

Guidance on Additional Attachments for Researchers

NOTE: All consents and assents, as well as HIPAA and IAA forms may be accessed by going to our [website](#).

Consents and Parental Consents

Consenting is a process, it begins with the initial question to the participant asking if they want to be in the study, through the entire consent process, to all follow-up information given to participants on a study, the completion of the study and sometimes in follow-up information after participation has ended.

The actual consenting procedure may be done in steps: 1) if the participant is interested the researcher or one of the researcher team who are qualified on the study needs to go over the consent with the participant; 2) sometimes the participant takes the consent home to discuss with family/friends; and 3) at the next visit, the participants indicates willingness to sign after speaking again with the research team and the investigator to discuss additional questions.

Remember to use the forms on our website as a guidance. Please note that there are two versions of each consent form, one with HIPAA and one without HIPAA information merged into the consent language. These are marked clearly in the upper right hand corner of the document. Be sure to use the correct version. The Only Minimal Risk consents (with or without HIPAA) are used for procedures where the risks are no more than encountered in daily life. The More than Minimal Risks (with or without HIPAA) include drug or device studies, but also studies where there could be risk to the participants' social, economic, or emotional standing in society.

All consent forms and assents are templates. These should be edited to accommodate your particular study. Do not leave the instructions or the parentheses in the documents, take out any language that does not pertain to your research (such as the sentence regarding audiotaping or child abuse).

Unless a consent form alteration or waiver is requested with appropriate justification as described in the Consent Procedures section of the protocol Questionnaire, all consents must provide the basic elements of information to potential subjects listed below.

1. A statement that the study involves research; an explanation of the purposes of the research and the expected duration of the subject's participation; a description of the procedures to be followed; and identification of any procedures which are experimental; a description of any reasonably foreseeable risks or discomforts to the subject. If the study is more than minimal risk, describe the risks as frequent, less frequent and rare.
2. A description of any benefits to the subject or to others which may reasonably be expected from the research; these should be described as a benefit which may or may not occur.
3. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject, the consent form should always state that the participant may choose not to participate.
4. A statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained.

5. For research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available, please be sure to use the standard wording on the template.
6. An explanation of whom to contact on the research team for answers to pertinent questions about the research or to voice concerns or complaints about the research, and whom to contact in the event of a research-related injury to the subject.
7. Contact information for the IRB office to obtain answers to questions about the research; to voice concerns or complaints about the research; to obtain answers to questions about their rights as a research participant; in the event the research staff could not be reached; and in the event the subject wishes to talk to someone other than the research staff.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
9. For FDA-regulated studies, the possibility that the Food and Drug Administration may inspect the records needs to be included in the statement regarding subject confidentiality. Do not include this statement if the study does not involve drugs or devices.
10. For clinical trials, by federal regulation the following required language must be incorporated verbatim and *cannot be altered in any way*: *“A description of this clinical trial will be available on www.ClinicalTrials.gov as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.”*

Have signature lines for the participants and for the researcher obtaining consent, and offer a copy of the form to the participant.

If the study includes surveys, interviews, or questionnaires, the participant must be given the opportunity to see these before enrolling. This information should be given in the Description of Procedures section.

If there is likelihood that these surveys, interviews or questionnaires could lead to discomfort or stress, a counseling referral list needs to be attached to the consent form and should also be noted in the Description of Procedures section.

Additional elements of informed consent to be applied, as appropriate:

1. A statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable. (For example: Include when the research involves investigational test articles or other procedures in which the risk to subjects is not well known.)
2. A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. (For example: Include when the research involves pregnant women or women of childbearing potential and the risk to fetuses of the drugs, devices, or other procedures involved in the research is not well known.)
3. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent. (For example: Include when there are

anticipated circumstances under which the investigator may terminate participation of a subject.)

4. Any additional costs to the subject that may result from participation in the research. (For example: Include when it is anticipated that subjects may have additional costs such as for procedures, visits, babysitting, parking, and travel.)
5. The consequences of a subject's decision to withdraw from the research. (For example: Include when withdrawal from the research is associated with adverse consequences.)
6. Procedures for orderly termination of participation by the subject. (For example: To avoid further complications, the subject may need to go through a washout period for their safety.)
7. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject. (For example: Include when the research is long term and interim information is likely to be developed during the conduct of the research.)
8. The approximate number of subjects involved in the study. (For example: Include when the research involves more than minimal risk.) Multi-center trials should give the number of participants total from all sites.

For FDA-regulated clinical trials, when a subject withdraws from a study, the data collected on the subject up to the time of subject withdrawal will remain part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed.

For research not subject to FDA regulations, the investigator should inform subjects whether the investigator intends to either: (1) retain and analyze already collected data relating to the subject up to the time of subject withdrawal; or (2) honor a research subject's request that the investigator destroy the subject's data or that the investigator exclude the subject's data from any analysis.

Have signature lines for the participants and for the researcher obtaining consent, and offer a copy of the form to the participant.

If children between the ages of 7 and 17 are involved, there must be a parental consent. Only parents may agree to allow children's PHI data to be collected.

Parental Consents

Parental Permission and Assent

Parental permission may NOT be waived for FDA regulated research.

Parents or guardians must be provided with the basic elements of consent and any additional elements the IRB deems necessary.

It is possible to combine the parental consent with an assent form, if the following two conditions are met:

1. If the researcher is meeting the parent or guardian and the child at the same time to discuss participation. The investigator must make every effort to explain the study to the child and the child must agree.

2. If the child is under 12 years of age. However, any child older than 12 must sign a separate assent form (unless the child is of diminished capacity).

If the above is true, please add the following wording to the very end of the parental consent form after the signature lines: “My child appears to understand the research to the best of his or her ability and had agreed to participate.” Then add signature lines for the parent.

Assents

Assents must be used for children aged 7 through 17. The WVU IRB defines minors as persons under eighteen years of age.

Adequate provisions must be made for soliciting the assent of children and the permission of their parents or guardians. The Assent form must be written in age appropriate language. The researcher may need to use a number of assent forms to accommodate various age groups (e.g. 7 -10 year olds, 11 – 13 year olds, 14 -17 year olds).

The child must have the opportunity to see any questionnaires before signing and be told that they may skip any questions.

The researcher may not include request for HIPAA information in an Assent form. No child may give permission to collect HIPAA data.

When writing an Assent form, the researcher must:

1. State that this is research and tell why the research is being conducted;
 2. Describe what will happen and for how long or how often;
 3. Say it's up to the child to participate and that it's okay to say no;
 4. Explain if it will hurt and if so for how long and how often;
 5. Say what the child's other choices are;
 6. Describe any good things that might happen;
 7. Say whether there is any compensation for participating; and
 8. Include a statement asking the child if they have any questions.
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HIPAA

Please note that health information includes blood pressure, medications, physician or counseling visits, mental health issues, past illnesses, etc., but also must include an identifier – such as a medical record number, the individual’s name, actual dates, zip codes etc. (the 18 HIPAA identifiers can be found [here](#)). Both of these conditions, health information and identifier, must be met if the study is to fall under the HIPAA regulations.

If health information is de-identified when you receive it, it no longer is subject to the Privacy Rule and is therefore exempt from HIPAA.

All the following forms are for research involving HIPAA and can be found on our [website](#). The forms need to be completed and then uploaded to the *Notes and Attachments* section.

The consent form with HIPAA is the most commonly used form. The HIPAA information is under the Confidentiality section of the consent form. We strongly recommend using the templates on the ORIC website. They are clearly labeled as to which forms include the HIPAA language.

HIPAA Waiver Form: This form is to be used for most expedited category 5 studies. Any time medical records or charts are reviewed containing medical information without prior consent authorization, a HIPAA waiver form is needed.

HIPAA Form – This form is *only* to be used if the researcher needs to use a separate, stand-alone HIPAA form as required by the sponsor.

HIPAA Data Use Agreement: This form is meant to be used between two covered entities where identifiable HIPAA data is exchanged. These must be reviewed by Legal Counsel. The Limited Date Set Form is part of the Data Use Agreement.

HIPAA Decedents: This form is to be used when identifiable HIPAA information is used from deceased persons.

HIPAA De-Identification Certification Form: This is only to be used with an NHR and is to certify that the data was de-identified by a third party who is not on the research team.

HIPAA Privacy Authorization Form: This is only for VAMC researchers.

IAA

An IAA is an Inter-Institutional Authorization Agreements. There are two types of IAAs

1. One where WVU is the IRB of record. When [IAA – Individual Protocol – WVU IRB of Record](#) is used, the PI is asking that the submitted protocol can also be used at another institution. The other institution then agrees that the protocol can be used at their site as approved by WVU. Upon our IRB review, the IAA form will be signed by the ORIC office. The protocol must be submitted as usual for that type of review. The difference is that the IAA form must be attached for WVU to sign. Once the protocol is approved through normal review the IAA form will be signed, scanned, and uploaded into the *Notes and Attachments*. The researcher should then send the form to the other institution for signature. Once signed by both institutions the researcher needs to send a copy to IRB staff for filing, and keep one fully signed copy for themselves.
 2. The other situation is where the other institution is the IRB of record. In that case the PI need only send the [IAA – Individual Protocol – Non-WVU IRB of Record](#) form, accompanied by.
 - a) The IRB approval from the other site
 - b) A short summary of the study
 - c) These should be sent to the IRB office as an email attachment. The IRB staff may consult with an IRB member to judge whether we can accept the other site's review.
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