



National Institute for
Health Research

Patient Engagement in Clinical Development

INFORMATION SHEET FOR PATIENTS

Version 1.0 – 2 October 2018

Contents page

About the Service	Page 3
How to participate in the Service	Page 4
How will we safeguard your information	Page 4
Travel and accommodation arrangements	Page 5
Expenses and reimbursement	Page 5
Feedback, questions and complaints	Page 6
Terms of Service	Page 6

About the Service

1) What is the Patient Engagement Service?

The CRN launched the Patient Engagement Service in October 2018 with the purpose of introducing and facilitating partnerships between Life Sciences Organisations (such as Pharmaceutical, biotech, medtech companies) and Patient Groups for Studies which are in the early stages of clinical development.

The CRN has launched this Service with the aim of:

- Ensuring better study protocol design which could lead to better study delivery
- Encouraging and building positive relationships between Life Sciences, the NIHR and patients;
- Providing opportunity for study protocols to be reviewed and tested by patients to identify issues before a study is open to recruitment at site level

2) What are the benefits of the Patient Engagement Service?

Being part of clinical research can be a rewarding, interesting and enjoyable experience. By involving Patients at the very early stages of the clinical development, we can ensure patients are involved right the way through the decision making process.

3) How will the CRN introduce and facilitate working with Patient Groups?

The CRN using a network of Organisations will identify, introduce and facilitate the partnership between Life Sciences Organisations and Patient Groups for Study which are in the early stages of clinical development.

4) Do you need to be part of a Patient Group to participate?

For the initial launch, you'll need to be part of a Patient Group to participate.

5) What happens if you not currently part of a Patient Group

If you are not currently part of a Patient Group, then please visit our website "<https://www.nihr.ac.uk/nihr-in-your-area/>" where you'll find information about how to contact your local Patient and Public Involvement and Engagement officer related to your area therapeutic area. Your local PPIE will aim to signpost you to a relevant Patient Group.

Alternatively on our website, there is listing of Patient Groups affiliated as a Stakeholder with the NIHR who are proactively recruiting Patients.

How to participate in the Service

6) How do I participate in the Service?

In brief, our NIHR Patient Group Facilitator will send you information about opportunities to participate in research which usually include attending focus groups and workshops in order to:

- Identify research priorities
- Commenting and developing Patient information leaflets or other research materials
- Review study protocols
- Simulate study delivery approach
- Feeding back on marketing and recruitment materials
- Undertaking interviews with research participants

The information your Patient Group Facilitator will provide you about opportunities to participate in research usually includes:

- Therapeutic / Target Patient Group Area
- A description of the study
- A description of the eligibility criteria
- A description of the 'ask' for Patient involvement

In the event you would like to participate and match the eligibility criteria, we will request for your consent to share your information with the CRN in order to support with making the necessary arrangements. Your Patient Group Facilitator after you have consented to will share the following information with the CRN:

- Your name
- Your address
- Your email address (if available)
- Your telephone number (if available)
- Your bank account details

The CRN will then work with your Patient Group Facilitator in order to make arrangements with Life Science Organisation for your participation (for example, a focus group, an interview or a workshop).

How will we safeguard your information

7) What type of information will be shared with the CRN?

In the event you would like to participate and match the eligibility criteria, your Patient Group Facilitator will request for your consent for the following information to be shared with the CRN:

- Your name
- Your address
- Your email address (if available)
- Your telephone number (if available)
- Your bank account details for receipt of reimbursement of payment

Please note: Your bank account details would be required only to reimburse you for any expenses incurred and a contribution to your involvement in the study. You will not be charged for participating in the Service. You will not be charged for withdrawing at any point.

8) Who at the CRN will be able to see my information and will this be shared?

Only approved members of staff based at the CRN will be able to access your information. This includes the Facilitator, the Head of Business Development and Marketing and the Stakeholder Engagement Manager at the CRN.

Your information will be stored in a private Google Sheet hosted on the [NIHR HUB](#).

The CRN will receive your information from your Patient Group Facilitator in order to process payments as part of the 'facilitation' part of the service, e.g. remuneration for your time spent and reasonable expenses

The CRN will not pass on any of your personal Patient information to Life Sciences Organisation either as part of the 'referral' or 'facilitation' or any other Organisation. The CRN will inform the Life Sciences that a number of Patients have been identified which match the eligibility criteria. Just to confirm, the CRN will not disclosure any of your personal information such as the following with the Life Sciences Organisation:

- Your name
- Your address
- Your email address (if available)
- Your telephone number (if available)
- Your bank account details

Travel and accommodation arrangements

9) How will I arrange travel and accommodation?

The CRN will book travel arrangements and where required accommodation. We'll email you directly with booking reference numbers and confirmations of bookings. If you book a taxi or public transport on the day, then please keep your receipt and we'll reimburse you for the expense.

Expenses and reimbursement

10) What will I be reimbursed for?

The CRN will reimburse you directly for your involvement in any meetings or participating in the study. This will consist of:

- Payment for your time,
- Any other subsistence costs
- Any other expenses incurred

We'll reimburse you directly into the bank account details provided.

Please note: You are required to notify HM Revenue and Customs local office of fees received only if your annual income exceeds your personal income tax allowance at the end of the financial year. You are responsible for calculating whether you need to pay any tax or National Insurance. The [INVOLVE guidance section 4.4](#) provide more details.

11) How much will I be reimbursed?

The CRN will use the [INVOLVE rates](#) as a standard guide to calculate and agree any costs. Payment will be made directly into your bank account after you've participated in an event. Payment usually takes 4 to 6 weeks to be proceeded.

You are not obliged to fulfil any activities and are free to withdraw at any time. You will not be charged or invoiced if you decide to withdraw at any time. If you have incurred any costs and then subsequently decide to withdraw, the CRN will reimburse you for these.

Feedback, questions and complaints

12) How do I withdraw my registration on the Service?

Please notify your Patient Group Facilitator you no longer wish to participate. Your Patient Group Facilitator will inform the CRN.

13) How will question, complaints and problems be managed?

A feedback form can be [found in the link here](#).

14) How will the CRN charge a Life Sciences Organisation for Patient participation

The CRN will charge Life Sciences Organisations for introducing and facilitating partnerships between Life Sciences Organisations (such as Pharmaceutical, biotech, medtech companies) and Patient Groups for Studies which are in the early stages of clinical development.

The CRN will charge Life Sciences Organisations for costs incurred (such as travel, Patient reimbursement costs, consumables, venue hire) and a 20% Service Charge to cover the CRN's overheads in introducing and facilitating partnerships between Life Sciences Organisation and Patient Group.

The 20% Service Charge will cover CRN's overheads for the effort and administration to identify the Patient Group and make all the necessary arrangements for this to occur.

The CRN is a not for profit Organisation hosted by the University of Leeds.

Terms of Service

15) Will any information related to this service be published?

Both the NIHR and the company may disclose or publish the nature and terms of this agreement for any legitimate purpose, including the disclosure of payments to healthcare professionals and organisations. Your personal information will not be shared as part of this.

16) How will personal data be managed?

The CRN shall comply with its obligations under the applicable data protection laws. The CRN will not share the personal data of the patients with the company, only the named individual who is nominated as the lead facilitator at the company. The CRN will have a separate agreement with the Patient Group Facilitator to share the Patient Group Facilitator personal information with the Life Sciences Organisation.

Your personal information is held and used in compliance with the General Data Protection Regulation 2016 (GDPR). The Department of Health and Social Care (DHSC) is the Data Controller under the provisions of the Regulation. Under GDPR, we have a legal duty to protect any information we collect from you and DHSC is committed to protecting privacy and to processing all personal information in a manner that meets the requirements of the Regulation. We will not pass your details to any third party or government department unless you give us your explicit consent to do so



**National Institute for
Health Research**

Leeds Office
21 Queen Street
Leeds
LS1 2TW

London Office
Minerva House
5 Montague Close
London
SE1 9BB