York Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S67

Participant Identification Centres: Setup & Management

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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	Date:	24th July 2017
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This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	30th January 2012	
2.0	23rd March 2015	Removal of references to the North and East Yorkshire R&D Alliance
3.0	24th August 2017	Rewritten in line with HRA Process Changes and expanded to include guidance for Research Teams in supporting a PIC site. Change of Author

Contents

1 Introduction, Background and Purpose

Participant Identification Centres (PICs) are organisations from which clinicians or clinical units refer potential participants to a research team based in another organisation, for assessment and possible recruitment to a study.

PICs are responsible for the identification of potential participants who are subsequently invited to take part in research through a different site which takes on responsibility for seeking consent and undertaking research procedures. The PIC retains responsibility for the healthcare of the patient outside the research, but the research site takes on the duty of care for them in relation to the research study.

The PIC's responsibility for an overall duty of care in relation to healthcare, provision of information, and participant identification activities is met through assessing issues of confidentiality, resource use and appropriateness of the participant identification activities.

PICs are not considered to be research sites. Research sites are defined as organisations responsible for participant-related research procedures specified in the protocol, including recruitment and informed consent.

In line with the Health Research Authority (HRA) approval process the Study Sponsor must seek HRA and Research Ethics Committee approval prior to opening any NHS organisation to PIC activities.

NHS organisations responsible for PICs must be made aware of their role in identifying potential participants, and must Confirm Capacity & Capability for the participant identification activities.

As the site would not be hosting the study and recruiting any patients PIC site studies do not form part of NIHR Performance Metrics such as the NIHR 70-Day Benchmark or Time to Target evaluations.

The purpose of this SOP is to provide guidance on how to obtain PIC site approval for PIC activities carried out in the Trust and to provide guidance to local Research Teams on how they should manage and oversee PIC activity once open.

2 Who Should Use This SOP

Chief Investigators, Principal Investigators, Sponsors or Clinical Research Organisations (CROs) wishing to establish a PIC site in the Trust.

R&D Unit staff processing applications for PIC sites.

Research Nurses and supporting staff who will be managing the PIC site activity or approaching participants

3 When this SOP Should be Used

This SOP should be followed as part of the PIC site approval process. All PIC sites should have been determined but no PIC site activities will have started.

In addition this SOP applies while performing and managing PIC site activities.

4 Confirmation of Capacity & Capability Review

In line with the HRA all studies conducted at NHS Organisations across England the Trust must conduct a Confirmation of Capacity & Capability review prior to research activity commencing, this is still the case for PIC studies.

The Research Team should inform R&D as soon as they have expressed an interest in becoming a PIC Site.

The Study Sponsor should notify the R&D Department by email to research.governance@york.nhs.uk once they wish to begin an application for the Trust to conduct PIC activity.

Once an application is received it will be assigned to one of the Trust's Research Deliver Facilitators (RDFs) who will begin the Capacity & Capability review.

The review will be split into three key stages; Assess, Arrange and Confirm. A checklist supporting the whole process is available as R&D/F80.

4.1 Assess: Assessment of Capacity and Capability

When an application is received by the RDF they will contact the Research Team to confirm that the Principal Investigator and Research Nurse are aware of their required duties during PIC activity and confirm that they have the Capacity to support this.

Should it be decided at this point, or indeed later stages, that the Research Team are no longer able to accommodate the PIC activity the RDF will contact the Study Sponsor to inform them that the Trust will not be proceeding.

Provided that the team have capacity to support the study the RDF will move onto the Arrange stage of the review.

4.1.1 Levels of Involvement for PIC Activity

The RDF and Research Team must carefully examine the involvement for the PIC study prior to making any commitments to deliver it. PIC activity for each study can vary and the team must be clear on what the Trust is agreeing to deliver.

Below are key examples of what the Trust may be expected to deliver;

- Advertising: In many cases the Research Team will only be expected to put up posters and/or leaflets in clinical areas to advertise the study. No patient interaction should be expected but the team must ensure that documentation is up to date.

- Patient Information Distribution: For the majority of PIC studies the Research Team will be expected to identify and approach potentially eligible patients. They will hand out Patient Information Leaflets and discuss the study with the patient whom will then agree to have their details passed onto the referring site or will contact the referring site directly.
- Consenting Patients: Though rare some PIC studies may require the Research Team to take consent or 'consent to contact' from an eligible participant whom they have approached and wish to undertake the study. It is important to remember that such consent does not account for an accrual for the Trust and will not be reported back to the NIHR in performance data.
- Follow-Ups: Some PIC studies may follow one of the above paths for recruitment but may still require the Trust to deliver Follow-up appointments for any recruited participants at a future date.

4.2 Arrange: Practical Arranging

As part of the application the Study Sponsor is expected to send a document pack of essential documentation that would be required by the RDF and Research Team to confirm capacity and put arrangements in place.

The following documents are required for a PIC site Confirmation of Capacity & Capability review:

- Current HRA approved study protocol
- IRAS form including details of all relevant PIC sites and PIC activities (Question A73)
- HRA approved Statement of Activities and Schedule of Events for PIC site activity (if Non-Commercial)
- Industry Costing Template or other written documentation providing costs (if Commercial)
- Current HRA approved Patient Information Leaflet and any related documentation such as posters or Invitation Letters that would be used by the research team during PIC activity.
- Site agreement for PIC activity if not included within the Statement of Activities
- Original HRA Approval Letter
- HRA Approval for addition of the Trust as a PIC site Note: HRA Approval for the site is not required if the site is only required to display leaflets or posters
- If not clear from the above a written summary of the PIC activities.

Once all documents are received the Research Delivery Facilitator will carry out the following local checks:

- Confirm that the Principal Investigator and Research Nurse are aware of their required duties during PIC activity and confirm that they have the Capacity to support this.
- Ensure that the site has been granted HRA Approval to conduct PIC Activity. This should be indicated on the original IRAS Application Form

under question A73, or in subsequent Amendments. Note: HRA Approval for the site is not required if the site is only required to display leaflets or posters

- Ensure that Patient Information and any Consent to Contact documentation is clear about which site is hosting the research and who will be providing compensation for any clinical negligence.
- Directorate Management Authorisation is not required as there should be no direct resource or cost implications for any Directorate involved in PIC activity. Any time spent by the Principal Investigator or fellow clinicians within the Directorate in identifying eligible patients should not be more than what they would be expected to do in any case.
- Ensure that the Research Team are in receipt of all documentation required to act as PIC Site. If the Sponsor is providing materials the RDF will ensure these have been delivered.

The Research Delivery Facilitator will log the PIC study and upload all documentation onto EDGE. The study will be provided with a unique R&D Reference which will consist of the IRAS Number, followed by Y or S to indicate the study site as York Hospital or Scarborough General Hospital and include the additional identifier 'PIC', for example, '123456Y PIC'

4.2.1 Variations between Commercial & Non-Commercial Studies

There would also be additional checks based on whether the study is commercial or Non-Commercial;

For Non-Commercial Studies the RDF must review the Statement of Activities and Schedule of Events to consider the resource implications for the Trust when measured against any resources or income the Study Sponsor will be providing.

For Commercial Studies must review the costs that are to be provided to the site by the Sponsor, these should be documented within the Industry Costing Template or in separate site agreement documentation. It is expected that there should also be a Setup-Fee attached to opening the study.

4.3 Confirm; Exchange Agreements and PIC Site Activation

Once the above checks have been reviewed the RDF will complete the relevant agreement, whether this is the Statement of Activities or a Site Agreement contract, it must be signed by all parties.

Once the agreement is in place the RDF will send the Study Sponsor a Confirmation of Capacity & Capability for PIC Site Activity email (R&D/T28) whilst ensuring that the Principal Investigator and Research Team have been copied in.

This email will provide the final confirmation that the Trust is ready to support the PIC study and, unless the Study Sponsor requires their own additional activation or 'green light' letter to be sent to the Research Team, will enable the Research Team to begin identifying patients on the date provided. The Research Team must ensure a copy of this email is filed.

Following this, a follow-up email will be sent to the Research Team to confirm that activity may begin and the approved document versions they must be using. The template for this email is R&D/T51.

The Study will then be marked as open on EDGE and all remaining documentation uploaded.

5 Research Team Management of PIC Studies

Once the PIC site has been opened, the Research Team will be responsible for its day-to-day management just as they would for any of their own recruiting studies.

Whilst the involvement required in managing a PIC study should be considerably less than a Recruiting study, the Research Team, Principal Investigator and R&D staff, must still ensure they follow relevant procedures and hold responsibilities as listed below.

5.1 Staff Responsibilities

5.1.1 Research Team

The Research Team must ensure that all study documentation is kept up to date and that any amendments that affect the Trust's duty as a PIC site are carefully reviewed and correctly implemented.

When a PIC study requires a Research Nurse to approach and refer patients directly, s/he must ensure the patient has fully read and understood the Patient Information Sheet prior to referring them to the Recruiting Site. The Research Nurse must also ensure that the patient understands that they are being approached about involvement in a study that will not be conducted by York Teaching Hospital NHS Foundation Trust. Patients must be made fully aware of which organisation they will be involved with.

When a PIC study requires the Research Team to display recruitment posters and put out Participant Information Leaflets in clinical areas or via Trust community services, the team must ensure that these documents are kept up to date (as per any future amendments), and any outdated patient information materials are returned, superseded and multiple copies destroyed.

PIC studies generate no accruals to the Trust; therefore the Research Teams are not required to upload any referred patients to the EDGE system.

For PIC studies referring patients to Clinical Trials of Investigative Medicinal Products (CTIMPs), prior to approaching a patient for participation, the PI and any delegated Sub or Co-Investigators must confirm that a patient meets eligibility criteria as stated in the study protocol.

5.1.2 R&D Staff

The Research & Development Team are responsible for ensuring that the Research Team is fully supported throughout the duration of the PIC study.

The Quality Assurance staff and Lead Research Nurse Coordinators can provide the Research Team with guidance and advice related to the day-to-day management of the PIC study and work with the team in overcoming any problems they encounter.

The Research Delivery Facilitator will be responsible for conducting the Confirmation of Capacity & Capability review, as stated in section 4. They will also aid the Research Team with any amendment, contractual or study closure related tasks and queries.

5.2 PIC Site File

The Research Team should maintain a PIC Site File in order to store current documentation for the study and to provide local information on the research staff, contact details, training records and referrals. However, a full Investigator Site File (ISF) as per recruiting studies is not necessary.

A template of the documents required within a PIC Site File is available as R&D-F120.

5.3 Amendments

Amendments for PIC Sites should only contain amended documentation in relation to the Trust's duties as a PIC; such as updated Patient Identification Sheets, Protocols, Posters, etc.

All amendments should be sent to Research.Governance@york.nhs.uk and will be reviewed by the Unit Administrator or RDF who will then ensure that the documents have been forwarded to the Research Team.

Once received the Research Team should inform R&D whether they have any objections to implementing the changes documented.

As per HRA categorisations, if no response form the Research Team is received within 35 days of receipt of the Amendment, approval will be assumed and the amendment implemented.

The following must be received prior to the Research Team implementing the Amendment;

- HRA/REC Approval
- No Objection sent from the Research Team to R&D, unless nom objections received within 35 days of notification.
- Any additional Regulatory Authorisation approvals, e.g. MHRA

Once these have been received the Unit Administrator or Research Delivery Facilitator will email the Sponsor to provide Continuing Confirmation of Capacity & Capability for the amendment and confirm that it may be implemented.

All updated documents will be uploaded onto EDGE and saved in the Project Folder on the R&D x-drive.

6 Related SOPs, links and Documents

IRAS guidance on PIC Site applications:

https://www.myresearchproject.org.uk/help/IrasPartCCollatedHelp.aspx#nhs_participant

HRA guidance on PIC site applications:

http://www.hra.nhs.uk/resources/after-you-apply/participant-identification-centres/

R&D/T28 Confirmation of Capacity & Capability Email to Sponsor: PIC Sites

R&D/T51 Confirmation of Capacity & Capability Email to Research Team: PIC Sites

R&D/F80 PIC Site Checklist

R&D/F120 PIC Site File: Template Contents List