



# Guidance on Informed Consent & Assent

Office of Research Integrity & Compliance

Version 2

Updated: June 23, 2017

This document is intended to educate researchers and reviewers on the elements of informed consent. If further assistance or clarification is required, please contact the ORIC at 304-293-7073, or at [IRB@mail.wvu.edu](mailto:IRB@mail.wvu.edu).

When completing the consent process, a copy of the signed informed consent document should be given to the research participant to keep.

## Contents

Elements of Informed Consent .....	2
Additional Elements of Informed Consent.....	3
FDA-Regulated Trials.....	3
Parental Consent.....	4
Assent from Minors .....	4
HIPAA .....	5
Personnel .....	5
Vulnerable Populations.....	5
Inter-Institutional Authorization Agreements (IAAs).....	6

## Elements of Informed Consent

Unless an Alteration of Informed Consent or Waiver of Informed Consent is requested and granted, all consent documents must provide the following, basic information, to the research participant. These elements should be also be included in Parental Consent Forms, for when parents are asked to consent for their child to participate in a research study.

1. A statement that the study involves research;
2. An explanation of the purpose of the research;
3. A statement regarding the expected duration of the subject's participation;
4. A description of the procedures to be followed;
5. Identify any procedures which are experimental;
6. Describe any reasonably foreseeable risks or discomforts to the subject;
7. A description of any benefits to the subject or to others which may reasonably be expected from the research;
8. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
9. A statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained;
10. 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;
11. 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;
12. Contact information for the IRB 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.
13. 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;
14. 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.
15. For clinical trials, by federal regulation the following required language must be incorporated verbatim and cannot be altered in any way:
  - a. "A description of this clinical trial will be available on [www.ClinicalTrials.gov](http://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."

## Additional Elements of Informed Consent

The following additional information should be included in the consent form, when applicable:

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.
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 for driving, overnight stays, babysitting, parking, etc.)
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: Include when the protocol describes such procedures.)
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.)

## FDA-Regulated Trials

For FDA-regulated clinical trials, when a subject withdraws from a study, the data collected on the subject to the point of withdrawal 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
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
3. 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. Also, if PHI is collected, the consent and/or parental consent used must state at the top right corner "with HIPAA."

## Parental Consent

Parental permission must be given for minors (any participant under 18) to participate in the research. Please refer to the [WVU Human Research Protections Program SOP](#) (Section 6.7) for more information regarding the consent process for research involving minors.

In general:

1. Parental consents must give permission for use of HIPAA (if necessary). The child cannot do so.
2. Parental permission may not be waived for FDA regulated research.
3. Parents or guardians must be provided with the basic elements of consent and any additional elements the IRB deems necessary. Please see above for information regarding the basic and additional elements.

**Note:** On the [IRB Forms](#) page of the ORIC website, WVU offers a parental consent form with assent, which contains the following:

“My child appears to understand the research to the best of his or her ability and had agreed to participate”

This may only be used if:

- a. 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; *and*
- b. The child must be under 12 years of age.

## Assent from Minors

Assent forms must be used for children aged 7-17. The WVU IRB defines minors as persons under the age of 18. Be sure that the IRB application includes adequate provisions for soliciting the assent of children, and the permission of their parents or guardians.

The assent form must be written in an age appropriate language with no jargon or technical terms in order to facilitate comprehension. Before signing the assent form, the child must have the opportunity to see any questionnaires and be told that they may skip any questions that they do not wish to answer.

**Note:** No child may give permission to collect HIPAA data.

The assent form must include the following:

1. A statement 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.
8. Ask for questions.

## HIPAA

Keep in mind that if information is de-identified, it is no longer subject to the Privacy Rule and is exempt from HIPAA. All of the following forms are for research purposes, and can be found under the [IRB Forms](#) page of the ORIC website. For more information regarding HIPAA, please see Section 16 of the WVU HRPP SOP.

**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 Data Set Form is part of the Data Use Agreement.

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

**HIPAA Form:** This form is only to be used if the researcher needs to use a separate HIPAA form as required by the sponsor. Everyone else should use the consent form with HIPAA. Almost all of the researchers use the combined form.

**HIPAA Waiver Form:** This form is to be any time medical records or charts are reviewed without prior consent authorization. This form typically accompanies category 5 expedited protocols.

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

## Personnel

All personnel including students and residents need to be listed in the Personnel Section of the IRB protocol application. There are some cases where study personnel are so numerous that the PI can attach a list of these persons, which will be checked by ORIC staff for training. The investigators and co-investigators must be listed in the Personnel Section of the protocol application.

The consent form should name the investigator and all co-investigators. If the PI intends to use other personnel to obtain consent, and they are not numerous, they should also be named on the consent. On the other hand, if there are numerous persons, the consent form should state “the consent has been explained to you by \_\_\_” and the qualified person’s name should be printed in; this should be in the introduction.

If anyone other than the PI or Co-I is obtaining consent, this needs to be indicated in the Questionnaire under the Consent Procedures section. The PI needs to confirm that all personnel obtaining consent have been trained, are well-versed in the study, and can answer questions from participants.

## Vulnerable Populations

For more information regarding vulnerable populations in research, please see Section 6 of the WVU HRPP SOP’s. The proposed research is targeting vulnerable populations:

1. If WVU students are involved, the PI must state that the students are informed in the cover letter of consent that the study is completely voluntary and their grade(s) will not be affected by their decision to participate or withdraw from the study.
2. If WVU employees are involved, the consent should say that their employment status will not be affected by their decision to participate or withdraw from the study.
3. If the targeted population is cognitively impaired, the PI has to explain how cognition is assessed. If the mental capacity of the participant is determined to be over 7 years of age, an assent is needed along with a parent/guardian consent.
4. If prisoners are targeted, the study must be reviewed at a convened full board meeting and a prisoner representative must be consulted.

## Inter-Institutional Authorization Agreements (IAAs)

An IAA is an agreement between WVU and a collaborating institution with a registered IRB. There are two types of IAAs:

1. WVU is the IRB of record: This agreement is used when the PI is asking that the submitted WVU protocol be used at another institution. The other institution then agrees that the protocol can be used at their site, as approved by WVU. Upon completion of the WVU IRB review, the ORIC will process the agreement and return it to the WVU PI for their records.
2. WVU is not the IRB of record: This agreement is used when a WVU researcher wishes to conduct an approved protocol (from another institution) at WVU. A submission to the WVU IRB is still required; however, the PI only needs to write in the Questionnaire section of the application 'See Attached Protocol Documents,' and attach:
  - a. The IRB Approval Letter from the other site/institution
  - b. The IRB approved protocol from the other site, including recruitment, investigational, standard of care (if applicable), and consent procedures.
  - c. The IAA form should be signed by the other site/institution before being submitted to the ORIC and attached to the protocol.

**Note:** The WVU IRB reviewer should judge whether we can accept the other site/institutions review of the proposed research.