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## **Patient and Public Engagement and Involvement Policy Document**

### **1. The NIHR Diagnostic Evidence Co-operative London at Imperial College**

#### **1.1 The National Institute for Health Research (NIHR)**

The National Institute for Health Research (NIHR) funds and co-ordinates research in the English National Health Service (NHS). It is funded by the Department of Health and aims to improve the health and wealth of the nation by supporting health care research. The NIHR provides the support and resources required to carry out health care research including infrastructure, research personnel and equipment costs.

#### **1.2 Introduction to DEC London**

*“Achieving excellence in point of care diagnostics from product design to patient benefits.”*

The NIHR Diagnostic Evidence Co-operative London is based at Imperial College.

Our mission is to establish a benchmark of excellence for supporting the lifecycle of Point-of-Care diagnostics from product design through evaluation, integration into clinical practice and eventual patient benefits.

To achieve this we aim to:

- Build a strong alliance of academia, clinicians, regulatory bodies, patient representatives, designers and industry;
- Conduct world-class research into Point-of-Care diagnostic tests;
- Work in collaboration with the other DEC's and the NHS to efficiently bring Point-of-Care tests into clinical practice.

Imperial College London is focused on science, technology, engineering, medicine and business and is also the only university to have had the application of its work to industry, commerce and healthcare central to its mission since its foundation. Imperial was the first of six Academic Health Science Centres (AHSC) to be established in the UK. The AHSC brings together the research strengths of the College and the resources of the Imperial College Healthcare NHS Trust to create an environment where innovation and discovery can thrive.

#### **1.3 What is a Diagnostic Evidence Co-operative (DEC)?**

The Diagnostic Evidence Co-operative London, based at St Mary's Hospital campus, is one of four national centres of expertise funded by the National Institute of Health Research and is a partnership between Imperial College Healthcare Trust and Imperial College London.

The Diagnostic Evidence Co-operatives (Leeds, London, Newcastle and Oxford) form a network of strategic partners and collaborators that collectively form a pool of expertise and resources for methodology research and evidence generation in medical diagnostics. Each DEC shares in the common goal to catalyse the generation of evidence for in vitro diagnostic tests whilst maintaining its own core focus.

Our focus is Point-of-Care (POC) in-vitro diagnostics (IVD). These are tests that give rapid results that allow prompt clinical decisions to be made. These may be tests carried out in hospitals, GP practices, nursing homes or by patients themselves in their own home. In many clinical areas such as diabetes these tests are already widely used. With advances in modern technology, there has been a rapid increase in the availability of these tests in other disease areas for screening, monitoring and diagnosis. However, their introduction into clinical practice is often delayed by a lack of streamlined methods to generate the evidence to their usefulness and where they may provide the greatest benefit to the NHS and patients.

### **1.4 Who are we?**

The NIHR Diagnostic Evidence Co-operative London brings together an exceptional combination of people who are committed and passionate about bringing new technologies into clinical practice and have an excellent track record in product innovation. We have a core methodology team who provide expertise in approaches to evidence generation including clinical studies, analysis of cost-effectiveness, patient engagement and design requirements. We integrate these skills into our clinical themes that are led by world leaders in their respective fields. Our clinical expertise extends across a wide range of clinical areas that include gut health, primary care, respiratory medicine, metabolic diseases, cardiovascular disease, cancer, women's health and emergency medicine.

### **1.5 How do we generate evidence?**

The required evidence differs with devices, tests and environments, as well as the stage in the product development cycle; therefore we have created a flexible approach for collaborative work and evidence generation.

We are continually developing our approach to diagnostic research in light of the challenges this area of research faces. Our 'toolkit' facilitates the efficient generation of evidence in the accuracy, usability and safety of diagnostic tests together with their impact on patient care and quality of life, their cost effectiveness and the barriers to mainstream implementation.

Our Centre will develop efficient pathways for evidence generation in partnership with industry and other diagnostic test developers. We also support the product design process as it goes through the iterative process of discovery, invention and evaluation.

### **1.6 Our mission**

- i. Map the available levels of evidence for existing POC-IVD and determine knowledge gaps that need evidence generation to facilitate the implementation into clinical practice;

- ii. Generate evidence on clinical validity, utility, care pathway benefits and cost effectiveness of POC-IVD;
- iii. Determine unmet clinical needs for the development of POC-IVD that enables moving care into the community and benefit primary care setting;
- iv. Develop a “diagnostic research toolkit” that includes methods to generate appropriate levels of clinical evidence, evaluate the impact on clinical pathway and project POC-IVD cost-effectiveness using a system-based and user-focused inclusive design approach for reliable rapid assessment of POC-IVD;
- v. Study the design specifications, impact on care pathway and safety requirements for home POC-IVD that are administered by patients and carers where the patient rather than professional becomes the source of medical error in a home environment containing several risk factors;
- vi. Investigate the challenges in scaling-up POC-IVD by involving all potential stakeholders, including patients and the public, in the development, evaluation and modelling of the impact of POC-IVD on care pathways;
- vii. Establish a strong engagement strategy with the IVD industry, clinicians, academics, NHS commissioners, regulatory organisations and patient associations; and
- viii. Develop a strategic national programme for POC-IVD research.

## **2. Patient and Public Involvement and Engagement**

### **2.1 As a research group we understand the value of working with patients and the public in all our research activities.**

The NIHR DEC London will always strive to share our information and in particular our new knowledge and discoveries from our research. This may involve open days, science festivals, media, press releases, and feedback from study participants as well as those involved in research. Information regarding this can be found on our website [www.london.dec.nihr.ac.uk](http://www.london.dec.nihr.ac.uk). With your input, we will further develop a patient space on the website to leave comments and suggestions about our research.

### **2.2 What is Public Involvement?\***

INVOLVE defines public involvement in research as research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them. This includes, for example, working with research funders to prioritise research, offering advice as members of a project steering group, commenting on and developing research materials, undertaking interviews with research participants.

When using the term ‘public’ we include patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services. Whilst all of us are actual, former or indeed potential users of health and social care services, there is an important distinction to be made between the perspectives of the public and the perspectives of people who have a professional role in health and social care services.

### **2.3 The Difference between Public Involvement, and Public Engagement and Participation\***

Researchers and others use different words to describe public involvement, for example words such as engagement and participation. When INVOLVE uses the term ‘public involvement’ we are not referring to researchers raising awareness of research, sharing knowledge or engaging and creating a dialogue with the public. We are also not referring to the recruitment of patients or members of the public as participants in research. However, these different activities – involvement, engagement and participation – are often linked and, although they are distinct, can complement each other. For example, the public can and do play a valuable role in advising on recruitment of patients as participants and on ways of engaging with the public.

INVOLVE uses the following terms to distinguish between the different activities:

***“Involvement – where members of the public are actively involved in research projects and in research organisations”***

Examples of public involvement are:

- as joint grant holders or co-applicants on a research project
- involvement in identifying research priorities
- as members of a project advisory or steering group
- commenting and developing patient information leaflets or other research materials
- undertaking interviews with research participants
- user and/or carer researchers carrying out the research.

***“Participation – where people take part in a research study.”***

Examples of participation are:

- people being recruited to a clinical trial or other research study to take part in the research
- completing a questionnaire or participating in a focus group as part of a research study.

***“Engagement – where information and knowledge about research is provided and disseminated”***

Examples of engagement are:

- science festivals open to the public with debates and discussions on research
- open day at a research centre where members of the public are invited to find out about research
- raising awareness of research through media such as television programmes, newspapers and social media
- dissemination to research participants, colleagues or members of the public on the findings of a study.

\*This text has been adapted from the INVOLVE website. Please visit <http://www.peopleinresearch.org/public-involvement/> for more information.

## 2.4 How are members of the public currently involved and engaged with the NIHR DEC London?

We currently have a patient representative as a member of our Steering Committee. This annual meeting includes all stakeholders in the adoption of diagnostics (commissioners, BIVDA (British In-Vitro Diagnostic Association, National Institute for Health and Care Excellence, Medicines and Healthcare Products Regulation Agency and National Institute for Healthcare Research). This meeting aims to provide an independent review of progress towards our goals and ensure our future strategies are in keeping with the requirements of all parties.

The NIHR DEC London regularly showcases our work at science festivals and open days, such as the BRC Open Day at Imperial, which took place in February 2016. We also raise awareness of our research through press releases in the media.

Patient and public involvement activities are varied depending on the level an individual wishes to contribute. Activities may be related to a specific project, involvement within a particular clinical area or related to the overall ethos of the organisation. Most usually involvement will include attendance at project meetings and the review of documents such as protocols, participant information sheets or grant applications.

The NIHR DEC London proposed a new structure of working with PPI. All lay members (i.e., those carrying out activities in involvement and engagement) will be named **Lay Associates**. There are two types of Lay Associates within the NIHR DEC London; i) Lay Advisors, ii) Project Associates. Lay Advisors will sit on the NIHR DEC London Board of Lay Advisors whilst Project Associates will be recruited to support specific projects carried out by DEC London. All members will be recruited using adverts for Lay Advisors or Lay Associates in INVOLVE's *People in Research* site. Links to this advert will be placed in appropriate resources (i.e. the NIHR DEC London's website, NIHR network resources such as websites and newsletters) to facilitate recruitment.

There are a few types of meetings attended by Lay Associates to be called by the NIHR DEC London. The table below describes the type of meeting, its frequency, attendees and the quorum i.e. the minimum number of members necessary to conduct each meeting.

Meeting type	Frequency	Attendee	Quorum
PPI Meeting	Quarterly	<ul style="list-style-type: none"> <li>• Lay Advisors</li> <li>• Researchers at the NIHR DEC London</li> <li>• Collaborators e.g. industry and NIHR network representatives</li> </ul>	4
Project Meeting	Project-dependent	<ul style="list-style-type: none"> <li>• Project Associates</li> <li>• Researcher(s)</li> </ul>	1

<i>Lab visit</i>	<i>Project-dependent</i>	<ul style="list-style-type: none"> <li>• <i>Project Associates</i></li> <li>• <i>Researcher(s)</i></li> </ul>	1
<i>Review meeting</i>	<i>Annual</i>	<ul style="list-style-type: none"> <li>• <i>Lay Associates</i></li> <li>• <i>Lay members who participate in the NIHR DEC London research</i></li> <li>• <i>Wider public</i></li> <li>• <i>Health care professionals</i></li> <li>• <i>Industry and Academic collaborators/future collaborators</i></li> </ul>	4

- *Lay Advisors*
  - All Lay Advisors are expected to attend a quarterly meeting at St. Mary’s Hospital. Lay Advisors may also attend via Skype/teleconference.
- *Project Associates*
  - There is no set meeting schedule. As each project has specific deadline, meeting will be scheduled according to the project timeline.

**2.5 How do I find out more about involvement, participation and engagement activities in the NIHR DEC London?**

Members of the public can express their interest in joining our PPI activities in several ways:

- By approaching the NIHR DEC London directly, perhaps having attended one of our engagement events after visiting the website [www.london.dec.nihr.ac.uk](http://www.london.dec.nihr.ac.uk).
- Being invited to participate through our clinical themes, perhaps if their clinical management involves the use of point-of-care diagnostics.
- Introductions through other members of our patient and public network.
- By responding to adverts for specific participation opportunities. For example, to take part in an interview study or focus group to inform on how to improve patient experience in a particular clinical area.

We will discuss with new members their areas of interest and the level of involvement they would like to have with the NIHR DEC London. For certain projects, there will be certain criteria for recruitment. For example, personal experiences with a condition. They will then be added to our panel and we will contact them regarding projects that we feel would be of interest based upon this with invitations to participate and project details.

Specific activities that the NIHR DEC London requires members of the public to participate in:

- (i) Interview Participants for Clinical Pathway Mapping and Stakeholder Analysis: The journey of a patient through the NHS, from initial consultation to diagnosis, treatment and recovery, can be mapped. Using Point-of-Care tests may dramatically alter existing care pathways,

depending on when and how the device is used e.g. at the GP practice for referral decisions, within secondary care for treatment decisions, or at the patient’s home for monitoring and surveillance purposes. From the pathway, stakeholders can be identified and an analysis of the social and economic impact of the new technology can be carried out. The attitudes and experiences of patient and public representatives is extremely important to this type of research activity.

- (ii) Participant in a Usability Assessment of a Medical Device or Diagnostic Test: It is highly important that devices and tests performed by patients are easy to use and interpret. If the instructions are hard to understand, or it is difficult to use, this may lead to errors in using the test and interpreting the results, which in turn may lead to a patient safety issue. Therefore, we may ask members of the public and patient representatives to take part in a usability assessment to determine whether a new test has any issues. We can then use this information to inform the manufacturer so that they can improve the design of the test.

## 2.6 What will you get in return?\*

We hope that working with us towards our research aims will be a fun and rewarding process. Members of public involvement groups will also be reimbursed for their time in keeping with NIHR Involve Guidelines and the ‘Rewards, Payment and Recognition for Patients/Members of the Public (PP) Involved in Research’ policy at Imperial College London NIHR BRC.

### Rewards

Rewards will vary depending on the project and level of preparation and responsibility required. Example fees for involvement can be found in the table below.

PPI activity	Type of PPI member	Rate of payment	Total
<b>Recruitment of project-specific PPI member</b> requires review and feedback of recruitment documents: <ol style="list-style-type: none"> <li>1. Plain English summary</li> <li>2. People in Research advert (linked to DEC London site)</li> <li>3. Role description</li> </ol>	Lay Advisors (currently 5)	£30 to review all 3 documents	(£30*no. of board members)  £150
<b>Involvement in research</b> e.g. planning research, developing and reviewing resources/output.	Project Associates (max 2 per project).	£25/hour ???Max 20 hours per project	£500
<b>Review of output</b> (note - though have access to other reports, each member	Lay Advisors (currently 5)	£30 per report	£150

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will have responsibility for only one output)			
<b>Travel and other expenses</b>	Project-Associates (max 2 per project).	£100/work package	£100/work package

It is important to remember that certain reimbursements are currently treated by benefit rules partly or wholly as earnings and can lead to benefits being affected.

All participation is on a voluntary basis and we will endeavour to always be flexible in how patients and public are involved in our research. However, there will be occasions when we will need to enforce deadlines for certain activities for example if a project is working towards a research grant. In some circumstances, specific training will be required for activities; this will be provided by the NIHR-DEC London.

\*Adapted from ‘Rewards, Payment and Recognition for Patients/Members of the Public (PP) Involved in Research’ policy at Imperial College London NIHR BRC.

Continued Professional Development (CPD):

The NIHR DEC London will provide a CPD framework that enables Lay Associates and Researchers at the NIHR DEC London to identify required training and attend courses to meet training requirements. Training will include away-days, conferences and courses. Training will be tailored to new members and those with experience.

Identified training	Target for training	Training provider
Basic computer training	Lay Associates	PSTRC/DEC/BRC/INVOLVE
How to obtain (from collaborators) and provide feedback for research	Lay Associates DEC London researchers	BRC/INVOLVE/PSTRC
Diagnostic development process	Lay Associates DEC London researchers	DEC/NIHR
Translational research in diagnostics (i.e. clinical utility).	Lay Associates DEC London researchers	The NIHR DEC London
Decision Analysis – why important for MedTech and diagnostic research.	Lay Associates DEC London researchers	The NIHR DEC London
Human Factor research in diagnostic development.	Lay Associates	The NIHR DEC London

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	DEC London researchers	
Health Economics and translational research.	Lay Associates DEC London researchers	The NIHR DEC London
Clinical research – how the work of the NIHR DEC London/MIC supports the planning, execution and analysis of clinical studies.	Lay Associates DEC London researchers	The NIHR DEC London

### 3. Resources

We have developed this document using guidance from INVOLVE. [INVOLVE](#) is part of, and funded by, the [National Institute for Health Research](#), to support active public involvement in NHS, public health and social care research.

The following links provide further information on INVOLVE and their guidance documents:

- [What is public involvement in research?](#)
- [Briefing notes for researchers](#)

### 4. Further contacts

For any further details please contact the NIHR DEC London PPI at [ppi.nihrdeclondon@imperial.ac.uk](mailto:ppi.nihrdeclondon@imperial.ac.uk).