**Informed Consent Guidelines**

Informed consent assures that potential subjects understand the nature of the research project and can make informed, voluntary decisions about participation. It is a two-part process of

1. providing potential participants with key information about the research and their rights as participants; and
2. obtaining their agreement to participate.

Informed consent information is provided to potential participants via a form or letter. When consenting to participate, the subject or the subject’s legally authorized representative signs the form. The researcher will store the signed form in a secure location, but the person who signs the informed consent form must be given a copy as a reference.

* In certain circumstances, the Institutional Review Board (IRB) can approve an alteration to the informed consent process. These alterations and circumstances are addressed in the Waivers section of this document.

Informed consent is mandated by Federal regulations ([**45 CFR 46**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)) and [**EIU Policy and Procedures for the Review of Research Involving Human Subjects**](https://www.eiu.edu/grants/files_irb/IRB%20Policy%202024.doc).

The IRB will need to review your plan for providing informed consent information (and assent, when applicable) and for obtaining subjects' consent to participate. In addition to this document, the Application for IRB Review contains links within each section to provide you with guidelines regarding what is required in the application. Utilize the links if you have any questions regarding Application requirements.

**Informed consent forms must be submitted for review with your research protocol.**

**The Informed Consent Document:**

Informed consent forms should be written **to** its audience (for example, use the word *you* instead of *subject*, *participant*, or *individual*). The information should be written and organized at a level of comprehension that is appropriate for the intended audience, free from jargon or concepts the potential participant may not understand.

**Requirements:** Certain information is **required** in an informed consent document. EIU’s IRB provides an [**Informed Consent Checklist**](https://www.eiu.edu/grants/files_irb/Informed%20Consent%20Checklist.docx) that can be utilized when developing your informed consent document. This checklist can be found at the EIU [**IRB Forms Website**](https://www.eiu.edu/grants/COMP_IRB_Forms.php)

In addition to the Checklist, an [**Informed Consent Template Letter**](https://www.eiu.edu/grants/files_irb/Informed%20Consent%20Template.docx)is also provided. While using the template is not mandatory, many researchers find it to be a helpful place to start, as it incorporates all of the basic elements that must be included in an informed consent form.

**Informed Consent Waivers:**

In certain circumstances, the IRB can approve an alteration to the informed consent process. This is called a waiver. There are two types of waivers:

* Waiver of documentation of informed consent
* Waiver of informed consent

**Waiver of Documentation of Informed Consent:** Participants receive informed consent information, but signatures are not collected.

For example, a researcher using a web survey will include informed consent at the beginning of the survey; the subject consents to participate by continuing to the next page to take the survey. The participant does not sign a form or type their name in the informed consent area at the beginning of the survey.

Federal regulations allow the IRB to approve this type of waiver only in certain circumstances:

* 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; or
* 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.

**Waiver of Informed Consent:** Participants do not receive informed consent information prior to participation, or they receive some information, but not all of the required elements of informed consent.

Federal regulations allow the IRB to approve this waiver only in certain circumstances:

* The research involves no more than minimal risk to the subjects;
* The waiver or alteration will not adversely affect the rights and welfare of the subjects;
* The research could not practically be carried out without the waiver or alteration; and
* Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**Assent:**

When children (ages 0 through 17) and/or people who are decisionally impaired are the subjects of research, there is a four-part process to obtaining their permission to participate:

First, you **must** obtain *informed consent* from the parent or guardian of potential participants using the informed consent guidelines outlined above:

1. Provide parents/guardians with required information about the research and their child or ward’s rights as a participant.
2. Obtain parent/guardian agreement to allow their child or ward to participate in the research.

Once informed consent is obtained from the parent or guardian, only then can you seek to obtain *assent*from the potential participant:

1. Provide developmentally appropriate information about research to the potential participants, using language and a method of delivery that is appropriate for the targeted subject population.
	* For example, a child who cannot yet read would need assent information delivered verbally. In this case, the researcher must write a script that will need to be approved by the IRB.
2. Obtain their permission (assent) to participate as subjects in the research. Assent must also be obtained in developmentally appropriate ways.

EIU’s IRB provides a detailed [**Guidelines for Assent**](https://www.eiu.edu/grants/files_irb/Assent%20Guidelines.docx)document to provide phrasing assistance and other assent process guidance at the [**IRB Forms Website**](https://www.eiu.edu/grants/COMP_IRB_Forms.php#InformedConsentAssent). The IRB has also developed an [**Informed Consent Letter Template**](https://www.eiu.edu/grants/Informed%20Consent%20Template%20-%20Letter%20to%20Parents.docx) for teachers to send to parents/guardians when children are the subjects of research. Utilizing this letter template is not a requirement, however, some researchers find it helpful.

**Assent forms or scripts and parent/guardian Informed consent forms/letters must be submitted with your research protocol for review.**

**Assent Waivers:**

As with informed consent, there are circumstances where the IRB can approve an alteration to the usual assent process (including to the parent/guardian informed consent portion of the process). These waivers include:

* Waiver of documentation of parent/guardian informed consent
* Waiver of parent/guardian informed consent
* Waiver of documentation of assent
* Waiver of assent

*Waivers of Documentation of Parent/Guardian Informed Consent*, and *Waivers of Parent/Guardian Informed Consent* can be approved by the IRB under the same circumstances as informed consent waivers for research involving participants who are adults with no decisional impairment.

**Waiver of Documentation of Assent:** It is understood that participants may not be signing a form, depending on the targeted population’s level of development. Assent can be documented in developmentally appropriate ways, either with a participant signature, or an audio/visual recording or by having a witness document verbal assent. If none of these methods for documentation will occur, the IRB can approve a waiver of documentation of assent in certain circumstances:

* The only record linking the subject and/or their parents/guardians and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; or
* 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.

**Waiver of Assent:** Participants do not receive assent information prior to participation, or they receive some information, but not all assent information. It is understood that participants will be presented with assent information that is appropriate for their level of development. Request this waiver only if you are intentionally not providing the subject with required information that is developmentally appropriate.

Federal regulations allow the IRB to approve this waiver only in certain circumstances:

* The research involves no more than minimal risk to the subjects;
* The waiver or alteration will not adversely affect the rights and welfare of the subjects;
* The research could not practically be carried out without the waiver or alteration; and
* Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**When Submitting Your Protocol:**

Informed consent forms (and assent forms, when applicable) must be submitted to the IRB for review. Include them with your research protocol when submitting it to the IRB.

Waivers to documentation of informed consent (or assent) will be requested by the researcher in the [**Application for Review of Research Involving Human Subjects**](https://www.eiu.edu/grants/files_irb/Application%20for%20IRB%20Review.docm).

Waivers to documentation of informed consent (or assent) procedure will be requested using the Application for IRB Review Addendum Waiver of Informed Consent or Assent.

Contact the Office of Research and Sponsored Programs at **eiuirb@eiu.edu** or 217-581-2125 if you have further questions.