Patient Information Sheet and Consent Form Guidance

Accessing Health Research Authority (HRA) Templates and Guidance:

- Participant Information Quality Standards - Health Research Authority (hra.nhs.uk)
- Participant Information Design and Review Principles - Health Research Authority (hra.nhs.uk)
- HRA Patient Information Sheets (PIS) & Informed Consent Forms (ICF) template can be accessed via: https://www.hra-decisiontools.org.uk/consent/examples.html
- HRA PIS & ICF guidance can be accessed via: https://www.hra-decisiontools.org.uk/consent/content-sheet-invite.html

Logos: Ensure logos are positioned clearly and consistently across all documents**.**
Queen Mary University of London (Queen Mary) Sponsorship: Include both Queen Mary and Barts Health NHS Trust (Barts Health) logos (if Barts Health is also a study site).
Barts Health Sponsorship: Include only the Barts Health logo.

Study Information:
Ensure you add the full study title, IRAS number, Chief Investigator (CI) information, and sponsor information.

PIS - Clarity and Accessibility:

1. **Write in a patient-friendly (plain English) format** (ensure to use British English, not American English) and consult a patient and public involvement group to ensure it is appropriate for the intended audience. Guidance for writing plan language summaries can be accessed via https://www.nihr.ac.uk/documents/plain-english-summaries/27363
2. **Include a brief summary at the beginning of the document**. This summary should cover the whole project from start to finish in a concise format.
3. **Write in first person, using informal, welcoming language**. For example 'we would like you to join our research project.'
4. **Start the text under the heading "Do I have to take part" with the word "No"**.
5. **Where approximately "XX ml" of blood is mentioned, add in brackets the volume in a more relatable unit, e.g. "X teaspoons",** to quantify the volume using lay language (if applicable). Please also explain radiation risk in plain language (if applicable).
6. **Explain any abbreviations at the beginning of the PIS** or the first time they are used and avoid technical or research jargon.
7. **Ensure all the consent form clauses are covered in the PIS** and there is no contradiction between PIS and consent form.
8. **Inform patients they have the choice to receive the end of study results** if they wish and ask how patient would like to receive these.
9. **Clearly indicate if the study is being conducted to fulfil an educational qualification**.
10. **Include information on the frequency of assessments/ activities undertaken as part of the protocol** and where applicable the time commitment for these (e.g. for questionnaires, how long on average these would take to complete). If there is some flexibility for appointments or participation timelines, please include this wording.

Please note this document has undergone review by a PPIE focus group and been updated according to their feedback.

11. **Consider adding a colour diagram/flowchart** to help patients understand the steps. Include timelines/ milestones for greater clarity where possible and ensure any labelling/ language is consistent with the rest of the document.
12. **Clarify: the known and potential risks and benefits to participants;** how high the risk is compared to normal standard practice; considerations relating to pregnancy, breast-feeding, and contraception (consult a pharmacist, use the SmPC and/or MHRA guidance). Include possibility of partner pregnancy where applicable.
13. **If your research project involves sensitive topics,** please provide information on available support and detail the process for handling participant distress.
14. **Include whether participants GP will be informed,** matching what is stated in the IRAS form and the consent form (if applicable).
15. **Consider if alternative formats might be appropriate** (e.g., large print, audio versions, or translations) to ensure inclusivity as per the Participant Information Design and Review Principles linked at the top of this document.
16. **Specify that participants should be given adequate time to decide whether to participate** and encouraged to discuss with family or friends if needed.
17. **Include guidance on whether incidental findings (e.g., health issues discovered during the study) will be communicated to participants**, and if so, how.
18. **Once the document is drafted, please consider:**
    a. Re-reading the entire document, with your participant group in mind. The whole document should read like a dialogue as opposed to instructions.
    b. Putting it through a readability index or similar tool to check how easy the document is to understand. Large chunks of text or long sentences may be overwhelming for the reader. Readability and editing tools include:
       - Microsoft Word Editor
       - Grammarly
       - Hemingway Editor App
       - The Writer readability checker

PIS - Use of Data, Samples and Devices:

1. **Explain what happens to patient data/samples if they withdraw from the study.** This should match the information in the IRAS form. Consider adding what will happen if a patient loses capacity during the study (if applicable).
2. **Clarify that any standard of care bloods/scans/photographs/surgery etc. would happen regardless of participation in the research**.
3. **Detail the use of internal and external laboratories in the PIS**, so patients know where their samples will be stored/ sent and what will happen to the samples/data once analysed by external labs. Similarly, if patient data is shared outside the sponsor, detail who it is shared with, in what format and what happens once data is analysed.
4. **Confirm what will happen to data/samples once the study has ended.** If samples need to be stored, please make sure they will be stored under a Human Tissue Authority license and mention this in the PIS.
5. **Clarify if any voluntary tests/scans/data are required from patients** and ensure it is clear these are voluntary.
6. **Specify if samples and tissues are used solely for the study purpose, for future studies, or both.** Clearly separate the use within this study from the use for future studies to avoid confusion (if applicable).
7. **Mention the actual device/s in the PIS if using any devices.**

8. **Clarify explicitly that participation in future research or secondary use of data is optional** and can be declined without affecting the current study.

PIS - Legal and Procedural Information:

1. **Provide further details in the PIS regarding the insurance/indemnity provisions for the study.** Example text is available on the HRA website here: (see section "What if something goes wrong?") https://www.hra-decisiontools.org.uk/consent/content-sheet-support.html
2. **Consider adding wording advising participants to check whether study participation will impact on any insurance they hold**.
3. **Add information regarding complaints** and the local Patient Advice and Liaison Service (PALS) procedure.
4. **Include the exact HRA General Data Protection Regulations wording via** Transparency wording for all sponsors - Health Research Authority. Add the data protection officer (DPO) details for Queen Mary or Barts Health, depending on who the study sponsor is.
   Where Barts Health is sponsor: DPO for Barts Health: 020 7480 4892 DPO.bartshealth@nhs.net
   Where Queen Mary is Sponsor: DPO for Queen MaryL: data-protection@qmul.ac.uk
5. **Leave space in the PIS for detail on which Research Ethics Council has reviewed/approved this study**, to be filled in once regulatory approvals are received.

Ensure your consent form includes:

1. A blank space for patients/researchers to manually enter the PIS version and date themselves. This should always match the PIS in current use.
2. To ensure on top of the boxes on the right-hand side, it states "to initial the boxes".
3. Information stating that one copy of the ICF is for the participant, one copy for the investigator file and one copy is for the medical records at the end of the form.
4. A point stating who can access medical records/data of patients in the research, such as the Sponsor or regulatory authorities.
5. A point stating should a patient withdraw, their medical care will not change as a result.
6. An OPTIONAL point for participants to agree to receive updates regarding the study outcome and to retain their contact details for this purpose.
7. An OPTIONAL point for patients to consent to be contacted for participating in future research.

Include each point separately in your consent form if your research involves (refer to HRA template):

1. Any samples/scans/photographs/recorded interviews.
2. The use of external labs (specify their name or location).
3. Notification of their participation with GPs.
4. Data is to be shared outside of sponsor (clarify if this will be fully anonymised, pseudonymised or identifiable).
5. Voluntary follow ups/tests/scans/data (Include a yes/no checkbox to indicate this optional participation).
6. Any sub-studies (Include a yes/no checkbox to indicate this optional participation).

Others:

Some translation services previously used for sponsored studies include:

- The Language shop https://languageshop.org/
- Global Voice https://www.globalvoices.com/ should you wish to get a quote from them for your project