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Information and guidance for primary care sites on the role of the Principal Investigator (PI)

The purpose of this guide is to provide primary care sites with guidance on who can act as a Principal Investigator and the responsibilities of the role.

1. Who is a Principal Investigator (PI)?

The principal investigator is the person at each site responsible for the day to day running of the research study.

2. Who can act as a PI?

For Clinical Trials of Investigational Medicinal Products (CTIMPs), the PI is usually a medically qualified doctor, however it is up to the sponsor to define the role requirements. This means that nurses, allied health professionals etc. can often be a PI on a non-CTIMP study, as can other health care professionals.

3. What does being a PI involve?

The responsibilities of the PI will be clearly delegated in signed agreements between the site and the sponsor. The PI may then delegate appropriate responsibilities to other members of the study team, however the PI must be involved in the active management of the study and should be able to demonstrate complete oversight at their site.

4. What are PI responsibilities?

i. Setting up the study:

- Inform the Research Development Unit (RDU) at Sheffield Health and Social Care NHS Foundation Trust (SHSC) for governance review and assurance rdu@shsc.nhs.uk
- Review and agree study finances and study payments
- Confirm there is adequate time to conduct and complete the study, including agreeing a realistic recruitment target
- Confirm there are adequate resources and facilities at the site to carry out and complete the study
- Ensure each member of the research team is suitably qualified/trained to deliver the study at the site
- Ensure external research support staff who will have direct involvement with research participants and/or person-identifiable data have a letter of access. See website for the templates-Practice sample Project-specific LoA and the Practice sample Time-specific LoA.
- Complete and maintain an up-to-date Signature and delegation of duties log.

ii. During the study:

- Make sure all research activities for the study adheres to the protocol
- Ensure the dignity, rights, safety and wellbeing of participants is a priority at all times alongside appropriate care
- Ensure informed consent of participants is conducted as outlined in the study protocol using the currently approved participant information sheet (PIS) and informed consent form (ICF) and that this is documented in the electronic health record (EHR)
- If a participant withdraws from the study try to ascertain the reason, while fully respecting their rights
- Have systems in place at site to ensure all staff are aware of each participant in the study
- Ensure procedures are in place to ensure collection of high quality, accurate data and that the data will be processed and stored in accordance with the Data Protection Act 2018 and the Caldicott Principles
- The study randomisation procedure is adhered to and, if applicable that the code is only broken in accordance with the protocol

- Assess causality of Serious Adverse Events (SAEs) Serious Adverse Reactions (SARs) and Serious Unexpected Adverse Reactions (SUSARs) and report them to the study sponsor as detailed in the protocol
- Report any urgent safety measures and/or protocol deviations to the study sponsor
- Ensure the Investigator Site File (ISF) and essential documents are kept up to date
- Demonstrate oversight throughout duration of study via regular recorded team meetings
- Be available for monitoring visits.

iii. When the study ends:

- Ensure appropriate medical care/follow up for participants and ensure the EHR are retained as specified in the protocol
- File the end of study report/summary in the ISF
- Make arrangements for the secure archiving of the study for the length of time specified in protocol.

5. Where can I find out more about a Principal Investigator?

https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/#pi (accessed 20/02/2023)

and this short video explores the PI role:

https://www.youtube.com/watch?v=qDEVt7Jzztc (accessed 06/03/2023)

6. Where can I find out more about study training?

GCP, informed consent, study specific training:

https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm (accessed 20/02/2023)

7. Where can I find out more about recording meetings?

A template can be found at https://learn.nihr.ac.uk/course/view.php?id=496 (accessed 20/02/2023)

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

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