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Information and guidance for primary care sites about Expressions of Interest (EOIs)

The purpose of this guide is to provide primary care sites with guidance on receiving and responding to expressions of interest for research at primary care sites.

1. What is an expression of interest?

An expression of interest is often abbreviated to EOI and is the initial enquiry being offered to join a research study as a participating site. Expressing interest in a study is not a commitment to definitely go ahead and deliver it.

2. How does an EOI start?

EOIs are normally circulated by the Yorkshire & Humber (Y&H) Clinical Research Network (CRN) Study Support Service (SSS) on behalf of a central study team or study sponsor. EOIs are usually sent as an email containing a brief overview of a study and how a site can respond if they wish to become involved. Occasionally a sponsor may send an EOI directly to sites that they have worked with previously.

3. What is in an EOI email?

The EOI email for non-commercial studies contains an overview of what the site will need to do if they want to become involved and what they will be paid (if applicable) for that involvement. The email also contains a table which should be completed before the email is returned to the Y&H CRN SSS. Example non-commercial EOI Email Appendix 1.

The EOI email for commercial studies will have Submission B and Site Identification documents attached. It may also contain a Schedule of Events. The Submission B contains information about the study. The Schedule of Events has usually been extracted from the protocol and is a table showing what will happen to an individual participant throughout their involvement. The Site Identification should be completed and submitted to the sponsor and the Y&H CRN SSS. Example Site Identification Appendix 2

4. What should we do if the study is not suitable?

Study sponsors can find it helpful to understand why sites cannot or choose not to take up an EOI. By declining an EOI it can demonstrate that a site may be interested in future studies.

5. Why do EOIs have such short deadlines?

The EOI process is designed to get a rapid reply and responses are often required within 2 weeks. This turnaround is a balance between realistic 'do-ability' within the NHS and usefulness to the sponsor. Expressing interest in a study is not a firm commitment to go ahead with it, nor is it a guarantee that your site will get selected to become involved.

6. What happens after we have expressed interest in a study?

Some studies have a lot of interest and not all sites will be selected, so ideally you should complete the EOI and submit it as soon as possible. If your site is selected the sponsor will be in contact to let you know and will forward the Local Information Pack (LIP). For commercially sponsored Clinical Trials of Investigational Medicinal Products (CTIMPs) the sponsor will normally request that the PI or research lead signs a confidentiality agreement (CDA) prior to them releasing any information about the study. The sponsor may then carry out an on-site/virtual Pre-Site Selection Visit (PSSV).

7. Can we still express interest if we missed the deadline?

You can still submit an EOI after the deadline date but you may be less likely to be selected especially if the study is popular.

8. If we submit an EOI do we have to take part?

Absolutely not. If you have expressed interest in a study and then received further information which means you are unable to conduct the study you are able to withdraw interest. This also applies if your site circumstances change.

9. What is a RISP?

A RISP is 'Research Information Sheet for Practices' which are used specifically for primary care sites and can sometimes be sent as an additional document but doesn't replace the EOI process. A RISP contains similar information to the EOI email and not all sponsors provide them. Example RISP Appendix 3.

10. Who do I contact if I have further questions?

For any questions, please email: rdu@shsc.nhs.uk

Appendix 1:

Example of EOI email

Dear Colleagues,

We would like to invite you to participate in this Clinical Research Study:

This section has brief overview of study

Study Title:

Study Number:

Commercial / Non-Commercial:

Expected Start Date & Closure Date:

Geographic Region:

Study Target: National Target and Site Target

Practice Involvement: The actions to be performed at the GP practice will be listed here e.g. database search, eligibility check, mail out.

Inclusion / Exclusion Criteria: Criteria is listed here.

Practice Payment: Service support costs/Research Costs/ETC

Where Are Accruals Mapped To?:

Deadline Date for Returning EOI:

To submit an EOI please:

- Send EOI by email to contact name/email of study team and cc studysupport.crnyorkshumber@nihr.ac.uk

Note: *Expressing interest does not commit the practice to participate. Equally it does not guarantee involvement in the study. In most cases sites are selected on a first come basis.*

Further Information: For more information see attached: Could be protocol or PIS

Please contact Study Coordinator:

Local CRN Study Lead: studysupport.crnyorkshumber@nihr.ac.uk

Please indicate if your site will be expressing an interest in this study: YES / NO Delete as applicable

Name of Responding Site: Enter practice details

If your site will not be expressing an interest in this study, please mark 'X' or include a description below: Complete table

Reason not suitable for this site	
No research interest in this area	
No patients with this condition seen at site	
Not enough patients at site to meet minimum target	
No capacity within team at present	
Do not have appropriate equipment/services	
Unable to identify an interested PI	
No 24/7 cover	
Other (please specify)	

Kind regards,

Study Support CRN Yorkshire and Humber

NIHR | National Institute for Health and Care Research

| NIHR Clinical Research Network (CRN)
e. studysupport.crnyorkshumber@nihr.ac.uk

Appendix 2:

SITE IDENTIFICATION FORM
EXPRESSION OF INTEREST TO PARTICIPATE IN NEW STUDY OPPORTUNITY
Commercial

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). Interested investigators/sites respond by completing this standard form. We will endeavour to obtain feedback from sponsors/study teams as to the outcome of your form submission/application whenever possible. Following an initial evaluation process responses will be used 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.

Study Title: IRAS ID:
☐ **Interested in participating in the study –** please complete the form to confirm interest. ☐ **NOT interested in participating in the study –** please provide feedback below which will be fed back to the sponsor.

Site contact information	
Research site ODS code	[insert name of NHS/non -NHS site and the research location where applicable e.g. hospital, GP, federation name….]
Trust	[insert name of the Trust the research sites falls under]
Investigator	Name and Role: [insert here] Email: [insert here] Telephone: [insert here]
Main contact for feasibility discussions	Name: [insert here] Email: [insert here] Telephone: [insert here]
Research Setting	Primary Care Y/N (_) Secondary Care Y/N (_) Community Care Y/N (_) Other [insert detail here]
Relevant LCRN contact details	CRN Yorkshire and Humber Industry Team Name and Role: Email: Industry.crnyorkshumber@nihr.ac.uk Telephone:
Participant recruitment	
Where and how will participants be identified at the Research Site Do you anticipate any challenges that may affect	[e.g. co-enrolment 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)] Enter as much detail as possible including number of potential participants from database search.

recruitment of this patient population?	
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? 5. Planned recruitment strategy:
Please briefly outline any ongoing or planned studies at the research site which may compete with or impact recruitment to the study	[Ensure any relevant confidentiality or nondisclosure agreement terms are not breached when providing such information] If there is potential for competition it should be identified as early as possible so mitigation steps can be put in place.
Available resource	
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 an opportunity to tell the sponsor about the staff in place to support the stud there are 3 investigators, 3 research nurses and a trials administrator, all GCP trai and with allocated time for research.
Please briefly outline the other infrastructure available to support participation in this study	Primary Care / Community Care/ Secondary Care e.g primary care model at LCRN, support in non NHS sites,central primary care feasibility, Clinical Research Facility, phase one unit for overnight stays, available equipment etc. Mention any branch practices or links with other practices that could act as PICs fo site.
Please describe any site-specific activities and how they may impact study timelines	Any pre-scheduled multi-disciplinary, federation requirements, feasibility meetings or other departmental requirements, (e.g. Pharmacy/R&D office): [State No or add description] Alternatives to the national templates used [State No or add description] Any other site-specific activities to highlight: [State No or add description]
Site past performance data (including start-up timelines)	
PLEASE POPULATE THIS SECTION. IT IMPACTS THE LIKELIHOOD OF SITES BEING SELECTED. • **Please include a brief description of start-up timelines.** • **Please include a brief description of your performance in commercial research in the**	

past 3 years. Completing this box helps the sponsor 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, then it is appropriate to mention any good performance on non-commercial studies.	
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	Yes, this will be a Network supported site. CRN Yorkshire and Humber (Y&H) is one of the largest geographical regions which covers 10% of the English population. Due to the large geographical spread of our region we have one of the highest number of Network supported sites at 135. In 2017/18 CRN Y&H successfully recruited to time and target in 82% of our Lead Network commercial studies which surpassed the national target of 80% recruitment to time and target. CRN Y&H consists of 22 Partner Organisations and 23 Clinical Commissioning Groups. We ensure equity of access for our patients, whether in a rural or urban setting. The CRN supports the delivery of high quality research within our Secondary Care Partner Organisations through funding Research Nurses to support recruitment into NIHR Portfolio studies. As well as funding research nurses in our acute Trusts, we have an exceptional Primary Care research team that supports recruitment into studies that are being delivered within the community. Our Primary Care Delivery Team supports recruitment into studies in General Practice, Dental General Practice, schools and prison studies. The team provides support in the following ways: • Identifies primary care organisations which want to get involved in research • Study set-up • Training and development of primary care staff • Performance management • Supports research in oral and dental settings, care homes and pharmacists, among others Alongside our dedicated Primary Care team we have our Study Support Service who supports both commercial and non-commercial research throughout the Yorkshire and Humber region. The Study Support Service provides researchers with a single point of contact for both our non-commercial and commercial studies. This ensures that researchers experience a streamlined and effective support service, ensuring that all queries are dealt with quickly and efficiently. Furthermore, the Study Support Service provides oversight of the performance of studies to ensure its successful delivery. In addition to our Study Support Service, the CRN: Yorkshire and Humber have access to a central workforce that are able to support researchers throughout the lifespan of their study.

Appendix 3:

Research Information Sheet for Practices Example

A Study

Sponsor:	**CPMS ID: IRAS:**
Funding body:	**Trial Manager/Coordinator:**
Chief Investigator:	
Tel:	**Tel:**
E:	**E:**

Aim of study: Brief explanation of study and objectives

Study design: Brief overview of study design.

Study eligibility criteria: eg

Inclusion criteria:

- **Age 18 – 65**
- **Type 2 Diabetes Mellitus**
- **Taking Metformin**

Exclusion criteria:

- **Unable to provide informed consent.**
- **Type 1 Diabetes Mellitus**
- **Taking insulin**

Practice involvement: eg

- Run a database search to identify potentially eligible patients.
- Screen the medical notes of patients identified by the database search to exclude any who would not be suitable to invite for study participation.
- Send out study invites by letter, email, phone or text message.

- Complete study training.
- Report adverse events/serious adverse events.

Patient involvement: eg

- Give informed consent/assent to take part in study.
- Attend study visits at GP practice.
- Complete study questionnaires.
- 12-month follow-up appointment with research team (may be done remotely).

Specifics:	
Target recruitment (practice):	Number of recruits
Study recruitment period:	Recruitment start and end date
GCP requirements:	To be listed if applicable
CCGs that can recruit:	To be listed

Reimbursement:	**Research Costs** Invoice Study Team	**Support Costs** Invoice CRN
One-off costs: **Site initiation, database search, eligibility check and mailout**	XXX.XX	XXX.XX
Per patient costs: **ETC per patient £XX.XX.* *Total ETC for practices that recruit 10 patients - £XX.XX*		

Total (excluding ETC):	XXX.XX	XXX.XX

Invoicing:	
Study Team:	*Some study teams raise invoices for research costs on your behalf but do keep a record of your recruitment activity.*
NIHR **CRN TVSM**	
ETCs:	*ETCs are Excess Treatment Costs for the study. You will be invited to invoice quarterly by the CRN once minimum threshold met (£500). If threshold for the quarter is not met, you will be paid outstanding ETCs that are less than £500 at the last quarter of the year.*

If you have any questions, please contact the Lead Research Facilitator for this study:
Name - E: contact details

Or the Trial Manager:

Name - E: contact details