


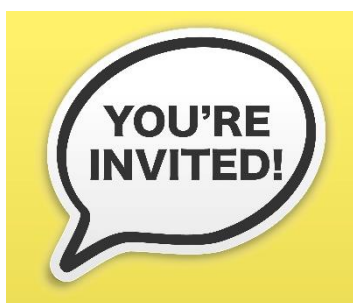
Is a participant information portal (a mini website) helpful to participants that have agreed to take part in a clinical study or trial?

PATIENT INFORMATION LEAFLET

Version 1.0, 18Aug2022

We would like to invite you to take part in a small research study that is for individuals that have agreed to take part in any research study or trial that is managed by the Oxford Clinical Trials Research Unit (OCTRU). ( www.octru.ox.ac.uk)

Invitation to join the PIPS project



Before you decide whether to take part or not, it is important that you understand why we are doing this study and what it will involve.

Please take time to read the following information and talk to others about the study. If anything is unclear, or if you would like more information, please ask a member of the study team who will be happy to answer any questions.

What is the purpose of this study?

Researchers want to find out if there are better ways of keeping connected with individuals that agree to participate in clinical trials/studies. As it is known historically that participants that take part in a trial/study may only be contacted if a visit is upcoming, or if a questionnaire has not been returned and may not be updated about how a research study is going until its very end – if at all. Often trial teams would like to do more but there are limited resources to do more and therefore the PIPS team have received a small amount of money to see if this can be improved in the creation of study/trial specific webpages that are visible only to you and update you on where you are in your study/trial journey.

What exactly is the Participant Information Portals?

Following discussions with some previous and current participants from clinical studies a mini-website (a portal) has been produced that is solely for participants of studies. The 'website' allows participants to log in to find out at a minimum:

- updates about a study,
- where a person is in their study journey,
- dates for any upcoming visits (if applicable)
- what is next for a participant – visit/questionnaire,
- study results (when they are produced).
- contact details for the IMPROVE study team

Who is taking part and why have I been invited to take part?

We are hoping to approach as many individuals as possible that have agreed to take part in an ongoing OCTRU managed trial/study to see if individuals are interested to taking part in a small evaluation of these individually tailored mini websites (portals) and how (if at all they get used) – the system is called PIPS (Participant Information PortalS).

You have been given this leaflet as you are an adult aged 18 years or older who has consented to an OCTRU managed study and therefore are eligible for an account to be created for you within PIPS if you agree to taking part.

Do I have to take part in this study?

You are under no obligation to take part in the PIPS project. Saying yes or no to this study – does not affect your ongoing involvement in the IMPROVE study. Deciding not to take part will not affect the treatment/care you receive from your team and the study that you have already agreed to take part in. It is up to you to decide whether or not to take part in PIPS. Please keep this leaflet and use it as it may help you make your decision. If you decide to take part, you will be asked to sign a PIPS consent form.

Should you decide to take part, you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive as either an inpatient or an outpatient from the NHS.

What will happen if I take part?



If you are happy to take part in this project, a researcher will pass on your email address to the PIPS study team along with your IMPROVE study ID number. The PIPS study team will then email you with a link to this PIS and a link to a PIPS consent form where you will be asked to give your consent to participate in the PIPS project. You can alternatively contact the PIPS team directly – their details are on the last page of this leaflet.

After consenting you will then receive an email – asking you to confirm the name of the study/trial that you have agreed to participate in, your study/trial number (if you know this) and your initials. On checking this information with your study team – you will then be sent a link which will not change for you to access your PIPS website (portal). Here you will find updates about the study, where you are in the study journey, dates for any upcoming visits, what is next for you as a participant and a link to the study results (when they are produced) at a minimum.

The PIPS team would like to know who is approached to consider using PIPS – they will ask the PIPS team to let us know the ethnicity (race), sex (gender), age and the first part of your postcode if any or all of this is collected in the study you are taking part in. Also for those that agree to take part – the PIPS team will need to know your email address, and your first and last name so that the PIPS team can personalise emails to you and the website for you.

There are no additional medical tests that you will have as a result of taking part in PIPS, and more information about the PIPS project can be found at www.pips.octru.ox.ac.uk

Are there any optional parts of the study?

All parts of this study are optional. We are grateful for anyone that agrees to be sent a log in to the study portal. Centrally the PIPS team will then be able to see how many people log into the system, how many times and which pages are looked at and for how long. We would however like to ask you after a while your thoughts on the system and where you think improvements/changes should/could be made. This would come to you as an email – with the questionnaire taking no more than 5 minutes to complete. This will then end any contact from the PIPS research



What are the benefits and risks of taking part in the study?

The PIPS research team hope that the PIPS project may improve participants' experiences of taking part in a research study – there should be no risks from taking part and we hope the portal provides a benefit of keeping you better updated of where a study is at and your study journey.

Who will know that I am taking part – will my details be kept confidential?

The only people who will know that you are taking part in the PIPS study are the members of the PIPS research team and the IMPROVE study team for the main trial you have agreed to be part of. You can tell anyone you would like to that you are taking part.



The only people who will have access to information that identifies you that is passed onto the PIPS research team will be the research team explicitly undertaking the PIPS study. Any analysis that is undertaken will only be on information that does not identify you. Representatives from the sponsor may also need access to monitor the study. Paperwork that is completed by the research team or participants will be uploaded onto an electronic database managed by the University of Oxford.

At the end of the study, all of the data will be de-identified so that no-one can be identified. With your permission, this de-identified data will be shared so that more researchers can gain a deeper understanding about how patients want to be and interact with participant portals. This information will not identify you, and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of trial methodology research, and cannot be used to contact you, nor will it affect your care.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information as part of PIPS, and using it properly. We will be using information from you and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 1 year after the project has finished including copies of your consent form.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at <https://compliance.web.ox.ac.uk/individual-rights>

You can find out more about how we use your information by contacting the PIPS study team on: pips@ndorms.ox.ac.uk

What will happen if I don't want to carry on with the study?

You are free to withdraw from taking part in the study at any time without giving a reason. Please remember, it is your decision to take part. If you agree to take part now, but you change your mind during the study, this will not change the standard of care you receive from the NHS. If you were to decide to stop taking part in the study at any time, any data collected on you would be kept, unless you specify that you want all your data removed. You would not be contacted about the study again or have any further data collected.

What happens at the end of the study?

We will share the results with healthcare researchers and professionals to improve future clinical trials that are being conducted across the UK. Also, we will present them in research reports, at scientific conferences, and publish them in scientific journals. The study results will also be publically available at www.pips.octr.u.ox.ac.uk at the end of the study.

We will not include any data that could identify you in the results. If the funders of this research ask us to make the study data available for other researchers, we will first make your information anonymous (i.e. we will take your name and other identifying details out) so that you cannot be identified.

Who is organising and funding the research?

The University of Oxford is organising this sub study. It is being conducted by a senior researchers at the Oxford Clinical Trials Research Unit (OCTRU). The study has been funded by the NIHR who support a lot of clinical trials that are conducted across the UK.

Who has approved this study?

A panel of independent researchers and patient representatives, as well as a Research Ethics Committee have reviewed and approved this study.

What if I have concerns?

The University of Oxford, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this sub study. If you have any concerns or complaints about any aspect of the study, please contact the PIPS research team using the details below.

You can also contact the University of Oxford Research Governance and Ethics Assurance office on 01865 616480 or by email on ctrq@admin.ox.ac.uk

If you would prefer to speak with someone who is not involved in the study, then please contact the local Patient Advice and Liaison Services (PALS) that were/are mentioned in the study information sheet you received for the other study that you have agreed to take part in.



If you have any questions about the study or would like to agree to take part in the PIPS study, please contact the PIPS team on Email: pips@ndorms.ox.ac.uk Telephone: **07900 580999**

Or tell your research team at site and they will contact the PIPS team on your behalf.

**THANK YOU FOR READING THIS INFORMATION
LEAFLET AND CONSIDERING TAKING PART**