**NIMH Documentation of Informed Consent Template**

***Tool Summary*** *(Remove Tool Summary before finalizing and distributing the document)*

***Purpose:*** *This template may be used to record and document the informed consent process.*

***Audience/User:*** *Principal Investigator and study team members who are delegated to obtain informed consent*

***How to Use This Template***

*This template contains two types of text: instruction/explanatory and example text.* ***Instruction/ explanatory text*** *are indicated by italics and should be deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included.* ***Example text*** *is included to further aid in document development and should either be modified or deleted. Example text is indicated in [brackets in regular font]. Within example text, a need for insertion of specific information is notated by <angle brackets>. Example text can be incorporated as written or tailored to a particular document. If it is not appropriate to the document, however, it too should be deleted.*

***Version control*** *is important to track document development, revisions, and amendments. It is also necessary to ensure that the correct version of this document is used by all staff conducting the study. With each revision, the version number and date located in the header of each page should be updated.*

**NIMH Documentation of Informed Consent Template**

Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol#: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Consent obtained by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |
| --- | --- | --- |
| **Topic** | **Yes/No** | **Initials of person verifying** |
| Discussed, explained and reviewed the consent form with subject. |  |  |
| Subject was given time to review the consent form and to discuss participation in this study with family members/others. |  |  |
| All of the subject’s questions were answered/concerns addressed. Document below.  |  |  |
| Subject did not have any questions/concerns. |  |  |
| The subject has agreed to participate in the study and signed/dated a valid consent form prior to the start of any study procedures. |  |  |
| A copy of the signed and dated consent form was given to the subject. |  |  |
| The original signed and dated consent form was placed in the research record. |  |  |

Signature/initials: Date:

Study was discussed/consent reaffirmed:

|  |  |  |  |
| --- | --- | --- | --- |
| Date | Time | Comments/Notes | Staff initials |
|  |  |  |  |
|  |  |  |  |