

Guidance on Additional Attachments for Reviewers

Consents and Parental Consents

Unless a consent form alteration or waiver is requested, all consents must:

To be valid, the consent process must provide the following basic elements of information to potential subjects:

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;
2. A description of any benefits to the subject or to others which may reasonably be expected from the research;
3. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
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;
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 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.

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.”

A copy of the signed and dated consent form must be given to the person signing the form.

Additional elements of informed consent to be applied, as appropriate: Page 101 of [SOPs](#)

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.)
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.)

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; 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.

If PHI is collected the consent and/or parental consent used must state at the top left corner with HIPAA.

Parental Consents

[SOPs 6.7.2](#): 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, as described in Section 5.4 of the [SOPs](#).

There is a parental consent form with assent containing the wording: "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: 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. And 2) if the child is under 12 years of age.

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 are made for soliciting the assent of children and the permission of their parents or guardians.

Must be written in age appropriate language.

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

No child may give permission to collect HIPAA data.

Assent form must contain:

1. 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. Ask for questions.
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Expedited Categories and what it means to the reviewer:

Involves no more than minimal risk AND is on this list

1. Clinical studies of medical devices – if a commercially used device and no investigational device exemption is needed
 2. Blood samples – the amount and frequency is detailed in the RFF and the **SOPs**.
 - 3, Prospective collection of biological specimens by noninvasive means; Remember tissue samples and body fluids require an IBC approval.
 4. Collection of data through noninvasive procedures routinely employed in clinical practice. There is a complete list of these in the documents. We have expanded that list for C-PASS and Engineering studies for physical exercise and physical measurements.
 5. Research involving material that have been collected for nonresearch purposes. Often this category is used for medical record review with identifiers. In that case the PI must also submit a consent form waiver as well as a HIPAA waiver.
 6. Collection of data from voice, video, digital or image recordings.
 7. Research on individual or group characteristics or behavior employing surveys, interviews, etc.
 8. A protocol that was originally reviewed per full board procedures and is up for continuing review where 1) no enrollment has begun, 2) enrollment is complete and only long term follow-up is conducted or 3) study is only open for data analysis. These can be reviewed per expedited review.
 9. A protocol that was originally reviewed by the full board for review of a device, where the Board determined at the meeting that the research is no greater than minimal risk and no additional risks have been identified may be reviewed as expedited continuing review.
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HIPAA

[SOPs](#): Page 185

If information is de-identified it no longer is subject to the Privacy Rule and exempt from HIPAA.

All the following forms are for research and can be found under forms on the oric.research.wvu.edu website.

HIPAA Form – This one 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 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 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 this form 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.
- 2) The other is where the other institution is the IRB of record. In that case the PI need only write in the Questionnaire see attached protocol pages and attach:
 - a) The IRB approval from the other site
 - b) The IRB approved protocol from the other site
 - c) The IAA form signed by the other site.

The IRB reviewer should judge whether we can accept the other site's review.

Personnel

All personnel including students and residents need to be listed in the Personnel Section. 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 me by _____” and the qualified person’s name should be printed in. 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.

Vulnerable Populations

The target group is vulnerable

- If students, the PI must state that students are informed in the cover letter or consent that the study is completely voluntary and their grades will not be affected.
 - If employees, the consent should say their employed status is not affected.
 - If the population is cognitively impaired then the researcher has to explain how cognition is assessed. If mental capacity is over 7 years of age, an assent is needed with a guardian consent.
 - If prisoners, the study must be reviewed per full board and a prisoner representative must be consulted.
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Initial Review of Research Proposal

1. The PI should identify the potential to enroll vulnerable subjects in the proposed research at initial review and provide the justification for their inclusion in the study.
2. The IRB evaluates the proposed plan for consent of the specific vulnerable populations involved. If the research involves adults unable to consent, the IRB evaluates the proposed plan for permission of legally authorized representatives.
3. The IRB evaluates and approves the proposed plan for the assent of participants.

4. The IRB evaluates the research to determine the need for additional protections and consider the use of a data and safety monitoring board or data monitoring committee as appropriate.
5. The PI should provide appropriate safeguards to protect the subject's rights and welfare, which may include the addition of an independent monitor. The independent monitor is a qualified individual not involved in the research study who will determine the subject's capacity to provide voluntary informed consent.
6. Examples of studies that warrant independent monitoring include those involving schizophrenic patients who will be exposed to placebo, and/or drug washout, and/or treatment with agents that are not approved by the Food and Drug Administration (FDA). Populations requiring independent monitoring would include individuals with schizophrenia, other psychotic disorders or conditions characterized by lack of reality testing (i.e., psychosis). Populations not usually requiring independent monitoring would include those with substance use disorders.
7. The IRB assess the adequacy of additional protections for vulnerable populations provided by the PI.