

**INFORMED CONSENT FOR RESEARCH**

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1. **Background**

Informed Consent is the process by which a subject voluntarily confirms his/her willingness to participate in a study, having been informed of the full details of the project. For consent to be considered both legal and ethical it must be:

* Given by a person with capacity
* Voluntarily given, with no undue influence
* Given by someone who has been adequately informed
* A fair choice

Consent is required for all research involving human subjects, their data or tissue (with the exception of anonymised secondary data, retrospective NHS patient information, and published literature). Using NHS patient information without consent requires approval from the Confidentiality Advisory Group (CAG).

1. **Purpose**

This Standard Operating Procedure (SOP) describes the process for obtaining informed consent from a study subject. The consent procedure for research involving human tissue is covered separately in [SOP MMUHTA001](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/rke/MMUHTA001-Obtaining-Consent%5B1%5D.docx).

1. **Procedure**

The consent process will vary depending upon the type of research and the type of participants. It generally involves:

1. The giving of information
2. The discussion and clarification of the information and finally
3. Recording the participant’s consent
	1. **Who should conduct the consent process?**

For single site studies, the Chief Investigator (CI) retains overall responsibility for the consent of participants. For multi-site studies, the Principal Investigator (PI) at the site has overall responsibility. The CI/PI may delegate the taking of informed consent to suitably trained and competent individuals. The CI/PI must be satisfied that staff conducting the informed consent process fully understand the study protocol and all risks involved with the research.

Any delegation of duties (including informed consent) must be recorded on the study [Delegation Log](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/linked-documents/Delegation-log-Template.docx) prior to performing any study related procedures. The PI should individually sign each entry on the form.

* 1. **Providing Information**

Potential participants should be given sufficient information about the research to enable them to decide whether or not to take part. The CI/Research Team should produce a participant information sheet (PIS) according to [SOP4 Participant Information Sheet and Consent Form Development](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP4-PIS-and-Consent-Form-Development.docx).

* 1. **Discussion and clarification of information**

Information should be provided to participants in advance of the consent process where possible to allow them time to fully consider the study. The minimum length of time required to consider a study will depend upon its complexity and risks.

The consent process should take place in a suitable environment where the potential participants can feel at ease, with adequate privacy if required. During the process, the researcher should:

* Confirm the participant’s eligibility
* Provide a verbal explanation of the study to the potential participant (and friends and family if appropriate). If necessary, diagrams should be used to explain the study. The explanation should, where applicable, cover:
	+ Why the subject has been approached
	+ Confidentiality will be maintained throughout the study[[1]](#footnote-1), should they decide to participate.
	+ Details of the study design
	+ The number of people taking part in the study and how many have been recruited to date.
	+ The duration of the study and the number of study visits involved. It should be explained where the subject will be seen and by whom.
	+ All procedures, such as blood tests, electrocardiograms (ECGs) etc that are required as part of the study should be included and explained in lay language e.g. 10mls (2 teaspoons) of blood.
	+ The potential benefits and risks of participation in the study
	+ The availability of compensation should something go wrong
	+ That the subject enters the study voluntarily and can withdraw at any time without any prejudice to them
	+ Any payments to be made for participation in the study or for out of pocket expenses.
	+ The responsibilities of the subject if they choose to take part, particularly if the study duration is lengthy
	+ Where participants are capable of consenting for themselves but are particularly susceptible to coercion, it is important to explain how their interests will be protected
* Allow time for questions throughout the discussion and adequately address questions
	1. **Assessment of capacity**

The researcher conducting the consent process must be satisfied that the potential participant has the capacity to give fully informed consent. If there is any concern that a potential participant lacks capacity, they should not be consented. A person with capacity will:

* understand the purpose and nature of the research
* understand what the research involves, its benefits (or lack of benefits), risks and burdens
* understand the alternatives to taking part
* be able to retain the information long enough to make an effective decision.
* be able to make a free choice
* be capable of making this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity)
	1. **Recording Consent**

Clear evidence must be obtained that the participant has given informed consent to take part in the study. The University expects that this will normally be in the form of a signed consent form although other evidence may be acceptable (for example by audio recording consent). Consent forms should be produced according to [SOP4 Participant Information Sheet and Consent Form Development](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP4-PIS-and-Consent-Form-Development.docx).

If alternative methods of obtaining consent are to be used, approval must be gained from the Faculty Head of Ethics. For questionnaire based studies additional written consent is not required as consent is implied by the participant returning the questionnaire (researchers are still required to send full study information to prospective participants).

Requirements for completion of a written consent form are:

* Participants (or their legally acceptable representative) must initial boxes adjacent to questions. Ticks or other marks are not acceptable except in special circumstances (see below).
* The participant (or their legally acceptable representative) must print their name, sign, and date the form
* The person conducting the consent process must print their name, sign, and date the form
* Any corrections must be initialled and dated by the participant

Where the participant population is likely to include a significant proportion of participants who cannot read or write, require translators or have cognitive impairment, appropriate alternative methods for supporting the informed consent process should be employed. This may include allowing a witness to sign on a participant’s behalf (in the case of problems with reading or writing), or allowing someone to date the form on behalf of the participant, or providing Participant Information Sheets in other languages or in a format easily understood by the participant population (in the case of minors or cognitive impairment).

Participants should be given a copy of the consent form, participant information sheet, and any other written material used during the consent process to keep. The original consent form should be stored securely by the study team (filed according to [SOP7 Study Master File and Site File Set-up](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP7-Study-Master-File-and-Site-File-Set-up.docx)), and a further copy stored in the participant’s medical notes (where applicable).

For participants recruited in NHS settings the consent process should be fully documented in the participant’s medical records. This should include the details of the first approach to the participant, which researcher took the informed consent, the version of documents used and explicit information to demonstrate that the participant fully met the inclusion/exclusion criteria of the study.

Informed consent must take place before **any** study related procedures take place.

* 1. **Additional Considerations for vulnerable Participant Groups**

The consent process for research involving those who are unable to consent for themselves varies depending upon the type of research and which UK nation the research is taking place in. Chief investigators should ensure that their consent process complies with the relevant laws. Up to date guidance can be found on specific groups here:

[Adults Lacking Capacity](http://www.hra-decisiontools.org.uk/consent/principles-ALC.html)

[Children](http://www.hra-decisiontools.org.uk/consent/principles-children.html)

[Emergency](http://www.hra-decisiontools.org.uk/consent/principles-emergency.html)

[Deceased](http://www.hra-decisiontools.org.uk/consent/principles-deceased.html)

* 1. **Reassessment of Consent**

The informed consent process should not end once the consent form has been signed. The practice of giving information about the study to participants should be an ongoing process performed by all members of the research team and any associated healthcare professionals. If changes are made to the study protocol that may affect the participant’s willingness to continue taking part in the study, participants should be re-consented using updated participant information sheets and consent forms. Updates to consent documents require ethical approval prior to their use (from NHS REC or MMU ethics process). Amended consent forms should be stored alongside the original consent form for each participant.

* 1. **Withdrawal of Consent**

Not all participants will complete a study as per protocol. For studies with NHS ethics approval withdrawals must be reported on the REC annual report. Information regarding withdrawals may help with analysis of results for all studies, and therefore clear documentation of this information is required. The method of recording withdrawals will vary depending on the study, but this should be clearly defined in the Protocol.

For the NHS REC Annual Report withdrawals should be categorised as:

(a) withdrawal of consent

(b) loss to follow-up

(c) death (where not the primary outcome)

It should be clear in the PIS and consent form what will happen to participant data if a participant withdraws from the study. Data collected up to the point of withdrawal should be retained unless the participant specifically requests that it is removed. In such cases, information regarding the participant should be retained at site as part of the participant notes, along with their withdrawal form and request to

delete data. Requests to delete data should be made in writing by the participant or their legal representative.

1. **Related Documents**

[Delegation Log Template](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/linked-documents/Delegation-log-Template.docx)

[SOP MMUHTA001: Obtaining Consent](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/rke/MMUHTA001-Obtaining-Consent%5B1%5D.docx)

[SOP4 Participant Information Sheet and Consent Form Development](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP4-PIS-and-Consent-Form-Development.docx)

[SOP7 Study Master File and Site File Set-up](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP7-Study-Master-File-and-Site-File-Set-up.docx)

1. **References**

HRA Guidance for researchers and Ethics Committees on Informed Consent

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

<http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/>

1. There may need to be limits to confidentiality, if for example a participant discloses criminal activity, abuse, or activity that could put others in harm. Participants must be informed in advance of the types of activities that must be disclosed, and to whom they must be disclosed. [↑](#footnote-ref-1)