Guidance on creating a Consent Form for

research participants

As a first principle, research involving human participants should only take place with the fully informed consent of the participant. In exceptional circumstances, consent can be given by a third party.[[1]](#footnote-1) Gaining informed consent is an ethical requirement of the research process. It must be thought about at the planning and writing stage of a research proposal and be tailored towards the specific research questions.

The following principles should always underpin gaining informed consent:

* Potential participants should not be under the impression that they are required to participate, or that there is any penalty or detriment to them if they do not take part;
* Participants should be aware of their entitlement to refuse to continue to participate at any time, for whatever reason without incurring any penalty;
* Potential research participants should be given sufficient information about a study, in a format they understand, to enable them to exercise their right to make an informed decision whether to participate in a research study;
* Participants should be aware of the benefits and risks to them of taking part in the research;
* Participants should be aware of how their data will be used, including whether their anonymised data may form part of a re-usable, published dataset;
* If participants form part of a vulnerable group, or could be made vulnerable as a result of their participation in the research particular care must be taken in relation to their consent and the conduct of the research to ensure their safety and wellbeing;[[2]](#footnote-2)
* Participants should be given sufficient time to reflect on their consent before and after making their decision;
* Signed Consent Forms should be dated, with a copy being given to the participant, and the original kept securely. Storage and destruction of the documents must meet UWE Data Protection and Information Security policies (either in a locked cabinet in a secure location, or securely digitised and kept on UWE OneDrive)
* ‘Tick boxes/initial boxes’ should not be used on a Consent Form unless the research offers an opt in/opt out option for the participant on various parts of the research;
* To comply with the Data Protection legislation a privacy notice must be included at the beginning of all online forms/surveys/questionnaires, and at the end of paper documents, when collecting personal data.

Example Consent Form

**[Insert project title]**

This consent form will have been given to you with the Participant Information Sheet. Please ensure that you have read and understood the information contained in the Participant Information Sheet and asked any questions before you sign this form. If you have any questions please contact a member of the research team, whose details are set out on the Participant Information Sheet

If you are happy to take part in [insert details of what the participant is agreeing to take part in, eg interview], please sign and date the form. You will be given a copy to keep for your records.

* I have read and understood the information in the Participant Information Sheet which I have been given to read before asked to sign this form;
* I have read and understood the Data Protection Privacy Notice that has been provided to me
* I have been given the opportunity to ask questions about the study;
* I have had my questions answered satisfactorily by the research team;
* I agree that anonymised quotes may be used in the final Report of this study;
* I understand that my participation is voluntary and that I am free to withdraw at any time until the data has been anonymised, without giving a reason;
* I agree to take part in the research

Name (Printed)………………………………………………………………………….

Signature……………………………………………………. Date…………………….

1. For example, research involving those who cannot consent for themselves including those without mental capacity. [↑](#footnote-ref-1)
2. The Mental Capacity Act 2005 came into force on 1 October 2007. It requires intrusive research to be subject to ethical scrutiny by a Research Ethics Committee established in England or Wales under the Governance Arrangements for NHS Research Ethics Committees (GAfREC, DH July 2001). Intrusive research is defined in section 30(2) of the Act as: “[research] of a kind that would be unlawful if it was carried out on or in relation to a person who had capacity to consent to it, but without his consent” and is not limited to medical and biomedical research, health-related research or research taking place within the NHS. [↑](#footnote-ref-2)