Participant Information Medium and Valid consent – Guidance and Checklist

Researchers should bear in mind that the checklists are indicative and not all this information woud be required for all types of research. A proportionate approach should be applied whilst maintaining the high standards for Valid Consent the University has.

The guidance is also designed to help researchers understand that consent 'forms' are not used to convey information, but that they are there to help record evidence of consent received (if appropriate), and therefore should not be confused with participant information mediums – one of the means of ensuring Valid consent.

For more information researchers should refer to:

- The ***Introduction to Research Ethics Blackboard Training module***, in particular the **section on Selection, Recruitment and Valid Consent.**

  To register on this module, please contact the Research and Knowledge Exchange Office via research-knowledge-exchange-office@westminster.ac.uk

- ***Researcher Guidance for research involving human participants***

What to include in 'Participant Information Medium': Each study will differ in what type or level of information should be provided, and this is also dependent on the potential participant set too. Usually as a minimum you should aim to provide your potential participants, in lay person and succinct language, in an age appropriate and culturally sensitive manner, the following:
1. What is the study or activity about?
2. Why is it being undertaken?
3. Who is undertaking it? Any funder associated, name of the Principal Investigator and their affiliation
4. Contact details of the Principal Investigator (your University email address should be the default)
5. Why am I being asked to participate? (selection and eligibility criteria)
6. What am I being asked to do, how often and for how long? Will I receive payment and expenses and if so, how much and how often and in what form?
7. A summary list of indicative interview questions
8. Any risks or benefits directly to the potential participant as a result of participating.
9. Information around participants being free to decline any information or action without providing a reason during the study or activity.

10. Clear information on how and when a participant may withdraw from the study or activity entirely without providing any reason and without negatively affecting their rights. Explain any points beyond which it may not be possible to withdraw their data from a study.
11 .A point of contact for 'Participant Complaints': at the University these must be directed to the Head of School or Head of College, where the Head of School or Head of College is/are directly involved in the research or KE activity, an alternate named nominee should be listed or provided via any medium of 'Participant Information'.
12. Is there clear information on what will happen to the participants data and whether the processing and storage of this data is in compliance with the EU's General Data Protection Regulation (GDPR). A simple statement committing to compliance is not sufficient and some evidence of compliance should be included in 'Participant Information'. i.e. how will any personal or sensitive information relating to me, including my name should it be provided be treated, who will have access to any identifiable data and for how long. When will my data be destroyed .
13. Have participants been given information or contacts for emotional support if needed?
14. Whether a debrief will be provided
15. If there is a risk that disclosures raising concerns for the safety of participants or others may occur, explain relevant measures in your 'Participant Information' that such incidental disclosures may result in the study team informing relevant local authorities, safeguarding or social care teams where there may be a potential significant or imminent risk of harm to others, including the participant and investigators.
Additionally, it may be suitable to include the following:
16. Requesting the participant report any to report adverse or serious events, or report any symptoms which may occur
17. Advise the participant to seek medical advice prior to agreeing to participate
18. What will happen to the results of this research and will these be publicly available , and if not will they be provided to the participants i.e. dissemination and publication plans , sharing of results with participant set.
19. Will individual results be fed back to participants, if applicable
IMPORTANT: If you are carrying out work falling under the Human Tissue Act then you must refer to UoW HTA-SOP-009 Seeking Consent for the Removal, Storage and Use of Relevant Material for the Purpose of Research.
DOWNLOAD OR PRINT THIS 'PARTICIPANT INFORMATION' GUIDE: REMEMBER – NOT ALL STUDIES WILL REQUIRE THIS AMOUNT OF INFORMATION AND IT IS IMPORTANT YOU CONSIDER THE INFORMATION WHICH IS RELEVANT TO YOUR STUDY AND PARTICIPANT NEEDS

Valid Consent

To gain valid consent participants should be recruited using fair selection criteria and clear and transparent recruitment information and processes. In order for consent to be valid it should be in light of all information which may affect a decision to participate, and in a suitable medium for conveying information to the particular participant set, for example age appropriate, using lay person language etc. The participant should be providing their consent voluntarily without any undue influence or pressure and be free to withdraw without penalty. Any restrictions on withdrawal would need to be conveyed to them and agreed by them.

A consent form, if used, should include basic information only around the:
• Study title, name of PI and affiliation, any funder, and date it was written, any ethics approval body name and reference number if relevant.
• A statement that the consent is being provided by the potential participant in light of the information provided by the investigators around the study which they understand.
• And their understanding that they may withdraw without negative consequence or reason provided.
• You may or may not need to record the name of the participant.

Consent forms should not be used to gather data

• The consent form could be used to indicate the potential participant's permission to be contacted for future parts of this study or other similar studies.
• The consent form could be used to ask permission for quotes to be attributed to the participant and an option not to agree to this but still participate, if practicable.

Unless the research is regulated research, such as medical or Human Tissue, then there is normally no need to provide statements of understanding or agreement around points already contained in the participant information mediums (i.e. check or initial boxes).

We generally recommend that you do not duplicate information which is provided via 'Participant Information Mediums' on a consent form. This can be confusing for potential participants and a waste of their time. It is better if you wish to re-iterate information that you do this through other participant information mediums, such as videos, adverts, conversations and the like, and then ask the potential participant to confirm via the Consent Form that they have gone through the additional information provided.

The consent form is not usually retained by the participant, unless the research is regulated.

Consent forms are simply to record or evidence that consent has been provided in light of appropriate information, they are not a medium for conveying information.

Note: There are additional requirements around valid and appropriate consent for regulated research, one example of which is research falling within the Human Tissue Act 2004 (HTA) and standards of the Human Tissue Authority (HT Authority). Individuals should refer to the University's HTA blackboard site (in particular **UoW HTA-SOP-009 Consent**) if working within the HTA, and also to their own professional, legal and regulatory requirements for other areas of regulated research. Similarly the Health Research Authority (HRA) as another example, will have specific requirements, including with regard to data protection.