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**PARTICIPANT INFORMATION SHEET AND CONSENT FORM DEVELOPMENT**

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| Reference Number | MMU-RKE SOP 004 |
| Version | Version 2, 15 October 2020 |
| Effective Date | 15th October 2020 |
| Review Date | 15th October 2021 |
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| **Version** | **Date** | **Reason for Change** |
| 2 | 15th October | Updated to reflect the GDPR and changes to HRA approval processes |

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1. **Background**

Participants in research must be provided with adequate information in order to make an informed decision on whether to participate or not. This information is generally provided as a Participant Information Sheet (PIS) in the first instance. Documentation of the informed consent process is required to establish that the subject was accurately and adequately informed and that no study-related procedures were initiated prior to obtaining informed consent. The consent process is usually documented using a Consent Form.

1. **Purpose**

This Standard Operating Procedure (SOP) describes the process for creating PIS and Consent Forms. It should be read in conjunction with [SOP10 Informed Consent for Research](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP10-Informed-Consent-for-Research.docx) which details the circumstances in which PIS and Consent Forms are required.

1. **Procedure**
	1. **Creating Participant Information Sheets**

Following development of the study protocol, the Chief Investigator (CI) / research team should create a PIS where required. The content and style of a PIS will depend upon the nature of the research and potential participant population. Detailed guidance on writing participant information sheets can be found on the [HRA](http://www.hra-decisiontools.org.uk/consent/style.html) website. The PIS should usually contain the following sections:

Title

Explaining the study in plain English

Invitation

* Invite potential participants to consider taking part
* Highlight that participation is entirely voluntary
* Explain briefly how potential participants have been identified and why they have been selected

Summary

A short summary of the research usually covering:

*Why?*

* What research question is being addressed?
* How is it of relevance and importance to participants / Participants and public?

*What?*

* Broadly what areas are being studied?
* What 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?

More Detail

More detailed information that will allow potential participants to decide whether or not to take part

* Explanation: purpose of and background to the research and invitation
* What would taking part involve?
* What are the possible benefits of taking part?
* What are the possible disadvantages and risks of taking part?

Supporting Information

* [What if something goes wrong?](http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html#one)
* 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. This information must be applicable to the setting in which the research will be conducted e.g. university, NHS, commercial or other public research facility etc.
* Complaints – Contact details of where a complaint can be made should be given to potential participants.
* First point of contact might be your contact details, or that of someone else within the research team.
* You should also provide a contact independent of the research team for more formal complaints.
* An example of possible 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 the researchers who will do their best to answer your questions [contact number]. If you remain unhappy and wish to complain formally, you can do this by contacting [insert details e.g. NHS Complaints Procedure or Private Institutional arrangements]. Details can be obtained from [insert details]
* 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.
* Details of insurance/indemnity schemes should be given, including whether compensation is dependent on demonstrating negligence or otherwise.
* If you are unsure what indemnity or insurance is available to you, you should speak to your R&D/ research / research governance office.
* NHS based research – NHS bodies are liable for clinical negligence and other negligent harm to individuals covered by their duty of care.
* NHS Institutions employing researchers are also liable for negligent harm caused by the design of studies they initiate.
* NHS Indemnity does not offer no-fault compensation i.e. for non-negligent harm, but they may offer an ex gracia payment.
* If NHS indemnity is in place for your study, you could include the following possible wording:
* In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against [name of Sponsor Organisation, NHS Trust, Private Clinic] but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).
* Universities – Universities employing researchers are liable for their employees' actions (undertaken as part of their job) and are expected to insure against the risk of claims relating to research studies that their staff design and undertake.
* They may have insurance that covers both negligence and no-fault compensation; this would normally exclude clinical negligence for which NHS bodies are liable.
* Appropriate statements should be included in the Participant Information Sheet (PIS), which describe what insurance cover is being provided, in terms that a lay person would understand.
* Commercial research – For a Pharmaceutical industry sponsored study, where there are Association of the British Pharmaceutical Industry (ABPI) or other no-fault compensation arrangements, you should include the following form of words in your PIS:
* We will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI).
* We will pay compensation where the injury probably resulted from:
* A drug being tested or administered as part of the trial protocol;
* Any test or procedure you received as part of the trial.
* Any payment would be without legal commitment. (Please ask if you wish more information on this). We would not be bound by these guidelines to pay compensation where the injury resulted from a drug or procedure outside the trial protocol or where the protocol wasn't followed.
* [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 make it clear at the outset what they should expect if they were to withdraw their consent. Some of the issues that may need to be addressed include:
* Does withdrawal simply mean that participants will no longer be attending further research clinics or taking any further active part in the research?
* Would participants wish that all their data be destroyed? Will it be possible to extract their data and destroy it, if this is what they request?
* Could participants withdraw their samples from further analysis?
* If your study includes medium to long term follow up, how can participants withdraw from this element? For example, if you intend to access registry data over time, how could participants withdraw from this?
* Could withdrawal post intervention pose a safety issue? If so, how would you manage this (e.g. with an exit check-up)? Participants should be able to ask that any information collected at an exit check-up be included or excluded from the study.
* Can participants withdraw both data and tissue samples from subsequent tissue or data banking?
* It is important to make your intentions clear to the participant, and not to make promises that you cannot fulfil. For example:
* If you withdraw from the study, we will destroy all your identifiable samples, but we will need to use the data collected up to your withdrawal.
* Or
* You can withdraw from treatment but keep in contact with us to let us know your progress. Information collected may still be used. Any stored blood or tissue samples that can still be identified as yours will be destroyed if you wish.
* [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. You may wish to tell potential participants how your procedures for handling, processing, storing and destroying their data match the Caldicott principles and/or appropriate legislation.
* The potential participant should be told:
* If 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? Potential participants should be informed of the importance of data sharing with other researchers; to ensure that research is open to peer scrutiny, to optimise the use of good quality research data and to support policy and other decision-making.
* 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?
* Who will have responsibility of acting as the data controller? This is the organisation legally responsible for the security and validity of the information held under the Data Protection Act. This is usually the organisation that physically holds the data either on their servers or in their filing cabinets.
* Who is going to act as data custodian (i.e. who is going to manage access to identifiable/non-identifiable data)?
* 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, including those abroad (especially outside the European Economic Area (EEA)) or commercial companies? If so, how are you going to ensure participants' confidentiality is maintained?
* If identifiable data will be shared with others outside the EEA, you should make potential participants aware that such countries might not offer the same level of protection of peoples' privacy as that demanded by law in the UK. However, you can inform potential participants of the steps you will take to ensure that any such transfer of information abroad will not compromise their confidentiality.
* You should avoid repeating information you provided earlier in your Participant Information Sheet. How much information and the nature of the information appearing in 'Supporting information' will very much depend on the type of study you are planning and the potential risks involved.
* [What will happen to the results of this study?](http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html#four)
* 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). Further guidance on health related findings is available from '[Content > PIS > Discovering health related findings](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html#twelve)'.
* You should also provide relevant assurance that individual participants will not be identifiable from any report or publication placed in the public domain. If you think there is a risk that identifiable information may be published, you must ask potential participants for their explicit consent for this, having ensured that they understand the potential implications of agreeing to this.
* [Who is organising and funding this study?](http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html#five)
* You should tell potential participants which organisation(s) is/are sponsoring and which is/are funding your research (e.g. medical research charity, pharmaceutical company, academic institution, NHS organisation etc).
* Potential participants should be told whether their doctor is being paid for their role in the study and if any conflicts of interest exist. The following is an example:
* The sponsors of this study will pay (name of hospital department or research fund) for including you in this study.
* Or
* Your doctor will be paid for including you in this study.
* [How have Participants and the public been involved in this study?](http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html#fiveb)
* What will happen to my data? (*for HRA-approved studies the* [*HRA standard GDPR wording*](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/) *must be used*)
* You should explain how you have involved patients and the public in the design of your study and how they will be involved in the conduct of the research. The following are examples of how you might have involved patients / the public:
* Service users helped develop the research topic and what research questions should be asked and one of them is a co-applicant who will continue to be involved in the study.
* Potential participants were involved in reviewing the Participant Information Sheet.
* In designing this study we have taken into account patient opinions on the frequency of participant visits and the tests that we will carry out.
* Potential participants were involved in describing the inclusion and exclusion criteria for people taking part in this study.
* Knowing how patients or the public have been involved in planning your study can give potential participants greater confidence in taking part, as it provides them with the assurance that what they are being asked to do is acceptable.
* More information on how to involve patients or the public in your study can be found on the HRA website and from [INVOLVE](http://www.invo.org.uk/) (further guidance is available from our ['Links'](http://www.hra-decisiontools.org.uk/consent/links.html#seven) page).
* [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: there are a number of web resources and booklets available, produced by research organisations, which explain why research is conducted, define some technical terms, and provide ideas as to the sorts of questions potential participants might like to ask before deciding if they will take part in research or not. Further guidance is available from our '[Links](http://www.hra-decisiontools.org.uk/consent/links.html#seven)' page.
* 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. If you also have a study website, details of where to find this should be included.
* Advice as to whether they should participate: this is usually a person who is independent of your study. It could be the potential participant's health care professional or a person you nominate who can provide support and who is independent of your study.
* Who they should approach if they are unhappy with the study: this would be a contact if participants have any concerns about your study and their involvement in it. 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.
* Your Participant Information Sheet should be dated and given a version number (referring to a protocol number if necessary). This can be done in a header, footer or within the body of the document.
* Version numbers will not only help you and your research team to manage consent paperwork 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.
* [Consent process](http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html#nine)

The PIS should be named and versioned according to [SOP2 Document Control](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP2-Document-Control.docx). The CI should submit the PIS to a research ethics committee for review (MMU Ethics or NHS REC as appropriate) before the study commences. Any amendments to the PIS will also need to receive ethical approval prior to use.

* 1. **Additional material to support the consent process**

For complex studies or those involving vulnerable Participant groups (adults lacking capacity to consent, children or emergency research), additional materials such as a reduced PIS, diagrams or flow charts may be required to help to support the consent process. These must also follow the document control procedure and be submitted for ethical review.

* 1. **Testing Participant Information Sheets**

Where possible the PIS (and any other written material to be used in the consent process) should be tested with an appropriate group e.g. Participant groups or other members of the public. This is to ensure that the style and format of the PIS aids understanding, and that risks/benefits relevant to potential participants are adequately highlighted. Ethical approval is not required for testing study documentation with Participant groups, however the CI should ensure that suitable access arrangements are in place for testing with vulnerable groups (e.g. via a gatekeeper).

* 1. **Consent Form Development**

Following development of the study protocol, the CI / research team should create Consent Forms where required. The content and style of a Consent Form will depend upon the nature of the research and potential participant population. Guidance on writing consent forms and templates can be found on the [HRA](http://www.hra-decisiontools.org.uk/consent/content-form.html) website. The form should be produced on headed paper and should clearly display the title of the research study. Consent forms usually contain the following sections:

General Statements

* I confirm that I have read the information sheet dated.................... (version............) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
* I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, (if appropriate) without my medical care or legal rights being affected.
* (If appropriate) I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [company name], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
* (If appropriate) I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.
* (If appropriate) I agree to my General Practitioner being informed of my participation in the study.
* (If appropriate) I understand that the information held and maintained by the Health and Social Care Information Centre (or amend as appropriate) and other central UK NHS bodies may be used to help contact me or provide information about my health status.
* I agree to take part in the above study.

Signatories, witnesses and legal representatives

* A section for each person involved in the consent process to print their name, sign and date the form
* There should be a space next to each item for the participant to indicate their agreement. For studies not seeking NHS REC or HRA approval a tick will suffice; for NHS REC and HRA-approved studies a signature is expected.

Spaces should be included for a Participant ID where appropriate. Consent forms to be used by legal representatives should clearly state that they are providing consent on behalf of, or advice with respect to a child / young person or adult lacking capacity.

The consent form should be named and versioned according to [SOP2 Document Control](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP2-Document-Control.docx). The CI should submit the consent form to a research ethics committee for review (MMU Ethics or NHS REC as appropriate) before the study commences. Any amendments to the consent form will also need to receive ethical approval prior to use.

1. **Related Documents**

[SOP2 Document Control](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP2-Document-Control.docx)

[SOP10 Informed Consent for Research](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP10-Informed-Consent-for-Research.docx)

1. **References**

HRA guidance on style and layout of consent forms and PIS

<http://www.hra-decisiontools.org.uk/consent/>