

## **NHS R&D Forum Response**

July 2019

**Opportunities to recognise and incentivise NHS Trusts, GP practices, and other associated organisations (e.g. Pharmacies/Dentists) to act as research Participant Identification Centres (PICS), taking into consideration opportunities to speed up recruitment and increase patient access to research.**

### **1. Background:**

The [Life Sciences Sector Deal 2](#) published in December 2018, highlights priorities to improve the clinical environment for both pharmaceutical and health tech companies, which includes a focus on Participant Identification Centres (PICS). The definition of a PIC is given in IRAS, (*see Appendix A*)

The Department of Health and Social Care, has requested the National Institute for Health Research Clinical Research Network (NIHR CRN) explore mechanisms to ensure patients are offered the opportunity to participate in research that is relevant to them, whether or not their regular healthcare provider is delivering it.

A specific focus is to identify opportunities to recognise and incentivise NHS Trusts, GP practices and other associated organisations such as Pharmacies and Dentists to act as PICS, taking into consideration opportunities to speed up recruitment and increase patient access. The project is being led by the NIHR Clinical Research Network Co-ordinating Centre and is linked to delivery of commercial contract research, however recommendations will be applicable to the wider research environment and consideration given to non-commercial studies.

The NHS R&D Forum has been asked to respond to this project and supports the ongoing development of solutions to improve research as core business for providers and commissioners of Health and Care. The Forum has a strategic commitment to supporting the embedding of research within health and care settings for the benefit of patients, and to the development and delivery of some key initiatives within the Industry Sector Deal 2.

The NHS R&D Forum is a UK-wide professional network and community of practice for the research management, support and leadership workforce in health and care organisations. Members of the NHS R&D Forum working groups have written this response on behalf of the community following a survey and consultation process.

**The following method was used to inform this feedback:**

- A workshop held at the Primary Care & Commissioning Working Group, led by NIHR CRN CC.
- Survey to all members with three main questions (*See Appendix B*) eighty survey responses were received from across the R&D management workforce and includes responses some from patients and the public (this was not specifically sought but arose because awareness of the survey was promoted via Twitter).
- Discussion at the Forum Strategy & Leadership Working Group and Service Users and Carers working group.
- Teleconference for members, including a research-active GP.
- Ad hoc discussions /emails from members and with stakeholders.

This response has been written in the spirit of partnership and as such we trust our comments will be taken constructively as they are intended. For further information on the NHS R&D Forum and our membership please see [www.rdforum.nhs.uk](http://www.rdforum.nhs.uk)

## **2. Our Forum response**

There is support for the benefits that Participant Identification Centres (PICS) can bring to research and care.

**These benefits for research are focused on:**

- The ability to increase access to research opportunities at organisations and practices that may not have the capacity or capability to set up as a full research site thereby offering a pragmatic route to realising the NIHR aspiration for increasing the number of health and care organisations active in research. It can also be a useful first step into research for GP practices and similar organisations
- Enabling Sponsors to concentrate delivery of a study at certain sites across the UK, (**NB** some have argued that a careful balance is required to ensure capacity for delivering research is maintained across organisations *in addition* to PIC activities. PICs must be incentivised *as well as*, not *instead of*, research delivery).
- Enabling Sponsors and research delivery teams to find participants in hard to reach communities.
- Increasing successful recruitment to studies by targeted screening for eligibility criteria.
- Building research awareness and culture that can improve research partnerships.

*“PICs are a valuable recruitment resource for research projects, especially in community settings where there is significant patient throughput and diverse populations are managed in the short and long term. Hard to reach populations are often encountered. Reach of recruitment can spread beyond acute and secondary care centres.”*

*“There is insufficient opportunity to access sufficient populations for RCT studies other than through NHS data holding systems.”*

*“There is huge unmet potential in the ambulance setting for being a PIC to assist research within setting, as well as the primary care / secondary care / specialist care settings.”*

**Benefits to patients and to care are focused on:**

- Enabling patients and the public to access research opportunities that might otherwise be unavailable to them.
- Making access to research participation more equitable across the UK, helping to inform and include rural communities and more isolated groups.
- Preventing onerous travel requirements, parking fees and time out of work etc. for research participants by providing an option for Sponsors to design studies where researchers can travel to the communities themselves.
- Enabling more organisations and practices involved in care to become involved in research and to provide information about research as their core business.
- Informing clinical teams about current research and generally improving awareness about innovations in care.

*“Historically the trust I work with has supported PIC activity. The positive impact of this is that this has contributed to strengthening the research awareness, culture, capacity and capability across the trust, built collaborations across trust services, and between our trust, other trusts and academics.*

*Supporting PIC activity has enabled our trust to participate in research that we might not otherwise been offered, or had the capacity and capability to support delivery of the full study. Thus PIC activity provides our clinicians the opportunity to offer more of our patients the opportunity to take part in research, that they otherwise may not have been offered.*

*PIC activity provides opportunity to build collaborations with key academics that subsequently lead to exploration of further research activity that is relevant to our patient populations. Collaborations with other trusts and academics are thus strengthened as is the potential for our community trust to develop and delivery future relevant research.”*

These benefits are well known and were described consistently in the feedback we received however PICs do not necessarily provide all of these benefits nor do they always do so quickly, easily, cost effectively or consistently.

### Themes & recommendations

The following themes have been identified as important to the process of incentivising NHS organisations to become PICS but also to how we might improve PIC activity and build additional ways of creating the benefits described.

#### 1. Governance processes for PIC activity

**Recommendation:** Consider whether it might be legally possible, ethically right and low risk to amend PIC governance requirements such that clinical teams can more easily share information about research opportunities to their patients as part of care and properly funded research-enabling activity.

- PICs are NHS/HSC organisations (inc General Practices) looking to identify potential research participants for research taking place at a separate legal entity, by processing personal data as instructed by a research sponsor (e.g. undertaking a database search). Limited information about the study is then passed onto the patient and they decide whether or not to make contact with the Sponsor or participating site, for further details.
- PIC activity is currently governed as a research activity because the search criteria for finding eligible participants and the subsequent limited but version-controlled and approved information provided to them is specified by the research Sponsor i.e. the activity happens for the *research* rather than for the *patient*. This means that the Sponsor is deemed to be the data controller who must, for GDPR purposes, then have agreements in place with sites as data processors and PICs as sub-processors. This is despite the fact that by definition a PIC does not undertake any protocol driven activities (see *Appendix A*) and is only making limited information about the research opportunity available to potential participants.
- The HRA have recently helped to ease the contracting burden by providing model PIC agreements (*see Appendix A*) for use between sites and PICs and this intervention to streamline is appreciated. Sites, however, have expressed some concern that these agreements are now their formal responsibility and an additional activity cost to them. PICS themselves may be unused to contracting for the *processing* (not sharing) of patient information, which may prove to be a dis-incentive over time. Contracts for funding do need to be put in place but these could be much simpler templates. There is some debate whether contracts should be with the Sponsor or the site but

anything that can be done to reduce an unfunded site burden and support PIC sites to recover funds easily should be considered.

- The processes involved in PIC activity itself (for example database searching, writing queries, posting letters, searching notes, and sometimes checking whether patients have died etc.) can be administratively onerous therefore support from research-enabling support staff can be significantly beneficial. There is however concern around how far the common law duty of confidentiality prevents such help. Although some organisations report to have successfully worked around it there is uncertainty and variation in practice across the country made worse by some confusion with GDPR.
- There was a lack of clarity evident in the feedback around the definition of a PIC and while the information is available in IRAS (see *Appendix A*), greater visibility and understanding around this written as NHS/Sponsor facing guidance may be beneficial. It would also be helpful to make clearer the difference between PIC activity and activity that refers a patient to another organisation for clinical treatment and includes research; how this can be better enabled and facilitated as good clinical care activity? The contracting process for PICS *may* unintentionally fuel misunderstanding around the difference between data processing and data sharing encouraging PIC 'creep'.
- The process feels overly cumbersome for an activity that is relatively low risk, straightforward and something an organisation *should* arguably provide as part of good care.
- We therefore suggest some consideration is given to whether any of the following are feasible:
  - (a) A better way of sharing information rather than trying to identify and pass on where this is possible, for example a system that enables Clinicians to *access* study eligibility and PIC screening criteria so the request for documents comes from the clinician for care, rather than from the Sponsor for research.
  - (b) To re-frame and value PIC activities as **research-enabling** and **research-identifying** rather than research itself. This would mean that the governance of PIC activity would move from that of research to that of information. Such a shift would help embed and normalise research enabling opportunities in care. By doing so PIC activity would become 'business as usual' and be delivered through pragmatic and proportionate information governance processes.

**NB:** we recognize there may be an inherent financial risk in arguing

for this activity to be considered care and not research and that the value in research-enabling staff and activities should be recognised and funded accordingly (see finance below for the importance of funding).

- (c) Consulting with patients and the public whether research-enabling staff might be legally and ethically acceptable as part of the direct care team for the purposes of supporting with the administrative burdens of PIC activity to provide opportunities to take part in research. There is already some [evidence](#) that demonstrates research office or network staff can provide very valuable services to support this but that understanding of the IG requirements is limited and the boundaries are unclear.
- (d) A review of IG arrangements with the ICO, HRA and others to see whether there is any scope to simplify them for PIC activity.
- (e) Any solutions to aide sharing and support at network or Integrated Care System level, for example and how the new Primary Care Networks be enabled to help.

## 2. Finance & Capacity

**Recommendation:** Ensure that PIC activity is appropriately, fairly and consistently financed with easy mechanisms for recovering the money to cover the cost. Enable additional staff to support where possible.

- The ability to appropriately finance PIC activity was raised in nearly all responses.
- There was a perception that underfunded PIC activity is often *'just'* facilitating income generation in the recruiting sites although conversely there was some concern that the method of paying GP PICs in commercial studies for example was overly burdensome to Trusts. For Trusts in particular the lack of finance for PIC activity makes it hard to prioritise over recruiting studies and in some cases the diverting of resources has adverse implications for other NIHR income streams, for example RCF.
- There was some divergence in practice around how PIC activity was charged back to Sponsors, sites or LCRNS. Some organisations received payment based on recruitment success and others were paid per study for the act of

searching and providing information. Clarity around this would help to reduce variation and overly complicated payment systems based on converting screening to recruitment.

- Comments about finance were nearly always hand in hand with comments about value, capacity, performance and recognition of effort based upon recruitment. There was some recognition however that funding this did not necessarily lead to improved capacity and that the current clinical workforce is under such immense pressure that additional and enabled research support staff may be just as important.

*“The perception is that one trust is helping the other to generate income and from my experience locally there has been a real reluctance to do this, especially with regards commercial income.”*

*“Disincentives NHS Trusts from using GPs as PIC sites because they have to pay each surgery to do so – if this was funded centrally in some way that would help.”*

*“In terms of CRN service delivery monies, the ambulance sector is the least financially supported research setting in England, as a result of which there is virtually no capacity to consider the addition of PIC activity.”*

*“The difficulty lies in use of resource to publicise studies where the Trust is a PIC site when under-resourced to run studies where the Trust is a full site. Taking time away for PIC site studies may have the consequence of reducing the number of patients enrolled into Trust studies and thereby affecting future NIHR funding.”*

- PIC activity although simple in nature was viewed by members to be administratively onerous at times, particularly for GPs or other front line clinical staff under current pressures.
- An argument was made that if there are specialist skills required for identifying the patients and approaching them, then doing more of this activity would ensure it becomes part of practice and makes it easier to fund as a result.



*“There is a misconception that PICs in primary care involve simply pressing a button and eligible patients’ records literally spew out of the clinical systems, which is an incorrect perception.”*

*“Primary care has particular strength around its use of coding (Read Codes/SnowMed) as the GP systems can be searched and lists of potentially suitable patients can be identified. Primary care often has a greater link with its patients. Also Primary Care is looking at the involvement of digital applications around research with providers such as EMIS. The development of Primary Care Networks may also help deliver research at a larger scale. The main challenge for primary care is the capacity to do this work. PC is struggling with delivery of clinical services. The CRNs are going to need to provide a structure or mechanism to support this work otherwise it is not going to happen.”*

### 3. Value & Recognition

**Recommendation:** Review the current NIHR portfolio recognition methodology to value all contributions to research including enabling activities.

- Value and recognition was a very big theme in our feedback. PIC activity was considered to be invisible and very difficult to prioritise/justify in the current system.

The emphasis on recruitment has served an important purpose but it is now time to change because it attributes research activity to a single organisation and often the research pathway for participants, crosses more than one organisation. This is more important than ever in the new landscape of Integrated Care Systems.

- Aspirations in the [Long Term Plan](#) mean that support must be given to embedding research across organisational boundaries, improved partnership working and facilitation of collaboration and co-operation in all research endeavors.
- Value, recognition and visibility of contribution were considered to be extremely important for incentivising PIC activity and we should improve this across the entire research pathway to reap the rewards.
- There were a number of comments about the change in ability to share recruitment numbers between organisations and that a whole systems approach is needed to move us forward.



*“I am concerned that practices will be fatigued by the constant requests for PIC work. It is low paid and can be time-consuming with no recruitment attributed. They will prioritise recruiting studies”*

*“Reduced incentive/ no recognition for recruitment work to PIC sites leads to reallocation of resources to other work streams. Current change is leading to frank discussion about whether collaboration is of any financial reward/ accrual and recognition reward with recruiting to other sites. When resources and budgets are already limited/ reducing the focus has to shift away from supporting PIC recruitment and focus more on more recognised work streams. As a community Trust that relies on PIC recruiting for much of its recruitment caseload, the reduced support/recognition invariably will reduce our accruals, and therefore the workstream will likely reduce.”*

### 3. Study design

**Recommendation:** Support Sponsors and researchers to design PICs into their recruitment process. Ensure the appropriate organisation is acting as site from the beginning.

- PICs have many benefits but they are not a substitute for poor design. Adding PICs to a poorly recruiting study never really solves the problem if PIC recruitment was not the original intention. Therefore PICs must be designed into the process and not used as a sticking plaster for poor recruitment
- Ensure that studies with an intervention in primary or community care have sites in those organisations and not in acute hospitals with primary care or community Trusts acting as PICs.

### 4. Gatekeeping

**Recommendation:** Explore and improve ways in which to increase the provision of information about research to patients themselves.

- In line with comments in the governance section we received some felt that identifying patients was the wrong approach and that we should shift our thinking to more to enable patients to find research.
- There are initiatives across the country (for example the [‘everyone included scheme’](#), Avon and Wiltshire mental health partnership NHS Trust) that have enabled support teams to help screen and provide project opportunities to patients, removing as much burden from the clinicians as possible and facilitating the sharing of information and patient decision making.

## 5. Opportunities for Embedding/context messaging

**Recommendation:** Ensure the language around incentivising and promoting PICs reflects the supportive message that research improves care. Consider funding streams for non-project specific, research-enabling activities such as PIC work and PPI.

- There is an opportunity here to further embed research engagement in care and we should be careful to ensure our language supports this.
- Make clearer (and fund) those activities around providing opportunity, information, promotion, Patient and Public Involvement (PPI) and communication that are not so much about project delivery but about research facilitation that will help to close the gap between research and care.
- If we can successfully enable research opportunities and information about studies to be made available so that patients and clinicians can access them, then this enabling activity becomes more embedded in care rather than in the research pathway itself. It also moves the governance of the research-**enabling** activity away from 'research governance', whilst at the same time properly funding and recognising all those contributions to making the research happen.
- Funding to support research activities outside of a specific project is very important for research culture and for improving attitudes towards being part of research.

Any comments or feedback on this response can be directed to [info@rdforum.org.uk](mailto:info@rdforum.org.uk)

## Appendix A: Definition of a PIC in IRAS

### Box 1 Guidance in IRAS

<https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#PIC>

#### Participant Identification Centres (PICs)

Participant Identification Centres (PICs) are NHS/HSC organisations that identify potential research participants. They are not research sites and should not be treated in the same way as research sites.

**What is a PIC?** An NHS/HSC organisation is operating as a PIC when it:

- Identifies potential research participants by processing personal data (e.g. through carrying out a search of patient records database to identify individuals that meet a study's eligibility criteria); and
- Is following the sponsor(s) instructions in identifying potential research participants; and
- Directs these potential participants elsewhere without undertaking any further research activity for that study (i.e. the research occurs at another legal entity).

However, an NHS/HSC organisation is not a PIC when it is:

- Within the legal entity where the research that it is identifying potential research participants for it taking place (e.g. the NHS/HSC organisation is a hospital identifying potential participants to be referred to another hospital within the same NHS/HSC Trust or Health Board). In this instance the whole legal entity is treated as an investigator site or participating NHS/HSC organisation; or
  - Responsible for research activities, such as:
    - Any protocol-specified assessment to determine whether the potential participant is eligible for the research study (e.g. a screening blood test or x-ray)
    - The recruitment (informed consent) of participants into the research study
    - The delivery of research procedures as specified in the research protocol.
- Or
- Identifying potential research participants through normal clinical activity (e.g. a routine clinic) and referring these individuals to a research study in order to gain access to clinical intervention(s).
- Or
- Advertising opportunities to participate in a specific study, e.g. via posters in waiting rooms.

**How do I set up NHS/HSC PICs?** It is recommended that research sponsors:

1. Consider the use of PICs at the study design/feasibility stage
2. Approach relevant NHS/HSC organisations to discuss their in-principle support to act as a PIC
3. Ensure appropriate contractual agreements are in place with the NHS/HSC PICs – see [below](#)
4. All activities/ resource requirements proposed for PIC organisations must be detailed

within the IRAS Form. You will need to answer YES to A73 to reveal the secondary PIC questions and include the contact details and activities of PICs associated with research sites (except where the activity is limited to displaying leaflets or posters only). Details of PICs should be entered in Part C of the form.

NHS/HSC PICs are not participating NHS/HSC organisations or research sites and so they cannot be set up through the UK Local Information Pack. PIC activity for:

- *NHS organisations in England and/or Wales* - may only commence once HRA and HCRW Approval has been issued and the instructions regarding the necessity or otherwise of the organisation acting as a PIC and the research site to confirm their capacity and capability to take part has been followed, and there is an appropriate agreement in place with the NHS organisation acting as a PIC.
- *HSC organisations in Northern Ireland* - may only commence once capacity and capability has been confirmed by the research site and there is an appropriate agreement in place with the HSC organisation acting as a PIC.
- *NHS organisations in Scotland* - may only commence once NHS permission is granted by both the research site and the PIC site and there is an appropriate agreement in place with the NHS organisation acting as a PIC.

**What will be reviewed by the PIC?** Organisations that are considering whether to act as an NHS/HSC PIC will primarily rely on the completed study-wide governance review (Scotland / Northern Ireland) and/or HRA and HCRW Approval (England / Wales) being in place. The organisation acting as a PIC will only consider the resource implications for the PIC.

**What contracting arrangements should be put in place with NHS/HSC PICs?** 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 model agreement:

- [model Commercial PIC agreement \(m-C-PICA\)](#)
- [model Non-Commercial PIC agreement \(m-NC-PICA\)](#)

**Appendix B:**

**Survey questions**

**Q1:** From your perspective are there any particular strengths, challenges, opportunities and threats of the CURRENT system of the NHS acting as participation identification centres

**Q2:** From your perspective what mechanisms/models would incentivise & recognise General Practices and NHS Trusts (and other associated organisations eg: Pharmacies/ Dentists) to act as participant identification centres?

**Please consider:**

1. Both financial and non-financial incentives
2. How we could best recognise this activity both nationally and locally

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