NHS National Institute for Health Research

Expression of Interest (EOI) Guidance (v2 May 2018)

The expression of interest process is intended to facilitate the rapid identification of interested sites for commercial sponsors. It is to help sponsors gather high level feasibility rapidly and to give them the information to be able to follow up with more detailed feasibility with those interested sites that meet minimum requirements (from the sponsors perspective).

As a site it is important to remember that this process is just an expression of interest and is not in any way a binding agreement. The sponsor is providing a limited set of information for the site to make an assessment on. If the site is interested and the sponsor wants to take it further the sponsor will then follow up with a confidentiality agreement so that they can send the site more detailed and confidential information such as a full synopsis or full protocol.

The EOIs can be considered similar to a CV; it is a concise set of information to enable the sponsor to decide if they want to consider the site to participate in their trial. This information is recorded in the 'Site Identification' form and has been updated by the NIHR Coordinating Centre, after consultation with various Industry bodies, and the new version is live as of the 5th March 2018. As with CV's there are certain traits that are more likely to give a positive outcome. It is highly recommended that the following simple principles are followed when completing the 'Site Identification' form:-

- Be concise. Keep the information provided to the point and avoid long text that does not add value.
- Be truthful.
- Be realistic.
- Be enthusiastic. Sponsors see a lot of 'Site Identification' forms . They are quite dry functional documents. A well written form that demonstrates enthusiasm stands out and may well make all the difference.
- Make sure to use good English and use spell check before submitting. (CRN: Wessex do try to correct spellings and correct any errors before we submit the forms if we spot them.)

The timelines associated with EOIs are not set by the CRN. The two-week turnaround is a balance between realistic 'do-ability' within the NHS and usefulness to the commercial sponsor. Sometimes a sponsor requests that we return EOIs more rapidly; on these occasions they are made aware that the expectation is 2 weeks and they may not get anything back in a shorter timeframe but we attempt to be accommodating and still go ahead with the service.

Sometimes the UK office of a sponsor may use the NIHR EOI service to help it bid to the global office to bring the study to the UK and when the CRN industry team knows this, we will include that information in our covering e-mail.

If you don't submit the EOI within the requested timelines Wessex: CRN will still upload the late EOI, however, you will be at a significant disadvantage as the sponsor has access to CPMS (central system) and has the option to download returned EOIs as they come in. In most cases they get more EOIs than they need so if yours is late there is a good possibility that they won't even look at it.

If you are not interested in taking part in the study or are not able to accommodate it for any reason then please do feed this back to your local R&D Office and to the Wessex Industry Team. This information is important for planning resources and strategic initiatives so please do respond to all EOIs.

The following section is the current EOI form with added commentary and examples of good practice (blue text). Please don't hesitate to contact the Wessex Industry Team if you have any questions or would like assistance with EOI or any matters concerning NIHR commercial research.

Carolina Paras, Industry Operations Manager, Industry.crnwessex@nihr.ac.uk

NHS National Institute for Health Research

EXPRESSION OF INTEREST TO PARTICIPATE IN NEW STUDY OPPORTUNITY

For the study: [CC to insert study acronym here] Expression of Interest study reference: [CC to insert CPMS number here]	
Research site	[insert name of NHS organisation and the research location where applicable e.g. hospital name]
✔ **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	

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: [insert here] Email: [insert here] Telephone: [insert here]
Main research site contact for feasibility discussions	Name: [insert here] Email: [insert here] Telephone: [insert here]
Supporting Local CRN to be included in feasibility discussions	Name or team: [insert here] Email: [insert here] Telephone: [insert here]
Participant recruitment	
Please briefly outline the access to required participant population during proposed recruitment period including a description of any anticipated recruitment challenges	[e.g. co-enrollment of patients in specific care settings, proposal for participating using patient identification centres, involvement of general practices or other independent providers (dental surgeries/community pharmacies)] This is an important question Don't just say something like "During clinics". Describe the clinics, their frequency, their size etc. If you have databases and search those to get an idea of potential recruits then explain this. Example: From the caseload of the PI, our research interested database and from other clinicians in the trust. The trust has a research interested database of over 400 people with X disease who have pre-consented to be

	contacted about research opportunities. We also have good links with Primary Care if PIC sites are required
Please briefly outline any ongoing or planned studies at the research site which may impact recruitment to this the study	If there is potential for competition it should be identified as early as possible so mitigation steps can be put in place. It will put a sponsor off if you identify a conflict but do not identify how you might get round it.
Site facilities	
Please briefly outline the research site facilities available to support participation in this study	This is the sites opportunity to tell the sponsor about the facilities in place to support the proposed study. Make use of this to highlight anything that could give you an advantage over other sites. Make sure to be concise. Some tips: • If there is dedicated research space – mention it. • If you have specialist equipment that may not be available to other sites - mention it
Please briefly outline the staff resource available to set-up, recruit and provide timely, quality data for this study (e.g. study coordinators, research nurses, data managers)	This is the sites opportunity to tell the sponsor about the staff in place to support the proposed study. Make use of this to highlight anything that could give you an advantage over other sites. Make sure to be concise. Some tips: • If the team is already GCP trained that is worth mentioning here • If you have special links with support departments - mention it • Please include any other relevant training Example: We have 3 investigators, 3 research nurses and a trials administrator, all GCP trained and with allocated time for research.
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): [State No or add description] Alternatives to the national templates used (ABPI model agreement or industry costing template): [State No or add description] Any other site-specific activities to highlight: [State No or add description] The guidance notes above included in the form are self explanatory, however, if you need assistance please contact us at industry.crnwessex@nihr.ac.uk for assistance
Site past performance data	
It is very important to the sponsor that their study is delivered on time and to target. Completing this box helps them to	

understand your track record. If you have a good track record it is really important to say so here. If you are new to commercial research (or haven't participated in any commercial research within the last 3 years) then it is appropriate to mention any good performance on non-commercial studies. It is also appropriate to mention any mitigating circumstances for commercial studies where you didn't meet target, however, make sure that your mitigations are valid.	
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	In some cases for sites in Wessex this section is not applicable, however, if in doubt please consult with your Wessex LCRN contact
Additional information requested by company	
[CC to insert from submission into rows here or reference feasibility questionnaire for additional completion attached to submission] Or [No additional questions required]	This section will be used by the coordinating centre to pose any additional questions from the sponsor
Estimation of potential recruits	
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	This may well be the most critical question on the form as far as the sponsor is concerned. The sponsor will have a UK/Global target that it must achieve. They will have a set budget and want to open sites that give them the best chance of meeting their targets. If you can demonstrate here that you can deliver the minimum site target (or exceed it) then you have the highest chance of being selected. However, simply stating a number is not really good enough. They really want to understand how you got to it and have some confidence that it is not just, at best a guess, or worst, simply the number you think they want to see. If you know the numbers of patients fitting the Inc/Exc criteria that are seen in a given time period, then say so. If you have databases and search them to get an idea of potential recruits, then explain this. NOTE: Even if you do not think you can meet the minimum requirement (stated in the Part B attachment) and you want to express interest; if you can demonstrate a well thought out calculation and confidence in a level of recruitment you might still be selected in the first wave or be considered at a later date. Example 1: Number of patients at this site with this condition is 400. Using the exclusion criteria we estimate of the 400, half would be eligible for this study. From our knowledge/experience we estimate that of those eligible

	50% would be willing to participate. Based on the study timelines and the above we estimate that we could recruit 15-20 patients to this study. Example 2: The practice has a list size of 13,400 patients in a searchable database. Our Initial search of patients with X Disease gives us a list of 70 potential patients, of whom about 50% are in residential care. This would leave us with a potential patient pool of 35 patients, although these records would need careful screening to exclude cases of Y and Z. In addition, we would expect to diagnose a further 10 patients over the recruitment window. We also have access to a further 16,000 patients through a PIC site. Taking all the above into account we feel confident of recruiting 8 patients over the 6 month recruitment window.