**Guidance for design of an informed consent form (Adult)**

**This template consent form is suitable for use in adults who are capable of giving consent. Guidance on additional consent/assent forms can be obtained from the Research Governance Team or via:** <http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/>

Centre number (if applicable), Study number (if applicable), title of project, and name of Chief Investigator (CI) should be typed onto the form before submission for required approval(s).

Participant ID Number for this form should be left blank. This should be entered by the researcher during the consenting process.

**Statement 1**: This **must** be included in the consent form. **The version number and date of the Participant Information Sheet (PIS) should be left as per template during submission of the form**. The relevant version number and date can be typed onto the form or handwritten on prior to participant completion. This ensures the consent form will not have to be resubmitted for approval if the PIS is amended in the future.

**Statement 2**: This **must** be included in the consent form.

**Statement 3**: This **must** be included in the consent form. Select the section of text relevant to your study (depending on NHS involvement).

**Statement 4**: This should be included in the consent form **if you intend to notify the GP** of the participant’s inclusion, otherwise please remove.

**Statement 5**: This should be included in the consent form if you intend to use recording devices. If you intend to use anonymised quotations for publications, permission for this should also be sought and included in this section. If this is not required, please remove. If you are using an external transcription service please state this and gain consent to do so.

**Statement 6**: This **must** be included in the consent form if you intend to take any sample(s) from participants. Otherwise please remove.

**Statement 7**: This **must** be included and edited to state which server(s) any electronic data will be stored on.

**Statement 8**: This **must** be included in the consent form for **all** projects.

**Optional points:** Anything that is deemed “optional” for participants **must** be clearly marked as so. Some common examples have been included in this template. These are **examples** and should be reviewed and removed if not applicable.

**Signatories:** Please note: If consent is being received by a supervised student, an extra signatory line must be added for the person supervising the consent process.

**Remember – only persons delegated by the PI on the delegation log are permitted to receive consent.**

**Consent form**

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| --- |
| **Centre Number (if applicable): Study Number (if applicable):** |
| **Participant ID Number: Title of Study:** |
| **IRAS reference:** |
| **Name of CI:** |
| **Please initial** |

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| --- | --- | --- | --- |
| 1. I confirm that I have read and understand the information sheet Version No: *<Current version No>* Date: *<Current version date>* 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, without giving any reason, without my medical care or legal rights being affected. Data collected up until the point of withdrawal may still be used in analysis.   ***OR FOR HEALTHY VOLUNTEERS:***  *I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected. Data collected up until the point of withdrawal may still be used in analysis.*  ***OR FOR STAFF:***  *I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my employment or legal rights being affected. Data collected up until the point of withdrawal may still be used in analysis.* | | |  |
|  | | |  |
| 1. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the University of Aberdeen, from regulatory authorities if appropriate, or from the NHS Board/Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.   ***OR FOR A PROJECT WITH NO NHS INVOLVEMENT (e.g. healthy volunteers or staff):***  *I understand that data collected during the study, may be looked at by individuals from the University of Aberdeen, the regulatory authorities if appropriate, or from the NHS Board/Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.* | | |  |
|  | | |  |
| 1. I agree to my GP being informed of my participation in the study. | | |  |
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| 1. I agree to my interview being audio/video recorded.   ***IF USING A THIRD PARTY TRANSCRIPTION SERVICE (remove if not required):*** *I agree to my interview being audio/video recorded. I agree that my interview may be transcribed by an external company contracted by the University of Aberdeen/NHS Grampian (delete as appropriate)*  ***IF USING ANONYMOUS QUOTES FOR PUBLICATION*** *(add to the relevant text if required): I understand that anonymised quotations from this interview may be used for presentations and publications.* | | |  |
|  | | |  |
| 1. I agree to give a blood/tissue/biopsy sample for this study. | | |  |
|  | | |  |
| 1. I agree for my information to be stored on *(please insert whether UoA or NHSG servers. This may be both).* | | |  |
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| 1. I agree to take part in the above study. | | |  |
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| ***Optional:*** | | | **Please initial** |
|  | | | Yes No |
| I agree that the research team may access my medical records to gather relevant information in relation  to my taking part in this research project. | | |  |
|  | | | Yes No |
| I agree that the study team may have long-term access to my medical records for *xxx* *months/years* to follow up my condition and treatment as relevant to this research project. | | |  |
|  | | | Yes No |
| I agree that my anonymous data/images/*add as necessary* may be used in future ethically reviewed and approved research. | | |  |
|  | | | Yes No |
| I agree that I may be contacted by the study team to take part in future ethically reviewed and approved studies. I understand that identifiable contact information will be kept after the end of this study and this information will be held in accordance with the UK’s data protection laws. | | |  |
|  | | | Yes No |
| I agree to the storage and use of my samples for ethically reviewed and approved future studies. | | |  |
|  | | | Yes No |
| I wish to receive a copy of the results once available. I understand that my identifiable contact details will  be kept securely for this purpose and that these will be stored in line with the UK’s data protection laws. | | |  |
|  | | | Yes No |
| I agree that anonymised data may be shared with *insert funder/collaborator/3rd party as required*. | | |  |
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|  | | |  |
|  | | |  |
| **Name of participant** | **Date** | **Signature** | |
|  |  |  | |
| **Name of researcher** | **Date** | **Signature** | |

***One copy for participant, one copy for researcher, one copy with hospital notes (if applicable)***

***Insert version number and date (in footer)***