**Consent Form Template – Guidance Notes**

**N.B. the template follows this guidance**

**Who should use this template?**

The template is for the use of any researcher who intends to conduct a study where a record of written consent is required.

**When should a written consent form be used?**

Consent to participate in studies should be obtained in most cases, and a record of that consent should be kept, but it is not always necessary to use a separate form, including identifiable details of any participant, and record their consent in writing. It is not normal to use a form in the case of surveys as often completion and return of a questionnaire can be taken as evidence of consent so long as the data is stored anonymously. Written consent might also not be necessary in the case of a digitally recorded interview as it is often acceptable to record and transcribe consent as an integral part of the interview. It is also accepted that expert, or well known (typically in public life) participants might be disinclined to sign a consent form. In this case the researcher should seek and make a record of oral consent. Formal written consent must always be obtained for participation in studies that pose risks extending beyond those experienced in day to day life. It should also be obtained if personal or special category data are to be collected and stored. It is essential if there is any intention to use data for any future research, beyond that described in the associated information sheet, or if the researcher intends to retain participant contact details with the intention of inviting them to particpate in other studies. There will always be a need for researchers to exercise judgment with regard to the medium to be deployed when seeking and recording consent; evidence of this judgment should be reflected in the application for ethical review.

It is always best practice to test a draft consent form with a member of the intended research population. Public and participant engagement in research design, including participant documents, is always desirable, and indeed often mandated for studies involving the NHS. The aim is to ensure readability and clarity.

**Who is the template designed for?**

The template is aimed at potential research participants who have capacity to consent. It is not lawful for any other person to provide proxy consent for someone else who has the capacity to consent, unless the participant is a minor – normally understood as being under 16 years of age. In this case a person or appropriate body (e.g. Social Services in the case of a looked after child) with parental responsibility can provide consent. If a minor under the age of 16 years has capacity to consent to particpate in the study in question they can consent for themselves (due precedence borrowed from clinical medicine known as “Gillick competence”, although not for studies that fall specifically under the Clinical Trials Regulations). It is a matter of debate (simply because the matter has never been addressed through the Courts) whether parental consent is required **in addition** to that of the minor, but it is wise to seek it, or at least inform parents of the research at least 24 hours before the research takes place. In the case of very young minors who lack the capacity to consent it is good practice to provide a simplified version of a consent form, often using illustrations, to enable the young person to register their **assent**.

If there are good reasons for recruiting adults (16 years of age or older) lacking capacity, the study has to be reviewed by an NHS Ethics Committee or the Social Care Ethics Committee. In this case the consent form has to be adjusted so that it comprises a declaration provided by a consultee. The consultee is required to declare that they believe that the incapacitated adult would have consented to each of the clauses within the consent form had they the capacity to do so. Research involving adults lacking capacity is legally and ethically complex – further advice should be sought at the design stage of the study.

**What must be included in a written consent form?**

The following elements are essential:

* Departmental headed paper identifying the researcher(s) and, if relevant, the supervisor(s).
* Study title – which must be consistent with any other references to the title in other documents – unless the study involves deception and the ethics committee gives a favourable opinion of the use of a different title.
* Document date and version number – normally in a footer. This is essential for tracking and identifying which document has been ethically reviewed.
* Reference to any associated information sheet identifying its date and version number.
* The mandatory clauses as shown in the template.
* Other clauses reflecting the demands of the study.

Overall it makes sense to seek consent to use data as widely as possible; this is particularly important where it seems likely that they will be useful in further research.

**What are the principles underpinning consent in research?**

The key ethical principle relates to respect for persons. This may be expressed in a variety of ways depending on the ethical framework adopted by differing ethicists. Sometimes it is expressed as respect for autonomy, in other contexts it is seen as a duty. The overriding requirement is that a person’s liberty should not be compromised without their explicit permission. Nothing should be done to a person, nor should their privacy be invaded without that person’s clear permission. It is recognised that any permission granted must be voluntary and based on sufficient and necessary information – hence the normal expectation that any consent form will be accompanied by relevant information, often in the form of a participant information sheet. Most researchers use the term ‘informed consent’ although it is perhaps more accurate to refer to “sufficiently” or “appropriately” informed consent. However, in addtion to information, particpants must have sufficient capacity to agree to participate and their particpation must be entirely voluntary. The latter is often expressed as a right to withdraw in person and / or a right to withdraw data. In many studies there will be a time limit after which it will not be possible to withdraw data – participants must be made aware of such a limit. In some studies deception is necessary; information might defensibly be incomplete or misleading. The Ethics Committee will decide whether deception is necessary to meet the scientifically determined objectives of the study and, if appropriate, agree to its use. It will always be necessary to debrief participants after they have been exposed to deception **and remind them of their right to withdraw any data – effectively re-confirming consent.**

When considering consent, researchers must consult key laws, policies, procedures, codes and declarations. It is helpful to refer to these in the application to the ethics committee. The following comprise the main sources – some are for guidance purposes, others state mandatory obligations. The majority of policies can be accessed using: <https://www.port.ac.uk/about-us/structure-and-governance/policies-and-standards>

* The University of Portsmouth Ethics Policy
* The University Research Data Management Policy, associated retention schedules and [practical guidance on storing and managing research data](https://library.port.ac.uk/researchdata.html).
* The UUK [Concordat to Support Research Integrity](https://www.universitiesuk.ac.uk/topics/research-and-innovation/concordat-support-research-integrity)- the University has signed up to the commitments expressed in the Concordat – researchers are required to respect these commitments
* The [UKRI Policy and Guidelines on Governance of Good Research Conduct](https://www.ukri.org/our-work/supporting-healthy-research-and-innovation-culture/research-integrity/) – this document is useful regardless of funding matters.
* The [UKRIO Code of Practice for Research](http://ukrio.org/publications/code-of-practice-for-research/) – the University has adopted this Code as its own. Any breach of the Code could invoke the University Procedure for the Investigation of Alleged Misconduct in Research
* Discipline specific guidance – most subject disciplines publish guidance on the ethical conduct of research
* As of 25th May 2018 the EU General Data Protection Regulation (GDPR) caused the UK to replace its 1998 Data Protection Act with the 2018 Data Protection Act. Specific guidance for researchers has been developed jointly by the Information Commissioner’s Office (ICO) and Health Research Authority (HRA). Researchers should familiarise themselves with the latest advice on the following links:

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/>

https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/the-research-provisions/

PLEASE NOTE: THESE REGULATIONS REFER ONLY TO THE COLLECTION AND PROCESSING OF DATA. CONSENT IS ALSO NEEDED FOR PARTICIPATING IN ALL OTHER ASPECTS OF THE STUDY.

**How should completed forms be stored?**

Consent forms include personal data; storage and management must reflect compliance with the University Research Data Management Policy, the associated retention schedules, and [practical guidance on storing and managing research data](https://library.port.ac.uk/researchdata.html).

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**PLEASE DO NOT SUBMIT THE UNEDITED TEMPLATE TO AN ETHICS COMMITTEE**

**THIS FORM MUST BE ON DEPARTMENTAL HEADED PAPER INCLUDING RELEVANT CONTACT DETAILS. THE FORM MUST HAVE A DATE AND VERSION NUMBER.**

**CONSENT FORM**

Title of Project:

Name and Contact Details of Researcher(s):

Name and Contact Details of Supervisor (if relevant):

Please initial box

University Data Protection Officer: Samantha Hill, 023 9284 3642 or information-matters@port.ac.uk

Ethics Committee Reference Number: (this may not be available at the time the form is submitted for review)

1. I confirm that I have read and understood 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.

1. I understand that my participation is voluntary and that I am free to withdraw at any time (or add the date after which withdrawal will not be possible) without giving any reason.
2. I understand that data collected during this study will be processed in accordance with data protection law as explained in the Participant Information Sheet (insert date and version of participant information sheet).

THE FOLLOWING MUST ALWAYS BE THE LAST CLAUSE ON THE FORM (so insert and number any additional clauses above)

1. I agree to take part in the above study.

**Name of Participant: Date: Signature:**

**Name of Researcher: Date: Signature:**

***Note****: When completed, one copy to be given to the participant, one copy to be retained in the study file*

**FURTHER ADDITIONAL, OPTIONAL CLAUSES (PLEASE ADD AS NUMBERED ITEMS TO TEMPLATE ABOVE ALONG WITH BOXES FOR INITIALS)**

**Additional, Optional Clauses**

Researchers should ensure that they include any additional clauses which they deem necessary for their study – this will often entail drafting original statements. The following comprise examples of frequently used clauses – it is not an exhaustive list. The model clauses can be adjusted to reflect the demands of the study. In some cases consent can be optional. **In such cases, it is helpful to provide two boxes: one indicating ‘yes’, the other ‘no’.**

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| **Procedures entailing some risk to the person or privacy of the participant** |
| I consent for photographs/video of me to be taken during the experiment for use in scientific presentations and publications (with my identity obscured). |
| I consent for photographs/video of me to be taken during the experiment for use by the study team only (my image will not be shown to others / and will be destroyed after the data has been analysed). |
| I consent for my interview to be audio / video recorded. The recording will be transcribed and analysed for the purposes of the research (add further details about destruction or subsequent storage of recordings and / or transcripts). |
| I consent to verbatim quotes being used in publications; I will not be named but I understand that there is a risk that I could be identified. |
| I understand that participation will include: (add any particularly demanding, painful, invasive or potentially embarrassing procedures). |
| **Wider use of data, tissue, DNA**  |
| Data will also be made available to other researchers as part of our open data policy. |
| I agree to the data I contribute being retained for any future research that has been given a favourable opinion by a Research Ethics Committee. |
| I understand that the information (or add other examples such as tissue, DNA, etc.) collected about me will be used to support other research in the future, and may be shared anonymously with other researchers (or add other organisations or other purposes e.g. teaching). |
| I understand that to maximise the re-use and societal benefit of this research, anonymous data (which does not identify me) will be publicly shared at the end of the project and made open access under a CC-BY licence. I understand that this means anyone else (including researchers, businesses, governments, charities, and the general public) will be allowed to use this anonymised data for any purpose that they wish (including commercial purposes), providing that they credit the University and research team as the original creators. |
| **Limitations to Confidentiality** |
| I understand that whatever I say in the interview is confidential unless I tell the researcher that I or someone else is in immediate danger of serious harm, or the researcher sees or is told about something that is likely to cause serious harm. If that happens, the researcher will raise this with me during the interview and tell me about what could happen if I continue to talk about it and explore how I would prefer to deal with the situation. The researcher will encourage me to seek support from (add relevant persons or agencies) to help me make the situation safer. If the researcher feels unsure that I will go and get support, they will talk to me about what they need to do and what might happen next. In an extreme case where a child (or add any other vulnerable person including the interviewee) is at serious risk, and I choose not to seek help/advice the researcher has a duty to disclose this to the relevant agencies.[[1]](#footnote-1) |
| I understand that should I disclose any concerns with regard to my own, or others’ professional practice in the course of the interview, the researcher might be duty bound to refer the matter to relevant agencies. |
| I understand that should I disclose possible criminal offences that have not been investigated or prosecuted, in the course of the interview, the researcher may report the matter(s) to relevant agencies. |
| I agree to be named as a participant and referred to accordingly. |
| **Dissemination of Results** |
| I understand that the results of this study may be published and / or presented at meetings or academic conferences, and may be provided to research commissioners or funders (*Give the name of the Company / Organisation here, or remove the reference if not applicable)*. I give my permission for my anonymous data, which does not identify me, to be disseminated in this way. |
| I would like to receive further information about the results of the study. (Add further information regarding the format of the results, e.g. personal or those relating to the study as a whole). |
| **Incidental Findings** |
| I understand that the tests / investigations (adjust as necessary) are designed for the purposes of the research and I will not receive any personal results relating to my health or well-being.  |
| I understand that the tests / investigations (adjust as necessary) are designed for the purposes of the research but in the event of the results indicating any concerns about my health or well-being, I agree to this information being passed on to (add GP or other Health Care Professional(s)) |

1. [↑](#footnote-ref-1)