



Waiver and Alteration of Informed Consent Request

An IRB may waive or alter some or all of the informed consent requirements under certain conditions.

- A full waiver of consent would most likely apply in circumstances when your research only involves the secondary use of existing data.
- An alteration of consent is used when it is appropriate to alter the standard informed consent requirements (described in WSU IRB policy 09-01 Informed Consent Options, and Federal DHHS Policy 45 CFR 46.116)

Select the applicable Waiver request (upload this document for eProtocol):

- Request for General Waiver of Informed Consent
- Request for Alteration of Informed Consent
- Request for Waiver of Written Documentation of Consent (Use of Information Sheet)
- Request for Waiver of Consent & Written Documentation of Consent to determine study eligibility
- Request for Waiver and Alteration of Consent in Research Involving Public Benefit and Service Programs

Complete descriptions of the waivers are provided below

General Waiver and Alteration of Informed Consent

- Request for General Waiver of Informed Consent

- Request for Alteration of Informed Consent

In order for an IRB to waive or alter consent the IRB must find and document the following:

1. The research involves no more than minimal risk to the participants
 2. The research could not practicably be carried out without the requested waiver or alteration
 3. If the research involves using identifiable private information or identifiable bio-specimens, the research could not practicably be carried out without using such information or bio-specimens in an identifiable format
 4. The waiver or alteration will not adversely affect the rights and welfare of the participants and
 5. Whenever appropriate, the participants or Legally Authorized Representative will be provided with additional pertinent information after participation.
- When elements of the informed consent have been altered or elements left out the IRB must grant an alteration informed consent.
 - Alternation of informed consent includes deception or intentionally withholding study information from participants about the proposed research. A debriefing plan must be provided of the plan to inform participant of all study details (include a debriefing script). If debriefing will not be done this must be stated in the IRB submission/alteration request. Indicating why it is not appropriate or impossible to inform participants of all aspects of the proposed research

Please note, If PHI will be used a Waiver of HIPAA Authorization may also be required.

Use of Information Sheet

Request for Waiver of Written Documentation of Informed Consent

An Information Sheet is an unsigned form of passive consent in which the adult participant indicates consent by proceeding with the minimal risk task (such as participating an anonymous interview, or completing an anonymous survey). When an Information Sheet is used, the IRB is waiving the documentation of informed consent. When an Information Sheet is appropriate the researcher must use the [WSU IRB Information Sheet template](#).

- ✓ Information Sheets are used for minimal risk research with prospective data collection in which the participant's signature on a consent form would be the only piece of identifiable information collected by the researcher.
- ✓ An Information Sheet also serves as a template for the prospective agreement indicated in Exempt Review Category 3 in which behavioral researchers employ benign behavioral interventions with research participants.

Use of Oral Consent

Request for Waiver of Written Documentation of Informed Consent

Oral consent is used in minimal risk research which involves prospective data collection in cases when use of the information sheet is not possible. When oral consent is used, the IRB is waiving the documentation informed consent. If the potential participant declines to participate, the researcher must thank the participant for their time, and promptly end the conversation.

Researchers cannot attempt to contact any individual who declined to participate.

When requesting IRB approval to obtain consent orally, a consent script must be submitted and approved by the IRB. The IRB does not have an oral consent script template. We recommend using the Information Sheet Template as a guide to ensure you include the all appropriate elements in your script.

The researcher obtaining oral consent must provide written documentation of the oral consent process. This documentation should include:

- ✓ Name of the potential participant contacted
- ✓ Name of the researcher requesting the participant's consent orally
- ✓ Date and time the potential participant was contacted
- ✓ The participant's decision to participate, or to decline participation.

Screening, Recruiting, or Determining Eligibility:

Request for Waiver of Consent and Written Documentation of Consent to determine study eligibility

An IRB may approve a research proposal in which an investigator will obtain information or bio-specimens for the purpose of screening, recruiting, or determining the eligibility of prospective participants without the informed consent of the prospective participant, or the participant's legally authorized representative (LAR) if either of the following conditions are met:

- The investigator will obtain information through oral or written communication with the prospective participant or LAR, or
- The investigator will obtain identifiable private information or identifiable bio-specimens by accessing records or stored identifiable bio-specimens. ***Please also remember to request a waiver of HIPAA Authorization for the HIPAA Submission Form.***

After a participant has been determined eligible and expressed interest in taking part in the research, the informed consent process must take place following all of the requirements described in WSU Policy 09-01- Informed Consent Options and WSU Policy 09-03 Informed Consent Process.

Requirements for Waiver and Alteration of Consent in Research Involving Public Benefit and Service Programs:

In order for the IRB to waive or alter consent the IRB must find and document the following:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - a. Public benefit for service programs
 - b. Procedures for obtaining benefits or services under those programs
 - c. Possible changes in or alternatives to those programs or procedures; or
 - d. Possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alterati