NIHR Patient Engagement in Clinical Development Service: Opportunity to share your opinion on a Participant Information and Consent Form – would this be suitable and of benefit for patients?

The National Institute for Health Research Clinical Research Network is pleased to share an opportunity to offer a remote document review of a Participant Information and Consent Form for a commercially led phase I acute myeloid leukaemia trial.

By reviewing the patient facing document, we'd welcome your thoughts on this. Is this document fit for purpose, does it answer the questions you may have, is it easy to read and if you were approached would you be comfortable to consider participation in this trial?

The intention to ensure that this would bring benefit to potential clinical trial participants and ensure that this is as accessible and as rewarding an experience as possible.

Am I eligible to participate?

The NIHR is looking for up to 8 adult individuals to participate in this opportunity.

We're looking for a diverse group of individuals who may be eligible to contribute to this and likewise we're interested to hear if you have participated in clinical trials previously – if you haven't been in a clinical trial don't worry, this isn't mandatory!

This will be a remote review to look at the document site and we don't anticipate this to take more than a couple of hours to complete.

Due to regulatory reasons you will be unable to participate if you are currently a prescribing clinician – if you're unsure, please get in touch (details below).

What do I have to do?

The NIHR CRN will share with you a Participant Information and Consent Form for participants who would likely be newly diagnosed with acute myeloid leukaemia and may be considering this clinical trial.

We'd like you to review the document and share with us your opinions of this, for example,

- Is the concept and benefit to a potential participant clear?
- Do you feel there is clarity to the information provided?
- Is the document easy to read and does it answer any queries you may have if you were eligible to participate?
- Would you have any concerns?
- Is there anything missing or you'd like to see included?
- Is the layout of the document helpful?

You will be asked to either comment directly on the document and or to provide a separate written statement depending on your preference and return this to us.

How long will it take?

The document is 44 pages in length, including a glossary and consent form.

We do not anticipate this to review to take longer than an hour or two for completion.

Is there a deadline for this?

Ideally, we'd require the completed review by the 19th January.

Who is supporting the activity?

All correspondence will occur with an NIHR Facilitator and we will be managing the delivery of this review.

Will I get paid?

The NIHR, on behalf of the life science company, will reimburse you £50 for your participation.

What's the NIHR Patient Engagement in Clinical Development Service?

The NIHR Patient Engagement in Clinical Development Service is a Service designed to enable the Life Science Industry to engage with individuals such as yourself, to ensure that trials can be co-designed with individuals most likely to be impacted by them, to ensure that the objectives of the trial align with the patient populations and that there as easy to join and complete as they can possibly be.

You can find out more about this Service at the following:

Information Sheet for Patients

Video: What does it mean to participate in the Service?

NIHR Patient Engagement in Clinical Development Service – Home Page

Are these commercial trials? What does this mean? Will they be able to access my information?

These are clinical trials created by and funded by a commercial Sponsor. They will be hoping to deliver these clinical trials with the NHS.

As the information at this stage is sensitive we can't share with you the company name but if you agree to participate we will be able to share this with you.

As the Service is being facilitated by the NIHR we will not be sharing your details with the Sponsor, this will be managed by the NIHR.

You can find additional information about this in the Information Sheet for Patients.

What Information will the NIHR need about me?

To ensue we're engaging with as diverse a demographic of people as possible we'd ask you to share with us your name, age, if you've participated in clinical trials previously or similar initiatives.

What happens afterwards?

Once the insight sessions have been completed the NIHR will arrange with you to reimburse you for your time and efforts including £50 for your participation.

Once your feedback has been digested and potential changes made to the documents, a report will be shared with you highlighting the impact that your shared insights have had.

I'd like to be involved, how do I found out more?

If you'd like to register your interest in participating in this opportunity or simply if you have any questions in relation to this please contact the following:

Gareth Powell

Patient Engagement in Clinical Development Service Project Lead

Gareth.Powell@nihr.ac.uk

07825 121 043