Report on the PIPS study

What did the PIPS study set out to do?
The PIPS study set out to create a patient dashboard so that participants could have access to a study dashboard specifically for themselves to map and track their progress in a clinical study. Such dashboards have become commonplace for central trial teams to manage the numbers recruited into trials, upcoming data points, overdue data points and actions to undertake.

Background
There are over 6,000 studies on the NIHR Clinical Research Network portfolio, comprising of interventional and observational, single and multi-site, commercial and non-commercial studies across a broad range of clinical specialties. The challenges of patient recruitment are well known. Research shows that recruitment to time and target is often missed by many trials [1-3]. However, recruitment into a trial is only the first step. Retention of subjects within trials is equally as critical. Participants need to be retained within trials to ensure data required to answer the research questions is obtained, allowing research questions to be answered and removing the chances of the introduction of bias, reductions in study power, and ultimately affecting the reliability and validity of the results.

As trials become more complex and the modalities of feedback required from participants increases this need will intensify. The traditional method of communication- the Patient Information Sheet is often long, cumbersome and not presented in a subject-oriented manner. It is also often not immediately accessible for patients over the course of a long study.

In 2017, Walters et al found that the median retention rate (proportion of participants with valid primary outcome data at follow-up) was estimated at 89% (IQR 79-97%) in nearly 50% of 151 HTA funded RCTs that [3]. The recently updated Cochrane review on strategies to improve retention in trials found that most of the strategies that were identified were aimed at increasing postal questionnaire returns. Interventions identified in this review included sizes of questionnaires, prompts, reminders and incentives. The review concluded that none of the comparisons were supported by high-certainty evidence. There is some evidence that the use of patient portals (web-based systems that display aggregated information to a patient) has a positive effect on participant retention and engagement, but sufficient data is not currently available to make a meaningful conclusion on their use [4].

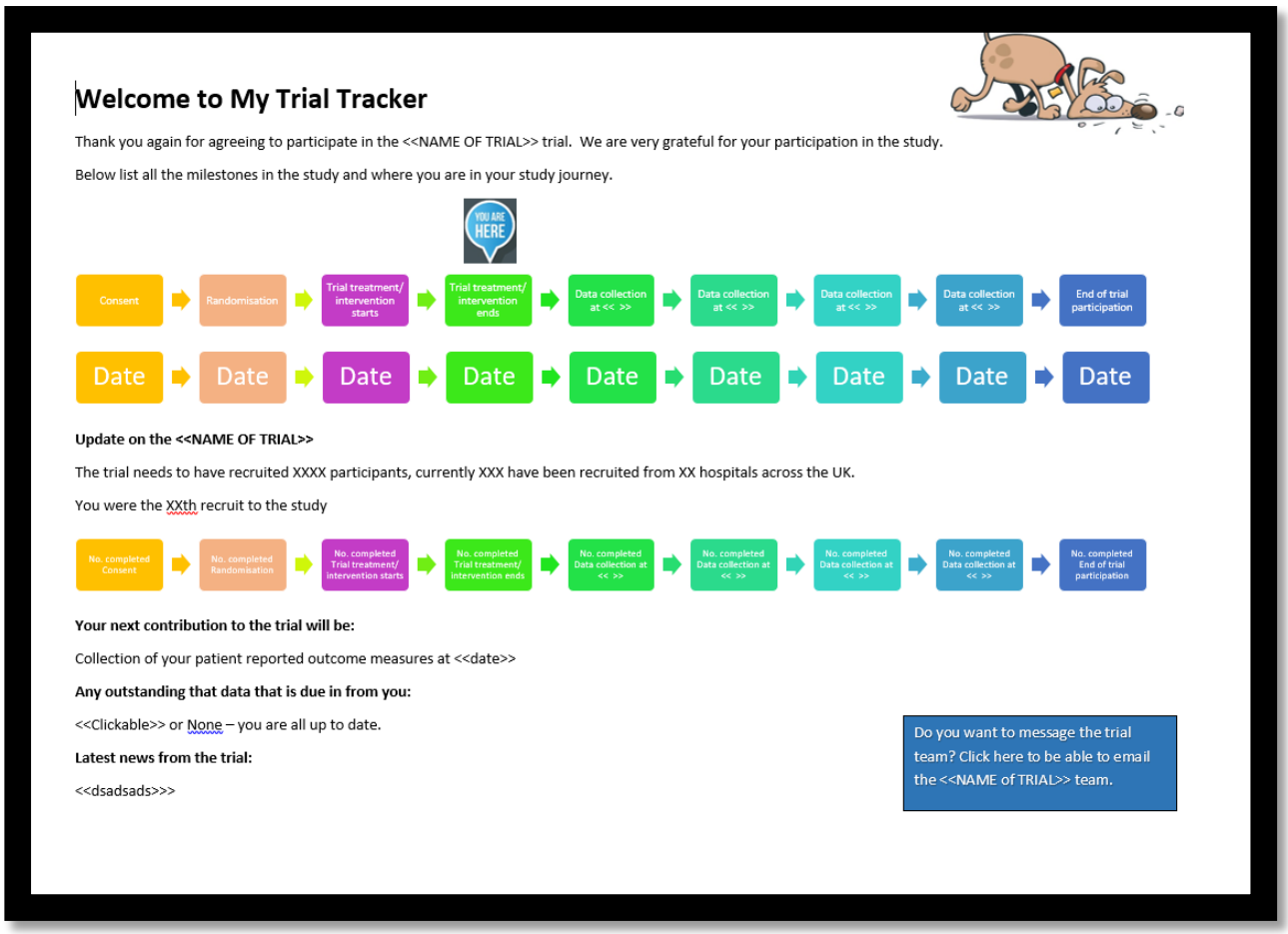
Spurred on by 5 key themes in the Department of Health document *The Future of UK Clinical Research Delivery* [5] and the rapid uptake from clinicians and the public of online working due to the global COVID-19 pandemic – the PIPS initiative aims to align with three of the aims of this paper:
* Streamlines, efficient and innovative research
* Patient-centred research
* Research enabled by data and digital tools.
The PIPS initiative aimed to contribute towards two of the action areas – Building upon digital platforms to deliver clinical research, and strengthening public, patient and service user involvement in research. Alongside this we aim to be compliant with the UK Standards for Public Involvement in Research – working together with trial participants and PPI groups to devise the end output from this project [6].

The PIPS initiative grew out of research published internationally on the issue of dynamic consent. Dynamic consent is an approach to consent that enables people, through an interactive dynamic interface, to make granular decisions about their ongoing participation. The theory behind dynamic consent is that it can enhance decisional autonomy and improve researcher-participant communication [7].

Project Plan

The PIPS initiative aimed to be developed along the same lines as dynamic consent. It aimed to create a portal where a trial participant could understand how they fit into a trial and where they are in their trial journey, which it is aimed would enhance their commitment to a trial and increase retention.

The PIPS initiative aimed to generate a web based system (customisable with trial logo, name, contact details and CRF/questionnaire schedule) that would connect to Data Collection systems such as REDCap (a data collection system rapidly growing traction in the UK academic clinical trials community) via the data collection systems API (application programming interface) (thereby making this application usable by all data collection systems that provide such interfaces). The participant would then be able to see where they are in their trial journey, short updates on the trial including the number recruited to date, where they were in that recruitment number and how the overall trial is doing regarding completion of the trial time points. Explicitly the portal would flag when their next contribution to the trial would be and if there is any outstanding data due from them, and if a clinic appointment was upcoming any restrictions/things they would need to bring to their next appointment such as drug bottles, completed questionnaires, trials diary etc. Below is a conceptual representation of what it was thought the PIPS "My Trial Tracker" page might have looked like.



Once the content of the Tracker has been agreed, we aimed to look to see if we could widen the potential accessibility of the site, specifically looking at how easy adding a multilingual functionality would be.

We also aimed to use a PPI advisory committee but as stated in the NIHR Going the Extra Mile Report – we will democratise PPI [8]. Having just a small number of individuals to make

a massive commitment, can sometimes mean that it is hard to find people who can do what is required and those who often come forward are probably not representative of the wider population.

Project Timetable (12 months)
Month 1 – Utilise the PPI representatives across the OCTRU Portfolio to recruit individuals of varying ages to act as the advisory committee for the PIPS Initiative Alongside this we would use social media to recruit individuals to add their opinions using and poll wider groups on the requirements/functionalities.
Month 2 – Virtual meeting with PPI representatives to introduce the PIPS initiative and to show first mock ups of the system.
Meeting aims – to agree what content would be important to enable the OCTRU team to take this forward.
Months 2&3 - Working mock ups made of the site and links sent out to PPI representatives to experience and feedback on
Month 4 - Further development by OCTRU team based on PPI feedback.
Month 5 - Updated mock ups and request for further feedback from PPI representatives

Month 7 onwards – Roll out of My Trial Tracker onto suitable OCTRU trials. In addition to the My Trials Tracker a pop up would ask those accessing the system – a few questions on how they have found the system and any suggested feature requests/changes.
Month 12 – Write-up the final report to funder and initial publication on the Initiative.

Full testing of the impact of such an initiative would be hard to achieve within a 12 month period that includes its development. However, once the system has been created we would include it on all our new trials to be able to generate metrics to determine the impact of the PIPS initiative on retention rates.
💻 https://pips.octru.ox.ac.uk/

Project Outcomes

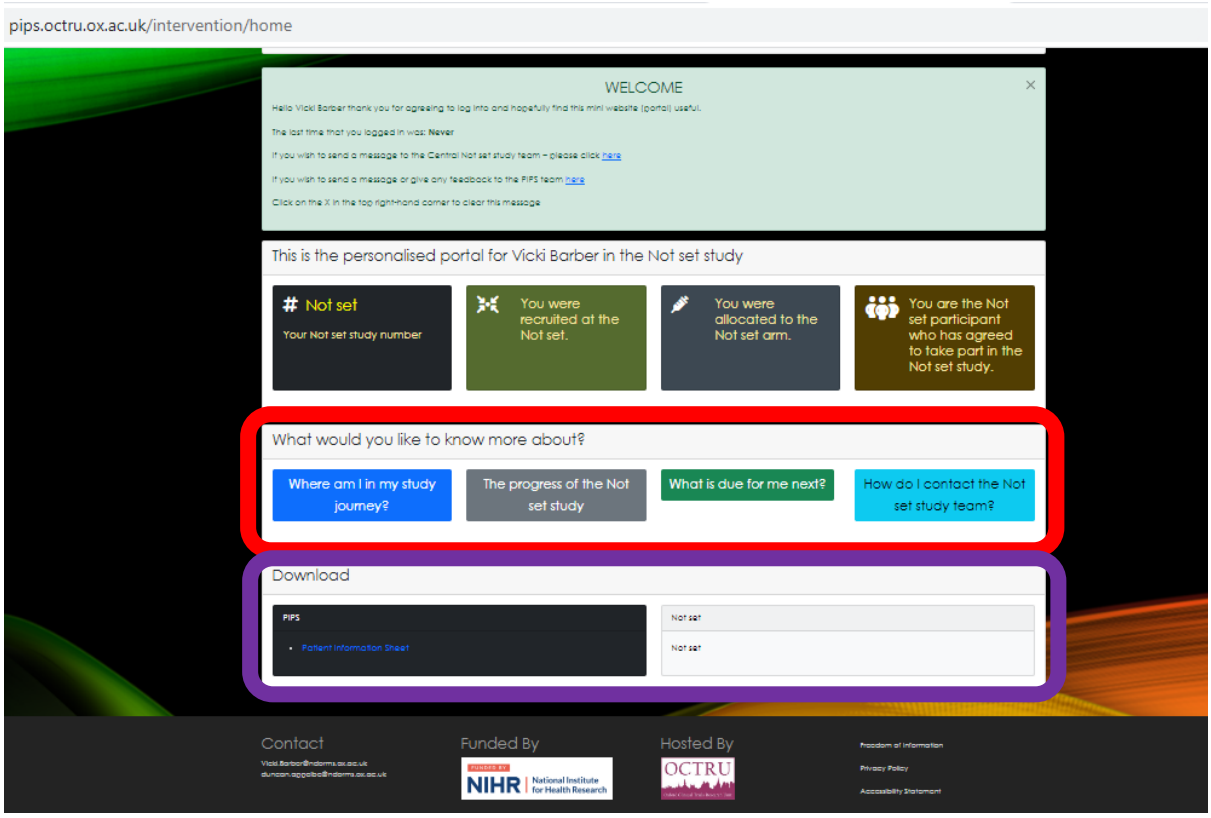
A project website was created for potential participants to learn more about the study.

💻 https://pips.octru.ox.ac.uk/

We then have created a remote electronic consenting system for participants to formally document agreement to take part in PIPS.

On consenting into PIPS – this PIPS system would automatically pull in data from the host trial.

The screen shot below shows an example home page.



The home page identifies the trial they are participating in, and their explicit trial details – including their study number, the hospital they were recruited at, their study arm and what number participant they are to enter the study.

There is then further information displayed for the participant – including being able to send direct messages (emails) to the host study and PIPS team.

The section highlighted Red allows clickable options for participants to:

- know exactly where they are in their study journey,
- what the progress is of the study,
- what is due next,
- contact the host study (a more visual option that that at the top of the home page).

Within our CTU there are multiple senior trial managers and trial managers and the premis of the PIPS initiative was presented along with the participant facing website and functionality. All were keen on the initiative and as many trials suffer with retention thought the system may add value.

Trialling of the System

We attempted to get the PIPS functionality added onto many of the existing trials running through our CTU but we encountered issue with our Sponsor office. We however were only able to include

the PIPS initiative in one of our more recent studies with an External Sponsor – the University of Birmingham.

The trial that the initiative was incorporate into was a COVID trial – the IMPROVE study (ISRCTN14197181), a study that looks at routine drug taking in immunocompromised individuals around the time of COVID vaccination. The IMPROVE study was approved by REC and HRA under IRAS reference: 319057 and PIPS was included from the start of the study. Potential participants for IMPROVE were approached with an IMPROVE Patient Information Sheet, and for those that went on to agree to participate in IMPROVE, were then given a PIPS Patient Information Leaflet. If they then wished to participate in PIPS they were asked to contact a member of the PIPS team to discuss the study and if they were then still willing to join, they were then asked for, and had consent taken electronically.

The IMPROVE study is currently looking to recruit 120 participants from 11 secondary care hospitals from across the UK – recruitment will finish at the end of June when the latest vaccination programme closes.

Each open site was sent 30 PIPS leaflets at site set up alongside the study PISs and asked to hand out to those that agreed to participate in IMPROVE. For those that showed any interest in PIPS the participants were directly to contact the PIPS team directly, or for the research team at site to contact the PIPS team to make contact with the potential participant with the participant's permission.

The table below shows the overview of the PIPS engagement at site.

Site No	Date Open	First screening	Total consented	Number of PIPS leaflets sent to site	Number of PIPS leaflets known to have been handed out at site	Number of recruits to the PIPS study
1	30/09/2022	09/10/2022	30	30	0	
2	07/10/2022	09/10/2022	26	30	16	
3	11/10/2022	17/10/2022	9	30		
4	12/10/2022	19/10/2022	8	30	5	
5	19/10/2022	22/05/2023	1	30		
6	31/10/2022	03/11/2022	8	30	5	
7	07/11/2022	20/03/2023	3	30		
8	22/11/2022	03/04/2023	2	30		
9	11/04/2023	18/04/2023	5	30		
10	27/01/2023	20/03/2023	2	30		
11	28/04/2023	10/05/2023	3	30		

Disappointingly we have had very poor engagement with sites – as you can see from the numbers of PIPS leaflets being distributed. Sites have regularly been reminded by the IMPROVE Trial Management Team of the PIPS initiative with the only thing being asked of them is to hand out the leaflet and then if a patient wants them to flag up their interest to pass their details over to the PIPS team. In the 8 months PIPS has been opened – we have had only 2 individuals show an interest in taking part in the initiative – this is out of at least 26 individuals who have received the PIPS information leaflet. The 2 individuals who showed an interest in the study both contacted the PIPS study team directly – one by emailing and one by phoning the PIPS team.

The two individuals spoke to the same person in the PIPS team and both readily agreed to take part in the initiative. Both consented via the PIPS eConsent portal and had accounts then immediately set up by the PIPS team.

The two individuals were from different sites, and are one male and one female.

The first individual consented to take part on 4th November 2022 but since creating their PIPS log in – they have not logged into the system once.

The second individual consented to take part on 24th May 2023 and logged into the site the next day.

The plan in PIPS was to contact individuals, 3 months after agreeing to take part with any comments/feedback on the system, when their host study journey has completed. With the first individual not having accessed the system – we have not contacted them for feedback, and as the second recruit has only just joined the system – we are yet to allow them time to access the system over the course of the IMPROVE study – which follows up individuals over a course of 12 weeks.

What's next for PIPS?

We still believe that the PIPS project has far more potential but this has still not been realised. Our CTU has quite a few new studies due to open quarter 3 and quarter 4 of 2023 and we are aiming to work with the Sponsor to get PIPS agreed and added to those studies.

The code written for PIPS will be made available for other units to utilise that could be add ons for those also running REDCap. We would aim to have that package ready before the end of the year.

PIPS INFORMATION LEAFLET

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 **💻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 team.

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

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 publicly available at pips.octru.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 ctrg@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: **01865 223469**
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

PIPS CONSENT FORM

PARTICIPANT CONSENT FORM

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

If you agree, please select Yes

	YES	NO
1. I confirm that I have read the information sheet dated 15Sep2022 (version 2.0) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.		
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.		
3. I understand that data collected during the study may be looked at by individuals from University of Oxford where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.		
4. I agree to take part in the PIPS study.		

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

References

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