**Guidance for the Content of a Participant Information Sheet for UHBW sponsored studies**

**Introduction**

The Participant Information Sheet (PIS) must ensure that all those who are invited to take part in a research study have been adequately informed prior to consent. In most circumstances it should be used to support conversations with potential participants, rather than being the sole source of information being made available to them. The information provided in this document is based on the HRA guidance <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/>. Please note, this is guidance only, as not all research studies are the same it is important to vary information accordingly. The detail will need to be proportionate to the type and complexity of study, risk/benefit profiles and burden for participants. Always ensure lay language is used and transparency of what you plan to do in the study is key.

Please read this in conjunction with *GD\_36 Guidance notes for the content of an Informed Consent Form* available on the R&Dwebsite: <http://www.uhbristol.nhs.uk/research-innovation/for-researchers/templates-and-sops/templates-and-guidance/>

The guidance provided in this document applies to studies involving adults with capacity in the non-emergency setting. There are further legal and ethical considerations that you need to make for studies involving adults not able to consent for themselves, Children and Young people and/or Emergency research. You can find additional guidance relating to this, including what information should be provided in the PIS, on the HRA and Medical Research Council online tool <http://www.hra-decisiontools.org.uk/consent/index.html>

**Content of Participant Information Sheet**

The content of your Participant Information Sheet (PIS) should describe clearly what a potential participant should expect if they agreed to take part in your study. It should provide sufficient information for the participant to make an informed decision.

We would suggest that you consider covering the following areas in your PIS. These areas are designed to act as a framework, remember one size doesn’t fit all. Ensure layout is easy to follow and content is easy to understand.

**Title**

Document should be headed: '**Patient information sheet**', '**Participant information sheet**' or '**Information about the research**'.

A consistent study title should appear on all the study documents which is understandable to the intended audience (i.e a short study title which explains the study in simple English)

**Study contact details and organisation logo**

At the top of your Information Sheet you will need to include the organisation logo (of the site delivering the study/research team running the study) and contact details of the local research team.

**Invitation and summary**

**Invitation**

You should make it clear that you are inviting potential participants to consider taking part in your research and that participation is entirely voluntary. You should explain briefly how potential participants have been identified and why they have been selected.

See the HRA online tool for example text <http://www.hra-decisiontools.org.uk/consent/content-sheet-invite.html#two>

**Summary**

You should provide a short summary of the proposed research, which covers the following:

**Why?**

• What research question is being addressed?

• How is it of relevance and importance to participants / patients and public?

**What?**

• Broadly what areas (disease, therapy or service) are being studied?

• What drug, device or procedure is being tested?

• What will the participant have to do?

• What will it mean to participants to take part?

**Who?**

• Who would be eligible?

**Where?**

• The sites where the study will be conducted

• How, when?

• How long will the study last; when will it start and end?

Do not to go into too much detail but try to ensure that potential participants can get a clear but concise picture of the research you are asking them to take part in.

**What’s involved?**

This section should introduce more detailed information that will allow potential participants to make a decision: to agree to take part in your research or to decline.

It should provide clear information on the essential elements of the study, such as:

* The condition or treatment under study;
* For studies involving therapeutic interventions, clarity on which elements of your study are research and which constitute standard care;
* Alternatives to participation (particularly important in therapeutic trials involving patients);
* What will happen to participants during and after the research study including continuation of any study medication as applicable;
* The potential benefits and risks / inconveniences or restrictions they might expect;
* Any treatment(s) that may be withheld;
* The participant's responsibilities.
* When and how it is anticipated that participants will find out the results of the study they are taking part in.
* When and how it is planned to reveal to participants which arm of a study they have been on (as applicable).

The information that you provide will be dependent on the specific type of research study and/or the specific types of people you are recruiting.

The use of tables or flow diagrams can help provide clarity when describing a complex series of interventions.

The following headings are common areas that need specific thought when preparing your Participant Information Sheet; not all of this guidance will be appropriate for all studies. Full guidance of what you should cover under each heading can be found on the HRA and Medical Research Council (MRC) online tool: <http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html>

**What are the possible benefits of taking part?**

**What are the possible disadvantages and risks of taking part?**

**For some specific types of study, you may also need to cover the following:**

* [Pregnancy and breast-feeding](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#two)
* [Young people and pregnancy](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#three)
* [Therapeutic research - clinical alternatives](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#four)
* [Pragmatic trials](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#fourb)
* [Side effects of treatments / therapies in trials](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#five)
* [Randomisation and blinding](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#six)
* [Screening and exclusion](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#seven)
* [Involvement of participant’s GP](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#sevenb)
* [Therapeutic studies - what happens when the research study stops?](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#seventeen)
* [Tissue samples](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#eight)
* [Research databases and tissue banks](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#ten)
* [Expenses and payments](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#eleven)
* [Discovering health related findings](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#twelve)
* [Genetic research](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#thirteen)
* [Impact on insurance](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#fourteen)
* [Radiation: Ionising Radiation (Medical Exposure) Regulations (IRMER)](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#fifteen)
* [Accessing ONS, NRS and other registry data](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#sixteen)
* [Generic consent](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#nineteen)

Further details of these and what to include in you PIS can be found on the HRA and Medical Research Council (MRC) online tool: <http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html>

**Supporting information**

The first part of your Participant Information Sheet (PIS) as detailed above provides potential participants with background to the study, overview of what’s involved and potential risks and benefits.

In supporting information it is recommended to include further information in more detail so that interested potential participants can obtain a wider understanding of some of the more detailed implications before making a decision. Remember to keep the language suitable to your audience.

**What if something goes wrong?**

The Participant Information Sheet (PIS) should describe how any complaints will be handled and what compensation may be available in the event of anyone being harmed.

**Complaints** – Contact details of where a complaint can be made should be given to potential participants.

* The first point of contact would be a member of the local study team,
* You should also provide a contact independent of the research team for more formal complaints.

An example of wording that could be used is as follows:

*If you have a concern about any aspect of this study, you should ask to speak to a member of the local study team who will do their best to answer your questions [contact email and telephone number]. If you remain unhappy and wish to complain formally, you can do this by contacting [insert details of the participating sites Patient Advice and Liaison Service (PALS)].*

**Harm** – You should provide potential participants with details of what redress and/or compensation should be available to them in the event that they are harmed as a consequence of taking part in your research.

The following standard wording should be used:

*This is an NHS-sponsored research study. If there is negligent harm during the clinical trial when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.*

[**What will happen if I don't want to carry on with the study?**](http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html#two)

Potential participants must be told that the decision to take part in your research is entirely voluntary, and that they can change their minds at a later stage. Potential participants will need to be assured that any such decision they may make to withdraw (or to decline the invitation to be involved in the first place) will not affect the care they receive from any

relevant service (e.g. for patients, from the NHS).

You should inform the participant what will happen to any data and samples (as applicable) when they withdraw from the study and whether they are able to request what happens to data/samples already collected and, where applicable, continued collection of their routine data. You should make it clear at the outset what they should expect if they were to withdraw their consent. Further details of what may need to be addressed can be found on the HRA and MRC online tool: <http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html#two>

[**Will my information be kept confidential?**](http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html#three)

You should tell potential participants how their confidentiality will be safeguarded during and after the study and how your procedures for handling, processing, storing and destroying their data are compliant with all applicable legislation including General Data Protection Regulation (GDPR) and the Data Protection Act.

The potential participant should be told:

* details of what personal identifiable information (for example initials/ NHS number/ name/ contact details) the local research team will be collecting and sharing with the central research team (if applicable); how this information will be used and who will have access to it. This should be in the form of a bullet list **[N.B. If you are also collecting special category data other than data related to health, such as ethnicity, genetic or sexual orientation this also needs to be clearly stated in the PIS. Further details on special category data can be found on the ICO website:** [**https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/special-category-data/**](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/special-category-data/)**]**
* Details of any intended data sharing during the study and how confidentiality will be maintained. Please also include details of whether data or samples will be shared outside of the UK.
* How the data will be archived or whether you intend to keep the data you collect for use beyond a specific research study/trial
* Is it possible that you might share anonymous information with others in the future?
* What arrangements are you going to make to ensure the information is kept secure? For example, will you keep direct identifiers, and separate them from health information? Will you destroy all direct identifiers and store only fully anonymised data in the longer term? Will you be storing link keys to identifiable information and what secure storage arrangements will be in place? (e.g. who has access/how is it restricted/who controls the linkage etc)
* Who will have responsibility of acting as **the Data Controller**? (University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) is the Data Controller for UHBW sponsored studies. For some studies conducted and managed by an external organisation (for example Bristol Trials Unit, University of Bristol), UHBW may be a joint data controller along with the external organisation.)
* Do you intend to ask for further ethics committee approval for each re-use of the data, or not?

Do you envisage sharing any of the information with others in the future? If so, how are you going to ensure participants' confidentiality is maintained?

The HRA has provided template transparency wording for sponsors to use in documents (including the PIS) provided to participants: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-for-all-sponsors/> For UHBW sponsored studies it is a requirement that the HRA provided standard wording is used.

**What will happen to my samples?**

You should inform participants about what samples will be taken and the plans for processing (including who your samples will be shared with and whether they are based in or outside of the UK). Ensure you are explicit about any DNA/RNA analysis and whether providing samples is a mandatory part of study participation or whether it is optional and what the plans are after the study has completed (e.g. storage in a tissue bank for future research, destruction etc). Make sure it is clear whether samples will be identifiable and how confidentiality will be maintained.

**What will happen to the results of this study?**

You should inform potential participants of your intentions with respect to publishing research findings, as well as how you intend to feedback findings to participants themselves. (This might include how you are going to handle individual health related findings, as well as overall outcomes of the study).

### [Who is organising and funding this study?](http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html#five)

You should tell potential participants that UHBW are the sponsor of your research and which funder/s is/are funding your research (e.g. medical research charity, pharmaceutical company, academic institution, NHS organisation etc). You should also inform them if the study is being conducted in collaboration with researchers from an external organisation, for example University of Bristol.

[**Who has reviewed this study?**](http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html#six)

You should include some form of assurance to potential participants that your study has been reviewed and approved by a research ethics committee.

The following is suggested wording:

*All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Research Ethics Committee*.

[**Further information and contact details**](http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html#seven)

You should provide potential participants with places where they can access more information, for example:

* **General information about research**
* **Specific information about this research study**: usually this would be provided by someone who is part of the research team; this could be you or some other member of your team. Potential participants should be given a name and contact details. For some studies, you may need to provide an emergency contact number that is manned 'out-of-hours'.

If you are conducting a study over a number of different sites, you should make sure that all of the contacts you provide are appropriate for each of the sites involved.

For some specific types of study, you may also need to cover the following:

**What if relevant new information becomes available?**

**Informing General Practitioner / other healthcare practitioner**

Further guidance on what to include can be found on the HRA and MRC online tool: <http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html>

**Version control**

Your Participant Information Sheet should be dated, given a version number (referring to a protocol and state the IRAS ID. This can be done in a header or footer (or equivalent if using electronic formats).

Date, version numbers and IRAS ID will not only help you and your research team to manage consent materials during the on-going study (including handling any subsequent amendment), but it will also be used by the research ethics committee, regulators or research governance offices when referring to 'approved' documents.