York Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S36

Completing an Expression of Interest (EOI) and Preparing for a Site Selection Visit (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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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SOP Reference:	R&D/S36
Version Number:	3.0
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Implementation date of current version:	15th April 2019

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	Date:	20th March 2019
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	Date:	20th March 2019

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	10th January 2018	
2.0	23rd May 2018	Updated version (1.1, 09April2018) of the Commercial EOI Form (Appendix 3). Radiology related additions.
3.0	15th April 2019	Update of EOI template content. Reduced SOP content to apply to Researcher and Research Team feasibility only. Change of link to R&D website.

Contents

1. Introduction, Background and Purpose

The Health Research Authority (HRA) and the Clinical Research Network (CRN) expects members of the local Research and Development team to collaboratively work with Investigators and Research Teams when they wish to express an interest in new studies. This Standard Operating Procedure (SOP) provides guidance to Investigators and Research Teams about what points to consider when completing an Expression of Interest (EOI) form and Site Selection activities for a new study.

2. Who Should Use This SOP

This SOP should be used by Investigators and Research Teams when they wish to complete an EOI for a new study or when they are organising and participating in a Site Selection Visit (SSV). This SOP can also be used by members of the Trusts Research and Development (R&D) Unit when assisting Investigators and Research Teams with the above activities.

3. When this SOP should be used

This SOP should be used when an Investigator or Research Team wish to complete an (EOI) to run a research study at a site/Hospital within York Teaching Hospital NHS Foundation Trust or when an SSV is required.

Note; SSV's may also be called a Site Evaluation Visit (SEV) or Pre-Site Visit (PSV).

4. Making an Expression of Interest (EOI)

When you would like to express an interest in running a study in the Trust please inform your Specialties allocated Research Delivery Facilitator (RDF). If you are unsure as to whom your RDF is please contact the R&D Unit. The RDFs are there to help with the completion and submission of EOI Forms and can be contacted for assistance via telephone or email.

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 show off your achievements, facilities and abilities.

The Head of R&D would prefer all EOIs to be returned to the Sponsor indicating an interest in participating in the study, unless we have a valid reason not to do so. Such valid reasons for indicating we do not wish to participate in the study would be for example; lack of PI, patients or equipment required. Capacity of the Research Team is not a reason as this can be addressed by the Senior Management Team as more information about the study is received and reviewed.

Commercial Studies (Pharmaceutical and Industry Sponsored Studies);

Commercial new studies largely come to the RDF and the Research Administrative Co-ordinator (RACo) via the Clinical Research Network (CRN) however, at times, they may be sent directly from the Sponsor to the Investigator

in which case the allocated RDF should be contacted. The CRN generally provide a standardised initial EOI form to use for Commercial studies. The current template can be found in Appendix 1 and provides guidance as to what to place in each section of the form. There is great emphasis on the RDF and RACo returning these EOI forms to the CRN to pass onto the Sponsor in a timely manner before the deadline noted. Once the Sponsor has had time to review all EOI Forms, which can sometimes take 3 months or more, they may approach the Investigator, Research Team or RDF to request the completion of a second, more comprehensive, feasibility form. These forms will be Sponsor specific but will often ask similar questions about the patient population, the Investigators experience, the Trusts resources and previous recruitment performance.

Non-Commercial Studies (often University or NHS Trust Sponsored);

Non- commercial new studies may be sent to the RDF and RACo by the CRN, or directly from the Sponsor to the Investigator, Research Team or RDF if there are previous relationships there. Often these studies will have a Sponsor specific EOI form to complete. Whilst the EOI forms provided may differ, the general principles of completing these are similar. Generally, there will be a greater time scale to complete these and they may be submitted by the RDF or RACo back to the CRN or the Sponsor depending on the guidance provided.

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 Capacity and Capability Assessment.

- 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.

  Note; 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, the patient and any support departments involved (Pharmacy, Laboratory Medicine, Radiology etc.)

- 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.

- 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.

- If there is time use the flow diagram in Appendix 2 to request a CPD search via the Trust IT Service Desk using the key inclusion/ exclusion criteria to aid generation of recruitment targets.

- If the study requests a minimum recruitment target that you feel is too high for your Research Site alone to achieve, consider the potential for extending the EOI to become Trust-wide and be a joint application for our key Research Sites; i.e. Scarborough Hospital and York Hospital. Your Specialty's assigned RDF covers your area's research activity throughout the Trust and will be happy to open up discussions with the other site's Research Team to look into this.

  Note; whether or not a study is suitable for being a Trust-wide project between multiple Trust sites is also at the Study Sponsor's discretion, as such it is advised where possible that you discuss this with the Sponsor prior to submitting the joint EOI.

- Check in the study information provided whether any support departments are required and if so include relevant contact details on the EOI form whenever possible.

- If there are Pharmacy, Laboratory or Radiology specific questions please do contact members of these teams to assist you in answering these. Contact details for the relevant support departments staff can be requested from RDFs and their RACo.

- 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 completed return this to your allocated RDF who will then forward it onto the relevant organisation. This may be the CRN 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.

  Note; When your EOI form has been sent off to the relevant organisation your allocated RDF and their RACo will forward on your completed EOI to the applicable support departments 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 from the support departments.

- 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 them when completing future EOIs.

5. Site Selection Visit's; Commercial Studies

Site Selection Visits (SSVs) 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 that they would like to perform an SSV let your allocated RDF know as well as those relevant support departments. A request for an SSV will be sent by the Sponsor to the Investigator, Research Team and RDF once the above noted EOI/Feasibility forms have been reviewed by the Sponsor and they are interested in our Trust as a potential Research Site.

Points to consider in preparation for the SSV;

- Every SSV may be different in format but usually they will include a presentation about the Protocol, discussion with the PI and a visit to Pharmacy Clinical Trials and Laboratory Research.

- Check with the Sponsor whether they require IT equipment to ensure a suitable room is booked.

- 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 MS Outlook invite to all with applicable information contained within it including, date, time and location.

- An email should be sent from the Research Team to the Sponsor with arrangements for the SSV including who will be attending, direction upon arrival and times to attend support department viewings (please refer to R&D SOP/66 for arranging meetings/visits to the Trust premises by external visitors).

- A copy of the Protocol, Laboratory Manual, and Pharmacy Manual should be requested from the Sponsor in preparation for the visit when it is not already provided. These should be sent on to relevant parties for their review.

- If the Sponsor requires a Confidentiality Disclosure Agreement (CDA) to be signed before they are happy to send the above documents then please send this to your RDF for review and signature. Please note only the Head of R&D, Research Advisor (in the absence of the Head), Chief Executive or Deputy Chief Executive can sign a CDA.

- Upon the receipt of the study documents please read through them 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.

- Always think about the challenges you have faced with previous studies and assess the current protocol for any suggestion that this study may present the same challenges.

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

- 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.

6. Related SOPs

R&D/S66 External Visits

Appendix 1: Commercial EOI Form

Red italics; guidance notes

Blue standard; suggestions of text to insert

EXPRESSION OF INTEREST TO PARTICIPATE IN NEW STUDY OPPORTUNITY

Study Title: *(Insert full title here if the CRN have not done so already. If the full title is not available use the short title)* **CPMS Reference:** *(Insert here if the CRN have not done so already. Examples; CANC 3455, MUSC 3748, DERM 4729)* **IRAS ID:**
☐ **Interested in participating in the study -** please complete the information table below to facilitate detailed site feasibility with the company ☐ **NOT interested in participating in the study (optional completion) -** option to provide feedback here which will be returned to the company

Site contact information for detailed feasibility discussions	
Research site ODS code **[CRN ONLY]**	York Hospital/ Scarborough General Hospital/ Bridlington District Hospital *(delete as appropriate). Please ensure you insert the actual Hospital name here and not the Trust name*
Trust	York Teaching Hospital NHS Foundation Trust. *Please ensure you insert the Trust name here and not the Hospital name which should go above*
Investigator	Name: *Name of Doctor/RN who has agreed to be Principle Investiga* Email: Telephone:
Main research site contact for feasibility discussions	Name: *Research Nurse leading on the study* Email: Telephone:
Research Setting	Primary Care Y/N Secondary Care Y/N Community Care Y/N Other *[insert detail here]*

Supporting Local CRN to be included in feasibility discussions *(details for this section is usually pre populated)*	CRN Yorkshire and Humber Industry Team Industry.crnyorkshumber@nihr.ac.uk e.g. Jacqui Dooley, Portfolio Delivery Facilitator 0113 206 0492 Jacqui.Dooley@nihr.ac.uk
Participant recruitment	
Where and how will participants be identified at the Research Site Do you anticipate any challenges that may affect recruitment of this patient population?	*Note here how patients will be identified such as the following methods; Outpatient Clinics, MDTs, Radiology Meetings, Advertising, searches on CPD, via Specialist Nurse/Staff Nurse/Consultant identification.* *If you note any recruitment challenges please note down also how you would endeavour to overcome these to ensure meeting the target specified. If you are unsure as to how you would do this speak with your RDF who will be able to help you.*
Based on all the considerations 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	*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.* 1. How many patients in this setting will be seen with this condition? 2. Using the exclusion criteria how many of these patients would be eligible to take part in this study? 3. What percentage of these would you expect will be motivated to take part? 4. Considering the answers above, how many recruits would you anticipate over the time period? ***Please note: the proposed recruitment target in Part B is*** *(this will be pre populated)* 5. Planned recruitment strategy:
Please briefly outline any ongoing or planned studies at the research site which may impact recruitment to this study	*Ensure any relevant confidentiality or nondisclosure agreement terms are not breached when providing such information. Do not name other Sponsors on the EOI form. Do not include information that would not be available to the Sponsor via the UK Clinical Trials Gateway/Trust Website. If in doubt check with your RDF.*
Available resource	
Please briefly outline the staff resource available to set-up,	Study set up would be overseen by the Specialties Research Delivery Facilitator (RDF) based in the R&D Unit who will review the local information pack, complete costing and contract

recruit and provide timely, quality data for this study (e.g. study coordinators, research nurses, data managers)	negotiations along with issuing Confirmation of Capacity and Capability. The RDF will continue to support the team once the study is open. *(insert speciality)* research team currently consists of • …. Research Nurse*/s* • Clinical Trials Assistant *(if applicable)* • Data Administrator *(if applicable)* • Research Practitioner *(if applicable)* The research team are managed by a Senior Research Nurse who will work closely with them to ensure they are fully supported in being able to deliver the study. In addition, we work on a flexible workforce model within the Trust. Therefore, all of our highly experienced Research Nurses and Clinical Trial Assistants can be moved between Departments to support studies where required ensuing recruitment to time and target wherever possible. We also host an in-house R&D Quality Assurance Manager & Research Adviser who are available to offer advice and/or internal monitoring/audits to the Research Team to ensure high quality data collection, and adherence to GCP and study protocols. The R&D quality management systems and standard operating procedures are outlined on the R&D website: https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/
Please briefly outline the other infrastructure available to support participation in this study	*Depending on the study you may like to outline some or all of the below;* *- Where patients will be seen i.e. outpatients, LaRC outpatients, on a dedicated ward, in a unit.* *- Parking arrangements* *- Laboratory Medicine including biochemistry, microbiology, and Histopathology. Lab Research Team.* *- Hospital Pharmacy including our own Clinical Trials Pharmacy* *- Radiology Facility* *- Pulmonary Physiology* *- Cardio Respiratory* *E.g.* York Hospital has a dedicated Outpatient Department where patients will be identified and seen by a Research Nurse alongside related specialist consultants. If space becomes a problem we also have access to outpatient rooms up in our Learning and Research Centre that are available to book to support research activity. *E.g.* We host a Clinical Research Laboratory consisting of 3 Associate Practitioners who oversee research samples handling, including processing, storage and shipping needs as required. Storage space includes -80 and -20 freezers and a refrigerator, with additional sample storage and processing space available within the Trusts Laboratory Medicine Department if required. The storage equipment is connected to a comprehensive 24/7 temperature monitoring system (Tutela). Our Associate Practitioners work closely with members of the histopathology, microbiology and biochemistry teams in order to facilitate the requisition and processing of samples.

	E.g. The Trust hosts an excellent Radiology Department that provides a range of imaging services. We have named research leads for each modality and calibration certificates for the machinery is available upon request. *E.g.* We host a Clinical Trials Pharmacy consisting of 4 Pharmacy technicians with the support of 2 Pharmacists who will be able to store, monitor, dispense and provide oversight on the IMP. They host their own dedicated and temperature monitored storage space and dispensing service to speed up the process for participants.
Please describe any site-specific activities and how they may impact study timelines	**Any pre-scheduled multi-disciplinary feasibility meetings or other departmental requirements (e.g. Pharmacy/R&D office):** *(Add description or note* None currently- formal feasibility at site will take place once we have received further information*)* **Alternatives to the national templates used (ABPI model agreement or industry costing template):** Not ideally **Any other site-specific activities to highlight**: *(State No or add description)*
Site past performance data (including start-up timelines)	
On average set up of our research studies usually takes between 30 and 40 days however, this does depend on the nature and complexity of the study. We have successfully delivered *(insert number) (Insert speciality)* Research Studies over the past three years and of these *(insert number)* % recruited to target. *(Note here any outstanding performances i.e. first site opening in the UK or first UK or global participants recruited.)* Trust performance data can be viewed here; https://sites.google.com/nihr.ac.uk/crn-yorkshirehumber-intranet/home/performancereports	
Local CRN support available	
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	*(This is not usually applicable for the studies we express an interest in. It may be more applicable to tertiary centres that are highly specialised in certain disease/techniques. If you are unsure as to whether to put anything here please ask your RDF)*
Additional information requested by company *Questions may be noted here if the Sponsor requires specific information to assess feasibility.*	

Note; the layout of this form may change when the NIHR CRN update theirs however the information requested will likely remain the same. Please do seek further guidance from your RDF if required.

Appendix 2: CPD search request flow chart

Check CPD for Existing patient lists/registers
All regular clinic attendees need to be on a list. Found on CPD via Forms>Medical Reviews/ Lists/Registers >Patient Register

NB; Research Nurses should have access to the lists relevant to their role, if not contact a consultant & IT to arrange.

If a relevant list exists use this rather than submitting a request to IT
e.g. a study on transplant patients - there will be a list of transplant patients, use this to narrow down the search criteria instead of asking IT to create a bespoke report.

Set out the study's key inclusion/exclusion criteria 2/3 (max.4) key criteria.
Don't copy everything from the protocol as you won't hear back. These need to be as study specific as possible. Pick criteria that will narrow down a search e.g. rare diseases.

Make sure inclusion/exclusion are relevant to CPD
Double check wording and make sure it's something that's going to be coded for. Pathology results - Make sure you're using wording and measurements as they appear on CPD. Don't use acronyms e.g Protein/Creat Ratio not PCR.

Make a note of ICD-10 code for a specific condition.
This will make it easier for IT and ensure you're getting results for the correct patients

Check it over with the rest of the clinical team
It can take around a month for IT to get results back so it's important that you're getting something useful. Ensure that the exclusion/ inclusion are correct. Make sure there's nothing obvious that's been missed.

E-mail the Auto-Service Desk with:
The reason for the request, study name, local study reference number, the inclusion/exclusion that you want them to search for and any other relevant information that may be useful

Make a note of the Call reference number
This will be e-mailed once the request has been received, the same as any IT Helpdesk request. You'll need this for any follow-up

Wait Patiently
IT are helping us out, they're not required to do this and chasing them for a quick response isn't going to help

Respond to queries from IT
It's not unusual for the team to seek clarification on data/information. The quicker you can respond to this the quicker they'll be able to complete the request

Receive a list of NHS numbers
Results come through as a list of NHS numbers to be screened through further.

Don't resubmit a similar request because you're not happy with the results/submit multiple requests for the same study.
This is why it's key to establish the key criteria to base the search on and double check prior to submission. IT have a lot on their plate and redoing work because the original query hasn't produced the results that had been hoped for will not endear them to you.

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