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Information and guidance for primary care sites on when to start a research study

The purpose of this document is to explain the study set up process and the documents/agreements that need to be in place prior to study start at primary care sites.

If the GP practice is a research site –

1. Does the study have Health Research Authority (HRA) approval?

HRA approval is required for all research involving the NHS in England. HRA approval involves the assessment of all study-wide governance checks and regulatory compliance for a research study by dedicated HRA staff and includes a review by the NHS Research Ethics Committee (REC)

2. Has the study had Ethics Review?

RECs are there to protect the rights, safety, dignity and wellbeing of research participants. All studies which involve patients, identifiable data or tissue need a REC review before they can proceed. Studies involving anonymised data or tissue, or research involving NHS staff and NHS facilities may not always need NHS ethical review. The RDU can be contacted for further advice.

3. Does the study have a letter of 'assurance' for primary care sites?

The Research Development Unit (RDU) at SHSC are commissioned to provide a research service to Primary Care sites in Sheffield which includes review the Local Information Pack (LIP) and once satisfied that all documents have been received and relevant approvals are in place, will issue a Letter of Assurance – with a copy to the sponsor. Information can be found on the SHSC website –

https://www.shsc.nhs.uk/get-involved/research

4. How will the research be funded?

i) Non – commercial study: Schedule of Events Cost Attribution Tool (SoECAT)

The SoECAT is a tool used to ensure that appropriate funding has been identified to support delivery of non-commercial research. It lists all study activities and how they are costed helping each research site to decide if they can deliver the study. The Organisational Information Document (OID) will also specify the research costs being paid to the site.

ii)Commercial study: interactive Costing Tool (iCT)

The iCT is the system used to ensure appropriate funding has been allocated to support the delivery of commercial research. It lists all study activities and how they are costed helping each research site to decide if they can deliver the study.

5. Is there a contract?

Some form of written agreement should be in place before a practice can start a study.

i)Non-commercial study: Organisational Information Document (OID)

The localised OID will contain all the information around study activities to be undertaken at the practice. It will include study start/finish dates, recruitment target, equipment and training requirements. The appendices include information about payments and data processing/sharing arrangements.ii)Commercial study: Commercial Primary Care Model Clinical Trial Agreement (PC-mCTA)

The PC-mCTA is a legal requirement for drug or device studies. The agreement will describe the obligations of the sponsor and practice whilst conducting the study. The appendices include information about study milestones and payments.

There are other agreements which may be used and RDU can advise further on these and also on non-model agreements.

A list of current agreements can be found by following this link - https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx

6. Who will be delivering the study?

The research team at the practice need to complete a delegation log. This log provides clarity regarding who is responsible for undertaking what activity during delivery of the study.

7. Can the practice deliver the study?

The research team will need to decide if they have capacity and capability to deliver the study. This should include review of the required documentation and ensuring that the team can deliver the study activities and that any payments are adequate. Once agreed the team can confirm Capacity and Capability with the sponsor.

8. What if I need support of external staff to deliver the study?

External staff can support research but will need to have a Letter of Access from the practice or sign a Confidentiality Agreement, more information this can be find here - https://www.shsc.nhs.uk/get-involved/research

Information about research support from the CRN Agile Research Team can be found here - https://sites.google.com/nihr.ac.uk/art/home

9. Do I need any specific training?

The sponsor will specify if the research team need to have Good Clinical Practice training and will provide any study specific training prior to study start.

10. What if I need specialist equipment?

This should be discussed with the sponsor as they can sometimes loan equipment to research sites.

11. If the GP practice is a Patient Identification Centre (PIC) -

PICs are not set up in the same way as research sites, however PIC activity for NHS organisations in England may only commence once a study has received –

- HRA Approval
- the research site linked to the PIC has completed its capacity and capability assessment.
- an appropriate agreement in place between the research site and the GP practice. Examples of PIC agreements can be found at - https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx

12. If the GP practice is displaying a poster -

Advertising opportunities to participate in studies e.g. via a poster in a waiting room, is not PIC activity, so any practice can do this without a formal agreement. However the practice should ensure that the poster has been approved by the HRA.

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

For any questions, please email: rdu@shsc.nhs.uk and see template 'study set up checklist'which may be useful to refer to.