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**UoM Template for Research Medical Consent Form V3**

Any research project should be compliant with the Data Protection Act 2018 and UK GDPR.

You must have a legal basis defined in data protection law for each purpose you wish to use personal information. Whilst the use of the personal information for the research itself or additional information generated from it, is likely to rely on the public interest task legal basis (and for special category personal information also the research legal basis), this must be cited in the participant information sheet. Consent in terms of Data protection is not used and should not be cited on this form.

This is a sample consent form which aims to explain the activities that may still require consent, this is consent in the ethical sense and to satisfy the common law duty of confidence. **NB: the information described in this template should be adapted, where necessary, where the participant is a lay person, child, adult with learning difficulties or a non-English speaker.**

We have provided **guidance notes in purple text** for you to consider, please ensure you **replace these with your own text, amend the consent points as appropriate and delete consent points if they are not applicable to your project**.

You must ensure that the statements you list here are also mentioned in your participant information sheet and data management plan.

If you are taking consent verbally, you will need to prepare a consent script, using the statements in this form as the basis. You should include an introduction, description of how the consent will work and each of the consent statements relevant to your study.

**Please also delete this guidance section.**

Please ensure you also **adjust the footer to the correct version number and date for your project**.

**If you are submitting your study for HRA approval, please read *2. UoM CF and PIS Guidance for NHS studies (located in section 15. Document templates* folder of the** [**Research Governance Pack**](https://documents.manchester.ac.uk/DocuInfo.aspx?DocID=29041)**) as you will be required to include additional information.**

**Below are examples of consent statements that you may use if relevant. Please ensure you delete any points which are not relevant to your study and renumber the statements as appropriate.**

**Title of Research**

**Consent Form**

If you are happy to participate please complete and sign the consent form below

For a consent script: If you are happy to participate, please state your full name and today’s date. I will then read each statement of the form and ask that you respond by saying either ‘yes’ or ‘no’. Saying ‘yes’ means you agree and consent to the statement, saying ‘no’ means you disagree and do not consent to the statement.

|  |  |  |
| --- | --- | --- |
|  | **Activities** | Initials |
| 1 | I confirm that I have read the attached information sheet (**Version XX, Date dd/mm/yyyy**) for the above study and have had the opportunity to consider the information and ask questions and had these answered satisfactorily. |  |
| 2 | I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving a reason and without detriment to myself. I understand that it will not be possible to remove my data from the project once it has been anonymised and forms part of the data set.  I agree to take part on this basis. |  |
| 3 | I agree to my GP being informed of my participation in this study. |  |
| 4 | I agree to have a **blood sample** taken for the research purpose as explained to me. I understand that the research using my sample will be **genetic research**. |  |
| 5 | I agree to the **interviews** being **audio / video recorded (delete as appropriate)**. |  |
| 6 | I agree that any research publications can include direct quotes of my responses in **anonymous** format. |  |
| 7 | I agree that **pictures of my face** may be used **in/for** **publications/conference presentations/teaching purposes**. |  |
| 8 | I agree that any data collected may be included in anonymous form in **publications/conference presentations.** |  |
| 9 | *[Data sharing: if you will be sharing anonymous data you MUST include ONE of the below statement, and this should be explained in more detail in your PIS, otherwise please delete]*  I understand that a fully anonymised dataset will be deposited in an open data repository at the end of the project.  **OR**  I agree that any anonymised data collected may be made available to other researchers |  |
| 10 | I understand that my full name and email address will be passed to the University's Finance team for the sole purpose of sending me the **shopping/Amazon voucher.** |  |
| 11 | I understand that data collected during the study may be looked at by individuals from The University of Manchester or regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data. |  |
| 12 | I understand that there may be instances where during the course of the research information is revealed which means the researchers will be obliged to break confidentiality and this has been explained in more detail in the information sheet. |  |
| 13 | *[If the study will be conducted outside of the UK and involve the transfer of personal data to the UK, you* ***MUST*** *include this statement, otherwise please delete]*  I consent to the personal information collected as part of this study being transferred and processed in the UK. This processing will be subject to UK data protection law. |  |
| 14 | I agree to take part in this study. |  |

**The following activities are optional, you may participate in the research without agreeing to the following:**

|  |  |  |
| --- | --- | --- |
| 14 | I understand that the sponsors of this study may make my **blood sample/DNA** available to other researchers **for future research and that this may include researchers working abroad**. I give permission for these individuals to have access to my **sample, (but not any personal identifying information about me,) I offer my blood sample as a gift.** |  |
| 15 | I agree that any **personal** data collected may be made available to other researchers |  |
| 16 | I agree that the researchersmay contact me in future about other research projects. |  |
| 17 | I agree that the researchers may retain my contact details in order to provide me with a summary of the findings for this study. |  |
| 18 | I agree that any research publications can include direct quotes of my responses in **identifiable** format. |  |

**Data Protection**

**The personal information we collect and use to conduct this research will be processed in accordance with data protection law as explained in the Participant Information Sheet and the** [**Privacy Notice for Research Participants**](http://documents.manchester.ac.uk/display.aspx?DocID=37095)**.**

For studies gathering sensitive data **and** recording consent via a mobile phone app or via a digital platform such as Qualtrics you must also include the following declaration statement:

By signing this consent form, I declare that I have provided accurate identity details (full name and electronic signature).

If this is not required for your study, please delete the above.

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Name of Participant Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of the person taking consent Signature Date

[Insert details of what will happen to the copies of consent form e.g. 1 copy for the participant, 1 copy for the research team (original), 1 copy for the medical notes]