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**OBTAINING INFORMED CONSENT IN HUMAN SUBJECTS RESEARCH**

**POLICY**

No investigator may involve a human being as a participant in research unless the investigator has first secured the participant’s informed consent or the IRB has waived the requirement that informed consent be obtained. If the participant is not competent to give informed consent, the investigator may get informed consent from a legally authorized representative. The “legally authorized representative” is determined by the law of the state where the research is being conducted. In many jurisdictions, the representative who can give informed consent for medical procedures is not the same as the representative who can give consent for research procedures. Under Ohio law, the Legally Authorized Representative/Guardian is/are individuals authorized to consent on behalf of a prospective subject to the subject's participation in the types of procedures involved in the research conducted by the organization and are "any person, association, or corporation appointed by the probate court to have the care and management of the person, estate, or both of an incompetent or minor". See Ohio Code 2111.01. For example, in Ohio, a family member may not give consent to research for an incompetent adult except in an emergency situation, even though the family member may give consent to medical procedures. In the case of VA patients, these criteria are consistent with those employed by the Department of Veterans Affairs but take precedence. When feasible, the participant who cannot give informed consent must assent to the research.

**THE INFORMED CONSENT PROCESS**

* The Informed Consent Process will be described in the protocol or petition and reviewed by the IRB.
  + The IRB approval of the wording contained within the consent document will be shown through the use of a stamp placed on each page of the informed consent that indicates the date of the most recent IRB approval of that document.
* The investigator or other study personnel who conduct the consent process must present information objectively so as to minimize the possibility of coercing the individual to participate or using undue influence.
* Prospective participants must be given sufficient time to consider whether to participate in the study and must have the opportunity to have all their questions answered.
* The researcher must provide information in language that is understandable to the participant.
* When the IRB believes appropriate, the investigator may be required to use tools or techniques that assess and confirm a participant’s understanding of the consent. Such techniques may include using a written comprehension tool, requiring a friend or family member to be present, requiring a waiting period or prior approval of the research by a community review board.
* The informed consent process will not contain any language through which the participant waives or appears to waive any legal rights or releases the investigator, the institution, the sponsor or its agents from liability for negligence.
* The IRB, the Institutional Official, or the designee of any of these has authority to observe the consent process for any approved study. This may be done as one means to protect participants, particularly if there is cause for concern (for example, if there have been complaints registered by participants). The IRB coordinator will make arrangement with the researcher should this be desired.

**DOCUMENTATION OF INFORMED CONSENT**

Unless the IRB has waived the requirement for written informed consent, the investigator must get documentation of informed consent by use of a written consent form, approved by the IRB that is signed and dated by the participant or the participant's legally authorized representative. This consent must embody the basic and appropriate elements of disclosure (see following section). All informed consent forms should be written at a level appropriate for the potential population. General formatting, readability and clarity must be acceptable to the IRB, and medical terminology must be defined in lay terms, ideally at a 7th grade (or lower) reading level. The participant (or the participant’s legally-authorized representative) must be given adequate opportunity to read the consent document before it is signed.

In addition to the signature of the subject providing consent, the person obtaining consent of the subject must also execute the consent form. These individuals must: 1) complete required human subjects protection training; 2) complete a Significant Financial Interest Disclosure; 3) be listed on the IRB petition and approved by the IRB as “investigator” or “key personnel”; 4) be trained on the protocol as documented in writing; and 5) delegated by the principal investigator to obtain informed consent. Note that for studies involving medical treatment, the physician investigator ordering and overseeing the treatment will determine subject eligibility but may sign the informed consent form proximate to the date of the subject’s enrollment when not immediately available. For multi-center studies, the sponsor may identify who will obtain informed consent and how this will be documented. Please consult with the IRB office, the sponsor, the performing location (e.g. hospital), etc. for guidelines to follow.

1. The IRB discourages the use of a signature/initial field on each page as this does not add to the consent process, and is easily missed resulting in noncompliance.
2. The IRB does not require (but does not forbid) that the time of consent be documented in the signature fields.

The researcher will give a copy of the signed informed consent to the participant, and the original will be placed in the research record maintained by the investigator. The IRB, the Institutional Official, the sponsor of the research, regulatory and accrediting agencies, and the designees of any of them are authorized to randomly review protocols for compliance with informed consent requirements.

The IRB may approve a telephonic consent procedure under which the subject’s legally authorized representative (“LAR”) is sent a faxed or hand-carried version of the informed consent document, a consent interview is conducted by phone while the LAR has the document in hand, and the LAR signs and returns the signed document to the investigator by return fax (or courier) before the subject is enrolled in the study. In cases where this process is used, a witness who is not connected to the study (e.g., as an investigator, coordinator, etc.) should monitor the consent process. Both the LAR and the incompetent adult patient must agree to participate. The LAR may not force the incompetent patient to participate against his or her will. The following may serve as legally authorized representatives:

1. A health care agent appointed by the person in a Durable Power of Attorney for Health Care (DPAHC) or similar document
2. A court-appointed guardian of the person

**REQUIRED ELEMENTS OF INFORMED CONSENT FORMS**

In accordance with 21 CFR 50.25, and 45 CFR 46.116, the following information will be provided to each participant:

1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
   1. **Differentiating Usual Care from Research.** This means the investigator provides for usual care. The subject needs to be able to identify which activity (e.g., treatment or service) is research, and which is usual care, and know who (the researcher or the subject’s health care provider) is responsible for:
      1. Explaining potential risks and benefits of the treatment or service to the subject;
      2. Providing the treatment or service;
      3. Monitoring the treatment or service, as applicable;
      4. Defining whether the adverse events result from usual care or research, as applicable;
      5. Alerting the subject if there is a problem with the treatment or service (e.g., a newly discovered risk, a product recall); and
      6. Documenting the subject’s clinical course while receiving the treatment or service, as applicable.
   2. This information will optimally be included in the consent document (or it must be documented how this information will otherwise be provided to the subjects)
2. A description of any reasonably foreseeable risks or discomforts to the participant.

**Note: Usual Care.** The investigator, or designee, must ensure the Informed Consent process clearly defines for the subject which potential risks are related to the research (see subpar. 10g and 38 CFR 16.116(a)(2)) and, therefore, must be discussed with the research team, versus those associated solely with usual care provided by the subject’s health care provider. For VA studies, the informed consent process **must** include language advising subjects to review the risks of the latter with their health care providers.

1. A description of any benefits to the participant or to others that may reasonably be expected from the research.
2. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the participant.
3. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. In the case of FDA-related research, the consent process must disclose a statement noting the possibility that the FDA may inspect the records. The consent form will include all individuals and organization that have access to a participant’s record, including the sponsor, funding entities, agents of Wright State University, and any other federal agencies.
4. For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained.
5. Protocols that are carried out at affiliated institutions (or institutions not a part of Wright State University) will carry only the compensation statement required by that institution’s specific policy.
6. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant.
7. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

**ADDITIONAL ELEMENTS OF INFORMED CONSENT**

When appropriate, one or more of the following elements of information will also be provided to each participant:

1. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus if the participant is or may become pregnant) that are currently unforeseeable;
2. Circumstances under which participation may be terminated by the investigator;
3. Additional costs to the participant that may result from participation in the research;
4. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;
5. A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant;
6. A statement about the amount and schedule of all payments.
7. The approximate number of participants involved in the study;
8. Additional information that, in the judgment of the IRB, would add meaningfully to the protection of the rights, safety, and well being of the participants.
9. Specific requirements exist for research that is to be carried out at the VA. These are discussed more fully at the end of this procedure. Specifically, VA-specific consent forms (form 10-1086), must be used.

Guidelines for drafting consent forms or cover letters are available at <http://www.wright.edu/rsp/IRB/Consent_Guide.doc>. The IRB encourages the use of the informed consent form templates available on its website.

**THE RESEARCHER’S OBLIGATION TO PROVIDE ADDITIONAL INFORMATION**

Researchers have an obligation to continue to provide information to participants or their legally authorized representatives throughout the study so that they can continue to consent to participation. If new information becomes available during the course of the study that could influence a participant’s decision, the researcher must inform the IRB, and if required by the IRB, must re-consent participants describing the new information.

**WAIVER OR ALTERATION OF SOME OR ALL ELEMENTS OF INFORMED CONSENT**

1. The IRB may approve a consent form which does not include, or which alters, some or all of the elements of the informed consent. In some cases this will occur because the study involves deception (the intentional misleading of subjects or the withholding of full information about the nature of the experiment). Federal regulations permit but establish limitations on the use of deception. The investigator must provide scientific and ethical justification for deceptive procedures for the IRB review and approval. The missing information should not increase the risks of the study, and subjects must be fully debriefed. Subjects must have the opportunity to ask questions about the new information and be given the opportunity to withdraw from the study and have their data removed. Deception may not be utilized to obtain enrollments.

The investigator must show, and the IRB must document in its approval, that all of the following criteria have been met:

1. The research involves no more than minimal risk to the participants;
2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
3. The research could not practicably be carried out without the waiver or alteration;
4. The research is not subject to FDA regulation.
5. When deemed appropriate, the IRB may require the investigator to prepare a written description of the research to be given to the participants (either before or after participation as appropriate to the study). The IRB will review this description as part of the approval process. If subjects have been deceived during participation in research activities, the WSU IRB expects investigators to debrief subjects after their participation. The debriefing should include a detailed description of the ways in which deception was used. The investigator is responsible for ensuring that the subject leaves the research setting with an accurate understanding of the deception. The debriefing process, including any written materials, should be explained to the IRB as a part of submitted protocols.
6. Consent may also be altered or waived for certain research or demonstration projects conducted by or subject to the approval of state or local government officials that are designed to study public benefit or service programs when the research is not subject to FDA regulation. See 45 CFR46 116 (C)

**WAIVER OF INFORMED CONSENT DOCUMENTATION**

Some research may not impose on the rights and welfare of human subjects so as to make informed consent a requirement. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all subjects in some cases when it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research (e.g., a cover letter). Examples of such research where use of a cover letter is generally appropriate are collecting data by survey or interview.

Any waiver of documentation by the IRB must be based upon clearly defensible grounds. A request for waiver of documentation by the PI must include justifiable reasons in the protocol. For research that presents greater than minimal risk of harm, a written copy of what the subjects will be told must also be submitted for review by the IRB at the time of the exemption decision.

**WAIVER OF ALTERATION OF THE PRIVACY RULE’S AUTHORIZATION (HIPAA) REQUIREMENT**

The Privacy Rule (45 CFR parts 160 and 164) establishes a category of health information, defined as protected health information (PHI), which a covered entity may only use or disclose to others in certain circumstances and under certain conditions. In general, the Privacy Rule requires an individual to provide signed permission, known as an Authorization under section 164.508 of the Privacy Rule, before a covered entity can use or disclose the individual’s PHI for research purposes. Under certain circumstances, however, the Privacy Rule permits a covered entity to use or disclose PHI for research without an individual’s authorization. One way a covered entity can use or disclose PHI for research without an Authorization is by obtaining proper documentation of a waiver of the Authorization by the IRB.

A waiver can occur when the IRB determines that no Authorization will be required for a covered entity to use or disclose PHI for a particular research project because certain criteria set forth in the Privacy Rule have been met. For example, if a study involved the use of PHI pertaining to numerous individuals where contact information is unknown, and it would be impracticable to conduct the research if Authorization were required, an IRB could waive all or the authorization requirements for research participants if the IRB determined that all of the Privacy Rule waiver criteria had been satisfied. If the IRB approves such a waiver, the receipt of the requisite documentation of the approval permits a covered entity to use or disclose PHI in connection with a particular research project without Authorization. A partial waiver of the Authorization requirements of the Privacy Rule might be requested, for instance, to allow a researcher to obtain PHI as necessary to recruit potential research subjects. For example, even if an IRB does not waive the Authorization requirement for the entire research study, an IRB may partially waive the Authorization requirement to permit a covered entity to disclose PHI to a researcher for the purposes of contacting and recruiting individuals into the study.

An IRB may also approve a request that removes some, but not all, required elements of an Authorization. For example, an IRB may alter the Authorization to remove the element that describes each purpose of the requested use or disclosure where, for example, the identification of the specific research study would affect the results of the study.

Requests for alteration on minimal risk studies (i.e. those originally approved by expedited review) may be approved by the IRB chair. Other requests may only be granted by the full IRB board. For a covered entity to use or disclose PHI under a waiver or an alteration of the Authorization requirement, the IRB must determine (and document in the minutes and to the investigator) that the following criteria have been met:

* 1. The PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on at least the presence of:
* (1) an adequate plan presented to the IRB to protect PHI identifiers from improper use and disclosure;
* (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and
* (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule
  1. The research could not practicably be conducted without the requested waiver or alteration
  2. The research could not practicably be conducted without access to an use of the PHI.

The IRB must specifically describe the PHI for which use or access has been determined to be necessary in connection with the specific research activity.

**OBTAINING CONSENT FROM THOSE WHO CANNOT SPEAK ENGLISH**

Individuals unable to speak English may not be excluded from participating in a study, unless the approved research protocol requires that subjects speak English. Investigators must provide an ethical and scientific justification for excluding non-English speaking subjects from research. Inconvenience or expense for the investigators is not an acceptable justification for excluding non-English speaking subjects.

The federal regulations (45 CFR 46.116 and 21 CFR 50.20) require that informed consent information be presented to a research subject “...in language that is understandable to the subject (or authorized representative)” and, except in infrequent situations, be documented in writing. Subjects who are not English - speaking should be provided with a translation of the consent document in a language understandable to them. The federal regulations (45 CFR 46.117 and 21 CFR 50.27) permit two methods by which this requirement can be fulfilled: (1) a written consent document translated into a language understandable to the subject (or their legally authorized representative), e.g., foreign language translation of the IRB approved English informed consent form or (2) a “short form” written consent document stating that the elements of consent have been presented orally to the subject (or legally authorized representative). The IRB determines which procedure is appropriate for documenting informed consent on a protocol specific basis. In general, the short form process (see below) is appropriate only for those occasions where a non-English speaking subject needs to be enrolled in a study that had not planned on enrolling persons speaking another language. Providing a written translation of the full English consent document is required when:

* The research targets a specific population that is non-English speaking
* A significant proportion of subjects are anticipated to be non-English speaking

The following should be submitted to the IRB for review and approval:

* 1. An English version of the informed consent document
  2. The consent document translated into the desired language(s). Information should be provided on who performed the translation and the qualifications of the translator to perform the translation (for example, expertise in the foreign language such as a certified translator, native speaker or other evidence of fluency, and an appropriate background to understand the information in the consent form). The researcher may perform the translation if he/she is qualified in the language.
  3. A back-translation of the translated consent document **or** certification from a translator that a back-translation of the consent was performed and found to be accurate. The back translation should be performed by a person OTHER than the original translator of the consent document. The name and qualifications of the back-translator should also be provided to the IRB.

Information should be provided in the study protocol about the process the investigator plans to use when obtaining consent from non-English speaking subjects. Unless the investigator is fluent in the participant’s language, a qualified translator must be included in the consent process (e.g. the consent discussion) and must also sign the approved, translated consent form as a witness.

**OBTAINING CONSENT FROM THOSE WHO CANNOT SPEAK ENGLISH OR ARE ILLITERATE**

Participants who are illiterate will also sign their mark on the signature line. When a study is expected to include illiterate participants, the investigator will describe during initial review how the consent process is to be carried out and will submit a “short form” consent document for approval (see below).

**SHORT FORM WRITTEN INFORMED CONSENT DOCUMENT**

A short form written consent document may be approved by the IRB for use when unexpectedly a research subject is to be enrolled who does not understand the language of the written consent. The Short Form process should not be used when the study plans or expects to enroll non-English speaking subjects.

The short form must state that all the required elements of informed consent have been presented orally to the participant or to the participant's legally authorized representative, and the IRB must approve a written summary of what is to be said to the prospective participant. When this method is used, there must be a witness to the oral presentation. For participants who do not speak English, the witness must be conversant in both English and the language of the participant

* The person obtaining consent will sign and date a copy of the summary.
* The witness will sign and date both the short form and a copy of the summary.
* The participant (or the participant’s legally-authorized representative) will sign and date the short form.

A copy of the signed and dated short form as well as a copy of the summary will be given to the participant or his/her legally-authorized representative..

**Requirement for VA Studies**

1. Informed consent must be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject’s legally-authorized representative and the person obtaining the informed consent. It is not necessary to have the signature of a witness (unless the short-form consent process is employed) or the IRB requires a witness.

Note: An individual who is qualified to be a LAR for research purposes may not always qualify as a personal representative for purposes of consenting to use or disclose a living subject’s PHI (i.e., signing a HIPAA authorization). Therefore, in circumstances involving authorization for use or disclosure of a subject’s PHI, the investigator must ensure the LAR meets the requirements of a personal representative in HIPAA and the Privacy Act of 1974 (legal guardian or power of attorney) prior to the LAR’s signing a HIPAA authorization (see VHA Handbook 1605.1).

2. For VA studies, VA Form 10-1086, or an electronic version of VA Form 10-1086, must be used as the consent form. The sponsor or the IRB may require a witness to the subject’s signature or to the consenting process in certain situations. The witness cannot be the same person who obtained informed consent from the subject, but may be another member of the study team or may be a family member. A copy of the signed and dated informed consent form must be provided to the subject or the subject’s LAR.

3. For research involving more than minimal risk, there must be an explanation as to whether any compensation is available and an explanation as to whether any medical treatments are available if injury occurs and if so, what they consist of, or where further information may be obtained. Specifically:

* Protocols that are carried out at VA institutions will carry out the treatment requirements according to Title 38 Code of Federal Regulations (CFR) 17.85 “Treatment of Research-Related Injuries to Human Subjects.” The VA must provide necessary medical treatment to a research subject injured by participation in any research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, the necessary care must be provided in VA medical facilities. Exceptions include: situations where VA facilities are not capable of furnishing economical care; situations where VA facilities are not capable of furnishing the care or services required; and situations involving a non-veteran research subject. Under these circumstances, Directors may contract for such care. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. The informed consent form needs to include language explaining VA’s authority to provide medical treatment to research subjects injured by participation in a VA research project. (Note: These regulations as described in 38 CFR 17.85 on research-related injuries also apply to minimal risk research).
* The regulations at 38 CFR 17.85 does not apply to research conducted for the VA under a contract with an individual or a non-VA institution (although veterans injured as a result of participation in such research may nevertheless be eligible for care from the VA under other statutory and regulatory provisions). Information on the responsibility for research-related injury under such circumstances must be included in the consent form.

1. VA consent documents should contain a statement that a veteran-subject will not be required to pay for care received as a subject in a VA research project except as follows:
   1. In accordance with Title 38 Unites States Code (USC) 1710 (f) and 1710 (g) certain veterans are required to pay co-payments for medical care and services provided by VA. Veterans receiving medical care and services from VA that are not rendered as part of the VA-approved research study, must pay any applicable co-payment for such care and services.
   2. Suggested wording for the consent form needs to note this requirement. For example: Some veterans are required to pay co-payments for medical care and services provided by VA. These copayment requirements will continue to apply to medical care and services provided by the VA that are not part of this study.”
2. A waiver or alteration of the requirements for informed consent does not apply to FDA regulated research.
3. A progress note containing the following must be placed in the participant’s medical record at the time of consent:
   1. The name of the study.
   2. The person obtaining the participant’s consent.
   3. A statement that the participant or the participant’s legally authorized representative was capable of understanding the consent process.
   4. A statement that the participant was given the opportunity to ask questions.
   5. A statement that the study was explained to the participant.

**Applicable regulations:**

45 CFR 46.116-117

21 CFR 50.20-27

VA Handbooks 1200.1 and 1200.5