Appendix 1 for a list of those documents that make up the Local Information Pack.

For all studies, the RDF will confirm with the Research Team and the supporting services that they are in a position to run the study prior to requesting the complete Local Information Pack and triggering the 70 benchmark clock. Should the study Sponsor send the full Local Information Pack to the RDF before it has been requested, or if the RDF has no prior knowledge of the study in question, the RDF will not acknowledge receipt of this documentation until they have discussed with the Research Team, supporting services and PI that they are aware of the study and confirmed that they are in a position to commence study set up.

At the early stages before set up has been initiated the RDF may request that the Sponsor sends some documentation through to gather greater information on the study and complete pre-set up feasibility reviews, for example the study Protocol and Laboratory, Imaging or Pharmacy Manuals. This should not be considered by the sponsor as a request for the full Local Information Pack and if this Pack is sent receipt will not be acknowledged by the RDF aside from the named documents requested.

Appendix 3: Commercial EOI Form



National Institute for
Health Research

EXPRESSION OF INTEREST TO PARTICIPATE IN NEW STUDY OPPORTUNITY

<p>For the study: <i>(Insert here)</i></p> <p>Expression of Interest study reference: <i>(Insert here)</i></p>
<p><input type="checkbox"/> Interested in participating in the study - please complete the information table below to facilitate detailed site feasibility with the company</p> <p><input type="checkbox"/> NOT interested in participating in the study (optional completion) - option to provide feedback here which will be returned to the company</p>

The NIHR Clinical Research Network provides a nationwide mechanism through which all NHS organisations and General Practices can be notified of the latest research opportunities and express an interest in participating. Through this service, sites are provided with limited, non-confidential information and the study schedule of events (if provided) submitted by the company. Interested investigators/sites respond by completing this standard form. Responses are used by the company to facilitate detailed feasibility discussions with interested investigators/sites; at which time additional study information, for example the study protocol, will be provided directly to the investigator/site.

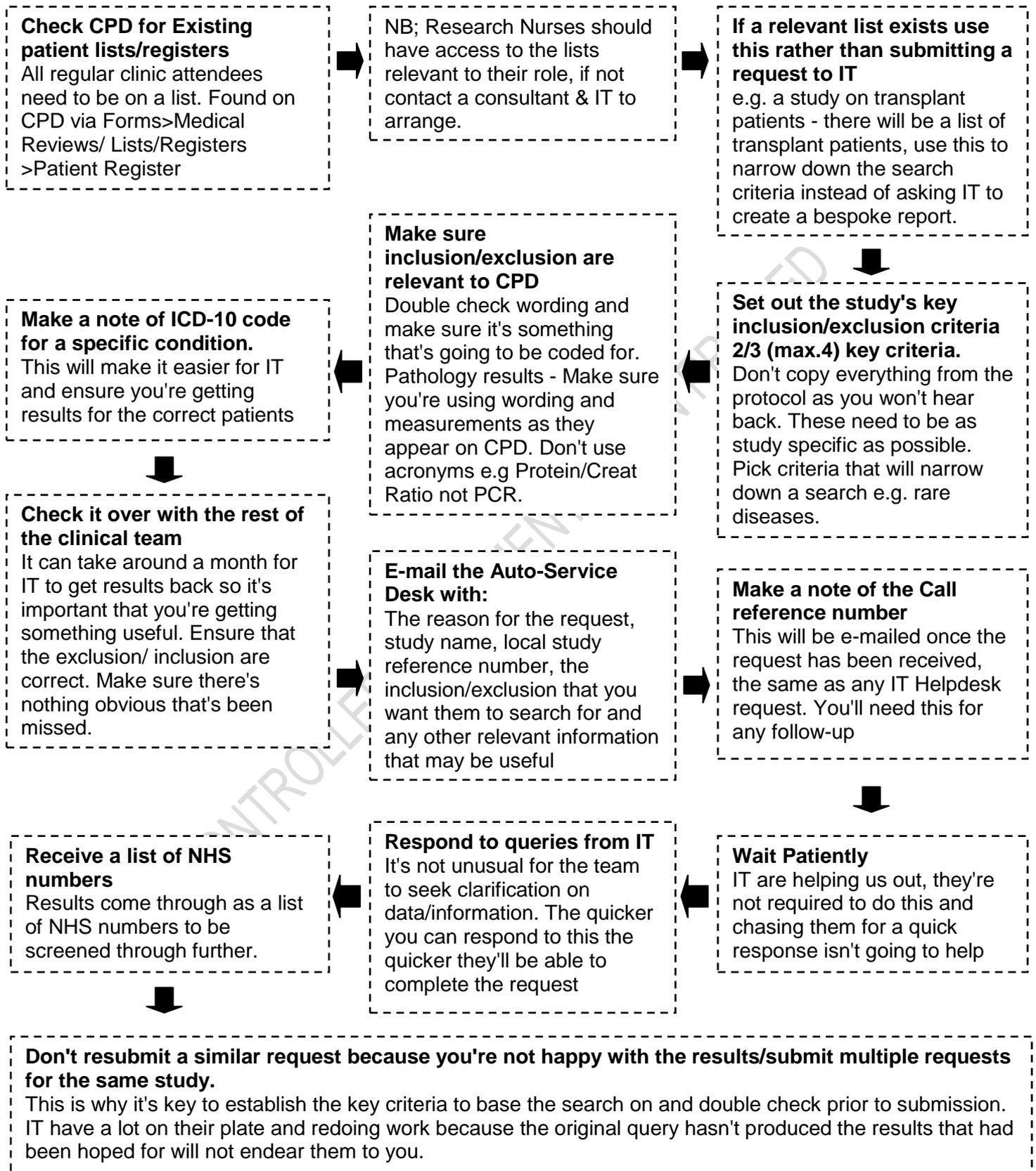
Site contact information for detailed feasibility discussions	
Investigator	Name: <i>[insert here]</i> Email: <i>[insert here]</i> Telephone: <i>[insert here]</i>
Research site	York Hospital/ Scarborough General Hospital/ Bridlington District Hospital <i>(delete as appropriate)</i> . <i>Please ensure you insert the actual hospital name here and not the Trust name</i>
Trust	York Teaching Hospital NHS Foundation Trust. <i>Please ensure you insert the Trust name here and not the Hospital name which should go above</i>

Main research site contact for feasibility discussions	Name: <i>[Research Nurse or PI- insert here]</i> Email: <i>[insert here]</i> Telephone: <i>[insert here]</i>
Supporting Local CRN to be included in feasibility discussions	CRN Yorkshire and Humber Industry Team Industry.crn.yorkshumber@nhr.ac.uk Jacqui Dooley, Portfolio Delivery Facilitator 0113 206 0492 Jacqui.Dooley@nhr.ac.uk
Participant recruitment	
Please briefly outline the access to required participant population during proposed recruitment period including a description of any anticipated recruitment challenges	<i>Note here how patients will be identified using any of the following methods; Outpatient Clinics, MDTs, radiology meetings, searches on CPD, via Specialist Nurse/Staff Nurse/Consultant identification.</i> <i>If you note any recruitment challenges try and note down also how you would endeavour to overcome these to ensure meeting the target specified.</i>
Please briefly outline any ongoing or planned studies at the research site which may impact recruitment to this study	<i>[Ensure any relevant confidentiality or nondisclosure agreement terms are not breached when providing such information]</i>
Site facilities	
Please briefly outline the research site facilities available to support participation in this study	We have a dedicated Clinical Trials Pharmacy and an experienced Laboratory Research Team as well as commitment from our Radiology Department to deliver research at our hospitals. <i>(If applicable)</i> We also have regular scheduled clinic room availability to see patients in for their study visits.
Please briefly outline the staff resource available to set-up, recruit and provide timely, quality data for this study (e.g. study	The <i>(insert speciality)</i> research team currently consists of <ul style="list-style-type: none"> • A Research Delivery Facilitator • Research Nurse/s • A Clinical Trials Assistant <i>(if applicable)</i> <p>In addition, we work on a flexible workforce model within the Trust. Therefore, all of our highly experienced Research Nurses and</p>

<p>coordinators, research nurses, data managers)</p>	<p>Clinical Trial Assistants can be moved between Departments to support studies where required ensuing recruitment to time and target wherever possible.</p> <p>Our Research Delivery Facilitator based in R&D works with the Research Team, Support Departments and Sponsor to set up new studies at site including budget negotiation, contracting and issuing capacity and capability.</p>
<p>Please describe any site-specific activities and how they may impact study timelines</p>	<p>Any pre-scheduled multi-disciplinary feasibility meetings or other departmental requirements (e.g. Pharmacy/R&D office): [State No or add description]</p> <p>Alternatives to the national templates used (ABPI model agreement or industry costing template): No</p> <p>Any other site-specific activities to highlight: [State No or add description]</p>
<p>Site past performance data (including start-up timelines)</p>	
<p>We work to the 70 day benchmark metric with us aiming to recruit our first patient within 70 days of confirming receipt of the local information package. On average set up of our research studies usually takes 35 days however, this does depend on the nature and complexity of the study.</p> <p>We have successfully delivered <i>(Insert speciality)</i> Research Studies over the past three years and of these % recruited to target. % of these successfully achieved the 70 day benchmark for recruiting their first participant.</p> <p><i>(Note here any outstanding performances i.e. first site opening in the UK or first UK or global participants recruited.)</i></p>	
<p>Local CRN support available</p>	
<p>Please provide a brief outline of any unique elements of Local CRN support that may be required for the site to participate in this specific study</p>	<p><i>[State not applicable or add description of the support above the standard support services provided, for example bespoke support available for a specific new investigator at the site]</i></p>
<p>Additional information requested by company</p>	
<p>Estimation of potential recruits</p>	
<p>Based on all the considerations</p>	<p>Number of potential recruits:.....</p>

<p>outlined above and the information available at the time, please provide a realistic estimation of numbers of potential recruits by the end of the proposed recruitment period, including workings</p>	<p>Outline of calculations and any assumptions made:</p> <p>This number is based on a population of potential patient recruits seen in <i>our clinics/ on our unit/ with this disease (delete as appropriate)</i> that would match most of the inclusion and exclusion criteria specified given the month recruitment window noted on the B3 submission form.</p> <p>Disclaimer: This is an estimation only based on limited information regarding the study and therefore WILL NOT form part of the contract. Provision of additional study information, such as the protocol, is required to confirm the actual feasibility target proposed prior to site selection by the company.</p>
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Appendix 4: CPD search request flow chart



Taken with permission from the original CPD search request flowchart, 01/Mar/2017, Renal Research

UNCONTROLLED DOCUMENT WHEN PRINTED