Human Research Protection Program
Office of Research Assurances
Email: irb@wsu.edu
Web site: www.irb.wsu.edu

INFORMED CONSENT GUIDANCE

Justification of Review Requirements

The HRPP/IRB is responsible for reviewing informed consent procedures and materials to ensure the protection of the rights and welfare of human subjects and equitable participant enrollment. All proposed Informed consent procedures and materials must be approved by the HRPP/IRB before implementation and must comply with the informed consent and participant selection regulations pursuant to 45 CFR 46, 21 CFR 50.20, 21 CRF 50.25, and 21 CRF 56.111(a). Providing misinformation, even unintentionally, at the beginning of the informed consent process is not consistent with Part B: Basic Ethical Principles of the Belmont Report. Utilization of informed consent procedures or materials that differ from the approved protocol may lead to findings of non-compliance.

Obtaining Informed Consent

Researchers must obtain a valid **written** or **eSignature** from each participant who consents to the research, unless:

- The research qualifies for exemption under 45 CFR 46.104
- An addendum to request a waiver of consent or documentation of consent may be applied under 45 CFR 46.116 or 45 CFR 46.117.

Researchers should consider the cultural background of the population they are studying when obtaining informed consent. Depending on the culture of the population that is being studied and if their language has no written form, verbal consent may be more appropriate, and this justification should be included in your application and any applicable addendums submitted.

Resources for Developing Equitable Informed Consent Materials

- Informed consent templates are provided by the WSU HRPP/IRB to be a starting point for developing your informed consent materials. Please visit our Forms Index webpage to find informed consent templates relevant to your specific review level.
- Materials should be created to match the reading level of your prospective participants whenever possible. Resources for analyzing grade level appropriate language include but are not limited to:
  Readability Calculator
- If enrolling Non-English or English as a second language (ESL) participants, translations should be created and included in your submission packet for review. Resources for translation services include, but are not limited to:
  WSU Translation Services
- Informed consent materials should be created to be accessible to all whenever possible. Resources for how to format and create accessible materials, especially for people who use assistive devices include, but are not limited to:
  Creating Accessible Materials

Consent for Exempt Research

- Protocols qualifying for an exempt review are not held to the requirements for consent that are outlined in the federal regulations, however, ethical practices still need to be maintained when conducting research with human subject participants.
- The researchers must provide sufficient detail about the research to allow individuals to decide whether they wish to participate in the research or not.
    - When research requires the use of deception (or withholding some information about the true purpose of the study), a debriefing form must be provided to each participant following completion of the study.
- While written or eSignatures for consent are not required for exempt studies, there should be a consent *process* that includes the basic elements of consent presented to potential participants.
- Consent can be obtained in the form of a "click to agree" page prior to study procedures, a physical consent form, or through verbal consent.

Electronic Consent Guidance for Non-Exempt Research

While a wet signature is a traditional pen and ink signature, an electronic consent allows subjects to use a computer-based consent form. A person can access this via computer, mobile, phone, or another device. This allows subjects to see hyperlinks, videos, sound files, or other media that might enhance understanding of the consent process.

The following are electronic options for participants to provide informed consent:

1. **Electronic Signature** – An electronic signature is proof of "intent" to sign a document, but not an actual signature. Examples include a "Click to Agree" signature or a "cut and paste" signature.
    - **Please note:** The IRB may approve this under a waiver of documentation of consent. To request a waiver of documentation of consent, please complete and submit the Addendum: Informed Consent.
2. **Digitized Signature** – This can take different forms – (a) A contract is signed on paper as a wet signature, the document is then scanned or photographed and sent via email to the other party, or (b) A person signs a signature pad with a stylus. This can be further verified by having each party retain proof of the correspondence emails so that there is a "paper trail" of evidence – such as the email sending the documents back and forth, or the financial transaction record.
3. **Digital Signature** – A cryptographic signature. These usually contain a certificate of authority which confirms identity. Private vendors offer these such as Adobe, Windows, or DocuSign, however, there is a licensing and verification fee for each user. Another option is an internal verification system, such as the WSU validation of its internal users through Human Resources which allows, for example, the IRB to accept a protocol from a WSU PI's email address without a wet signature.
4. **Multi-Factor Authentication or Dual-Verification** - The user logs into a system by entering a name and password. A passcode is then sent to the user's personal device (such as a phone). The user enters that passcode into the system for a one-time "key" into the system.

The state of Washington considers a legal electronic signature to be one that has dual authentication. Both Qualtrics and REDCap are WSU-licensed platforms that allow dual authentication to be set up for electronic consent.

Guidelines for Developing Informed Consent Materials

The following should be included for both Exempt and Non-Exempt research (basic elements of consent):
Study title
PI's contact information: • First Last name • Phone number • Email address
Name of affiliate university and department
A brief description of the purpose of the research
A brief description of the eligibility criteria
A brief description of the procedures: • Participant involvement • Approximate time commitment required • Where the research will take place • The extent, if any, to which confidentiality of records will be maintained
A straightforward, truthful description of the benefits *If applicable *Note: Compensation is not considered a benefit*
A straightforward, truthful description of any risks and any planned protections in place to mitigate risks
A brief description of any compensation/reimbursement awarded for participation *if applicable
A statement that participation is voluntary, including: • Refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. • The participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled
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
Include HRPP/IRB placeholder approval language: • **Exempt studies:** "This study, IRB #####, has been certified as Exempt by the WSU Human Research Protection Program." • **Non-Exempt Studies:** "This study, IRB #####, has been approved for human subject participation by the Washington State University Institutional Review Board."
The IRB contact information: irb@wsu.edu, 509-335-7646, should participants have a question about their rights as a research participant
Additional criteria required for Non-Exempt research:
If form exceed 2,000 words, a "Key Information Section" needs to be included at the top of the form
Approximate number of planned participants to be enrolled
A statement about any external funding sources or financial conflicts of interest *If applicable
Any additional costs to the participant that may result from enrollment in the research*If applicable

Anticipated circumstances under which the participant's enrollment may be terminated by the investigator without regard to the participant or the legally authorized representative's consent *If applicable
The consequences of a participant's decision to withdraw from the research and procedures for orderly termination *If applicable
A statement that significant new findings developed during the research that may relate to the participant's willingness to continue enrollment in the research *If applicable
A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions *If applicable
A statement that the involvement of biospecimens will or will not include whole genome sequencing *If applicable
A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit *If applicable
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant *If applicable
Avoid:
Exculpatory language
Language or graphics that may be coercive or misleading
Claims that state or imply a certainty of a favorable outcome or other benefits beyond what is outlined in the consent document and protocol
Emphasis on payment, including bolding or highlighting the compensation language
Use of the term "free" in reference to treatment or procedures
Claims that the drug, biologic or device is safe or effective for the purpose under investigation
Claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling
Use of the term "new treatment", "new medication", or "new drug" in reference to a drug or device without explaining that the test article is investigational
Research jargon or complex terminology to describe study procedures. Instead, study procedures should be described in lay language.
Ensure:
Language utilized is appropriate given the subject population
Translations have been created and included in the submission materials* if applicable
Materials have been created/formatted to be accessible to all whenever possible
Materials have been created/formatted to be culturally sensitive
Participants will be provided with sufficient time to review the consent form and ask questions if needed