How to guide: Understanding the role of PICs

This guide outlines key information about the role of the Participant Identification Centre (PIC). PICs are NHS/HSC organisations that identify potential research participants to be recruited at a separate research site, should they wish to participate.

Key information you should be aware of:

Practice staff should be aware of their responsibilities with regard to research and should only take part in approved studies. Practices continue to be responsible for their own patients' care but PICs are not research sites and are not treated in the same way as research sites. Practices should understand study requirements and what can and can't be done by reviewing the study protocol and Organisational Information Document (OID) and should ensure that data protection guidance is followed.

- PICs are not considered to be research sites
- PICs retain responsibility for the healthcare of patients outside of research but research sites have duty of care for participants in relation to research studies
- PICs should assess studies in relation to practice capacity and capability, and the appropriateness of participant identification activities
- Data protection needs to be given consideration

Highlights

- What is a PIC?
- Overview of the role of PICs
- Things to consider
- Contracting arrangements

Full guide

What is a PIC?

- Participant Identification Centres (PICs) are NHS/HSC organisations that identify potential research participants.
- A GP practice is operating as a PIC if its role involves:
 - identifying potential research participants by processing personal data (e.g. searching patient record databases);
 - it is following sponsor instructions in identifying potential research participants;
 - the practice then directs potential participants to a separate research site without undertaking further research activity for a study.

Overview of the role of PICs

- Some studies recruit participants via general practices but then any further research activity takes place in another setting e.g. a hospital. These are known as Participant Identification Centre (PIC) studies.
- If a GP practice agrees to be a study PIC then the study team does not have permission to carry out research activity at the practice but general practices can be involved in supporting recruitment to studies by identifying participants. This can involve:
 - conducting a search of a database to identify a list of participants who fit a study's inclusion/exclusion criteria;
 - o sending out an invitation to patients to introduce a study e.g. a letter, email or text;
- A practice is not acting as a PIC if:
 - o informed consent of the participant is taken by practice staff;
 - any assessment outlined in the study protocol to determine whether potential participants are eligible for the research study (e.g. a screening blood test or x-ray) is carried out by the practice, or any aspect of research delivery outlined in the protocol is carried out by the practice;

- potential research participants are referred to a study as part of normal clinical activity (e.g. routine clinics) in order to gain access to clinical interventions;
- 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.
- If the study requires the health care professional to consent patients or carry out any other research activity (e.g. follow-up tests) then it is should be treated as a full research study and not as PIC activity.
- PIC activity for NHS organisations in England <u>may only commence once</u>:
 - a study has received HRA Approval;
 - the research site linked to the PIC has completed its capacity and capability assessment or other review as appropriate;
 - there is an appropriate agreement in place between the research site and the NHS organisation acting as a PIC.

Things to consider

- If you are considering whether to be a study PIC you should consider:
 - o Does the patient information clearly detail who is delivering the research?
 - Is HRA approval in place and has West Yorkshire R&D (or your local R&D team) had sight of this study?
 - Have you considered the finance and resource implications of being a PIC? Some service support costs (SSC) and research costs may be reimbursed by the NIHR Clinical Research Network or the study team to cover, for example, postage costs or the time taken by practice staff to carry out a search.

Contracting arrangements

- As per IRAS guidance: NHS/HSC PICs should be set up by through a sub-contracting arrangement with the participating NHS/HSC organisation that the PIC supports. Appropriate data processing arrangements should be put in place by using the appropriate agreement. Best practice is for studies to use a model agreement:
 - o model Commercial PIC agreement (m-C-PICA)
 - model Non-Commercial PIC agreement (m-NC-PICA) site to PIC
 - model Non-Commercial PIC agreement (m-NC-PICA) sponsor to PIC
 - Source: <u>https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx</u>

Glossary of Acronyms and Terms

- NHS National Health Service
- HSC Health and Social Care Services
- PIC Participant Identification Centre
- HRA Health Research Authority
- OID Organisational Information Document