Note: In most circumstances, to be GDPR compliant, you will need a consent process that includes two steps:

The first step of the consent process is the “Letter of Information” which is what we typically think of as the body of consent. To create the Letter of Information, you should use the appropriate NU IRB approved consent template that fits with your study and simply remove the Optional Elements and the signatures which come at the end of our consent template.

The second step of the consent process is what is referred to as the “Consent Document” and it follows the Letter of Information. The GDPR Compliant Consent Document is intended to include short concise sentences (see below) of the activities of the research study and what the participant is agreeing to after having read all of the details in the Letter of Information.

For Greater than Minimal risk studies, the Consent Document must be a separate document from the Letter of Information.

For Minimal Risk studies, the Letter of Information can have the “Consent Document” attached but it must be separated by a page break and titled as the “Consent Document.”

Delete any text in red. Delete all elements that do not apply to your study. Add any additional elements that are relevant to your study.

**CONSENT DOCUMENT**

**Title of Research Study:**[insert title of research study here]

**STU#:** [insert NU study number]

**Principal Investigator:**[insert name of principal investigator]

**Supported By:**[List all monetary and non-monetary support for this research. If not externally funded, state your school or department] This research is supported by \_\_\_\_\_\_\_\_\_\_\_\_\_.

|  |  |  |
| --- | --- | --- |
|  |  | *Please initial each box* |
| 1 | I confirm that I have read and understand the Letter of Information version dated \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. |  |
| 2 | I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without any adverse consequences [academic or other penalty]. |  |
| 3 | I understand that research data collected during the study may be looked at by designated individuals from Northwestern University where it is relevant to my taking part in this study. I give permission for these individuals to access my information and research data. |  |
| 4 | I understand that the researchers will not ask about child [or elder] abuse, but if I tell them about child [or elder] abuse or neglect, they may be required or permitted by law or policy to report to authorities. |  |
| 5 | I understand that this project has been reviewed by, and received approval by the Northwestern University Institutional Review Board. |  |
| 6 | I understand who will have access to personal data provided, how the data will be stored and what will happen to the data at the end of the project. |  |
| 7 | I understand how this research will be written up and published. |  |
| 8 | I understand how to ask a question, raise a concern or make a complaint. |  |
| 9 | I consent to being audio recorded. |  |
| 10 | I consent to being video recorded. |  |
| 11 | I consent to having my photograph taken. |  |
| 12 | I understand how audio recordings / videos / photos will be used to aid in data analysis. |  |
| 13 | I understand the results of this study may be used for teaching, publications, or for presentation at scientific meetings. |  |
| 14 | I agree to take part in the study |  |
| 15 | I agree for research data collected in this study to be given to researchers, including those working outside of the EU, to be used in other research studies. I understand that any data that leave the research group will be fully anonymised so that I cannot be identified. |  |
| 15 | I agree for my personal data to be kept in a secure database for the purpose of contacting me about future studies. |  |

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Signature of participant Date

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

Printed name of participant

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Signature of person obtaining consent Date

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

Printed name of person obtaining consent