Participant Information Sheet (PIS) - Guidelines

The Participant Information Sheet - or "PIS" - is a vital document for any human participant research study. Think of it as a pamphlet, flyer or information sheet which helps someone understand what they might be getting into from the outset before they think about providing consent and signing up.

💡***You are welcome to use your own PIS forms, but for a simple and streamlined submission, we recommend you follow this form as a guideline when creating your own PIS***.

💡***There is a template which complements this form which can be found here.***

The sections below indicate what you need to provide in a typical PIS. We've included tips for you to better understand what the committee's expectations might be.

⚠️ It's important to remember that the committee will need to see all of your submission forms ***as is*** – whether this is a .docx, .pdf, or a screenshot – of how it will appear to a potential participant in a document, on a web browser or app. In this way, the documents you provide to the Ethiclear committee as part of your submission will be the ***same ones*** you will show the participants (including any dates, text, images, version numbers, logos, styling, fonts etc.).

✅ Actions / Checklist

👉 Create your PIS (You can begin by using **this template** if you want to).

👉 Use the *guidelines* below to populate your form (or web form or app if the PIS will be digitally distributed to participants).

👉 Save it, and add it to your application with all other relevant files with your application here: https://www.ethiclear.com/new-application. Accompanying documents will include an Informed Consent Form (ICF), Study Protocol and other files, such as CVs of key personnel and any recruitment information (e.g. flyers, email invitations etc.).

💡 **Don't forget, the PIS you submit should be "as is", and exactly what the prospective participants will see.**

PIS Content Guidelines

💡*Remember, you can access a template containing these fields here.*

Document date	Document version number
💬 **Tip**: Date format DD/MM/YYYY	💬 **Tip**: For version tracking throughout the review process.

Study title (≤20 words)

💬 **Tip**: Something short that is easily understandable by anyone who might want to take part.
⚠️ **This should be identical to the title in your Study Protocol**

Welcome the participant to the study (≤75 words)

💬 **Tip**: A brief statement welcoming/inviting the potential participant to the study. You should inform them that they need to read the sections of the document carefully which explains what the study is about, why it's being undertaken and what it will involve.

What is the purpose of this study? (≤200 words)

💬 **Tip**: Insert some basic background information here on the study. What is it about? What are the aims? Will any samples need to be provided? Why is it of interest and what does it hope to achieve?

Who can take part and why have I been invited to take part? (≤200 words)

💬 **Tip**: Explain briefly here any inclusion or exclusion criteria for the study. Is it for females only? For certain age groups? For shift workers? For dog walkers? For council staff? Explain why the participant is appropriate for the study and why they are seeing this

document.

Do I have to take part? (≤200 words)

💬 **Tip**: Explain that taking part is entirely voluntary. If they wish to take part, they will need to provide consent in a separate consent form. No reason needs to be provided if they don't wish to take part. At any point before or during the study they can also withdraw without needing to provide a reason.

What does taking part involve? (≤200 words)

💬 **Tip**: Describe from the participants perspective what taking part involves. Over what timeframe will it take place? When will it start? What things will be asked of them? Interviews? Biological samples? App installations? Off-site or remote activities? Site visits?

Will I be paid for taking part? (≤200 words)

💬 **Tip**: A quick 'Yes' or 'No' for clarity, followed by any additional information. Are they being reimbursed for their time? How much? What format? Vouchers, cash or bank transfer? If the latter, how are these gifted? Any remuneration should be minimal so the participant doesn't feel unduly coerced into taking part for significant personal or financial gain.

What are the possible benefits of taking part? (≤200 words)

💬 **Tip**: Might the participant expect some reasonable benefit from taking part? Do not exaggerate or guarantee the likelihood of any potential benefit/s. If there are none, please state this, and feel free to describe how their contribution might benefit the outcome of the study, the research team and potentially any work thereafter with any specific context.

What are the possible risks of taking part? (≤200 words)

💬 **Tip**: Be very transparent here about all potential risks. This could include any foreseeable discomfort or risks to health before, during or after the study. Also outline the likelihood of such risks becoming real during their participation. Describe all separate risk areas. For example, direct risks to physical or mental health, to data, to confidentiality and more. For each risk, outline any strategies to mitigate such risks to the participant.

Will I need to provide any personal data and how is it handled? (≤350 words)

💬 **Tip**: Describe all data items that will need to be collected. For example, name, address, date of birth, email address etc. How and where will they provide this? On paper, digitally, through an app or third party company/vendor? In line with the General Data Protection Regulation (GDPR), the study team must aim to minimise the data they collect – only obtaining data within the scope of the project.

What happens to my personal data? (≤350 words)

💬 **Tip**:
GDPR: GDPR applies when any data relates to an identifiable living person who can directly or indirectly be identified in any way as a result of data collected by the organiser, study team or sponsor in the study. In the UK and EU, the study team must be GDPR compliant and make this known. The participant always has the right to know what data is stored about them and how. They can also request copies or updates of inaccurate information about them which is stored. If personal data is collected, describe any ways in which you will anonymise/pseudo-anonymise or code participant data to mitigate risks of data exposure. Who will be the data controller? And the data processor? Who is the dedicated Data Protection Officer (DPO) and how can they be contacted? Mention that the participant can contact the Information Commissioner's Office (ICO) should they have any concerns about how their data is being handled.
Collaboration: Will the work be a collaboration between multiple entities? Will personal data be shared? How? Will these entities also be data controllers or processors in any way? - make this clear. Will the data be transferred to people or entities outside of the European Economic Area? What safeguards might be in place for the transfer of such data?
Data processing period: Detail the period you will be processing participant data over. Explain that the informed consent forms (ICFs) you will collect (with personally identifiable information) should be retained after the study for a period of time reflective of the risk level of the study. For example, for 3 years after study completion in case of internal or external audits by potential regulators.
Study withdrawal: Should the participant decide to exit the study at any point, what might happen to their data at that point? What if it has already been anonymised? Or summarised and communicated in some way (scientific publication, presentation, social media). Would it be possible to de-anonymise this data? Explain what might happen in such situation/s should they be relevant.

What happens with my data at the end of the study? (≤350 words)

💬 **Tip**: Explain how the data might be collected and compiled throughout and after the study completes. Will it be made public? Will the data be re-used in any way in the future for future research?

What happens with the results at the end of the study? (≤350 words)

💬 **Tip**: What is the end goal of this data? To anonymise, summarise and analyse it? Will it be shared on social media in some way? Through presentations, conferences or publications? For internal or external stakeholders?

What if there is a problem? (≤200 words)

💬 **Tip**: Make it clear that any problems that come up should be taken up with the lead of the study. This person is referred to as the Chief Investigator (CI) who assumes overall responsibility for the study and this person will be named in your **Study Protocol** which you will also submit accompanying this document. Concerns can relate to data handling, health concerns or anything else.

Who is organising this work and funding it? (≤200 words)

💬 **Tip**: Give a brief overview of the organisation who is funding the study. If relevant, mention the team or department. Finally, mention by name once again the Chief Investigator (CI) for this study.

Who can I contact? (≤100 words)

💬 **Tip**: The Chief Investigator (CI) will be the main point of contact for anyone in the study. Explain who they are, what their name and job role is and provide an email address and phone number if they have one.

“*Thank you for your consideration...*” (**≤100 words**)

💬 **Tip**: A short sentence or two thanking the prospective participant for reading the document and explain to them what the next steps are. For example, if they decide to take part, they can provide consent with the accompanying informed consent form (ICF). The study team can then follow-up with how to proceed. These more technical levels of detail will be covered in your accompanying **Study Protocol**.

If you have any questions, feedback or comments about this form, get in touch with the Ethiclear team at hello@ethiclear.com