



## INSTRUCTIONS FOR THE INFORMED CONSENT OR INFORMED CONSENT AND HEALTH INFORMATION USE AND DISCLOSURE AUTHORIZATION

### General Requirements [[cfr46.116 \(a,b\)](#)]

- No investigator can involve a person in a research study without the legally effective informed consent of the participant or the participant's legally authorized representative, unless it has been determined otherwise by [Northeastern University's Office of Human Subject Research Protection \(HSRP\)](#) in accordance with federal regulations.
- The investigator must obtain consent under circumstances that a) provide the potential participant or representative sufficient opportunity to consider participation and that b) minimize the possibility of coercion or undue influence.
- The information must be written in language that the person, or representative, can easily understand.
- The consent cannot include any language that waives or appears to waive any legal rights of the participant. It cannot include any language that releases the principal investigator, Northeastern University, a sponsoring agency or individuals from liability for negligence.

### Writing the Consent Document

To ensure that participants understand the nature of the research and their personal involvement, investigators must provide a thorough oral explanation to prospective subjects and answer their questions. For most research that qualifies for exempt, expedited or full committee review, investigators must also obtain a signed consent from participants. There are instances where the Federal regulations ([45 CFR 46.117c](#)) allow an IRB to waive the requirement for the investigator to obtain a signed consent form. [You may use the formats provided on our website](#) or you may alter the format if the information conforms to guidelines.

The nature of your research and the level of risk determine the type and amount of information that you need to include. Consider what the person will need to know in order to make an informed decision to participate. For example, interviews or questionnaires with highly sensitive questions require detailed information about procedures to protect confidentiality. Research involving therapy or exercise may need more information about physical risks.

Each section is not required for every consent. Sections marked \* are required unless otherwise determined by HSRP. You may also combine sections if that is a better way to present the information. For some research, additional information may be required. Check the listing following the signatures on the consent template.

Examples of wording are occasionally provided. Use this wording only if it applies exactly to the procedures you will be following. Otherwise, make appropriate modifications.

**Consent documents should be written at an 8<sup>th</sup> grade reading level or less** for the average adult population. Avoid technical or professional language used in grant submissions or with peers. Use short, clear sentences. Use bullets or timetables for multiple visits or procedures. Select an easy-to-read font size. Use second person (you) statements rather than first person. Use correct spelling and grammar. If the consent is more than one page, use footers: page 1 of 3, page 2 of 3, etc.



If some or all participants may not understand 8<sup>th</sup> grade English (e.g., children, non-English speakers, cognitively impaired persons), appropriate accommodations must be made to obtain consent.

Microsoft Word offers a useful tool to help you determine if your consent form is at an 8th grade reading level. To display readability statistics do the following:

1. Click on the Office Button and then click the “Word Options” button
2. Click “Proofing”
3. In the section with the heading “When correcting spelling and grammar in Word”, check the box for the choice “Show readability statistics”
4. Then click “o.k.”
5. Open your consent document and now run the “Spelling and Grammar” check function

When Microsoft Word finishes checking spelling and grammar, it will display information about the reading level of the document using the Flesch-Kincaid Reading Ease score, which rates texts on a U.S. grade-school level.

**TIP:** To lower the grade level, consider using shorter words and shorter sentences.

**For children** (<age 18 in MA) to participate in research, including surveys and interviews, signed permission is required from the parent or legal guardian and a signed assent from the child, unless otherwise approved by HSRP. See *Policies* section 7.0.

**Translations** of consent information are necessary for non-English speaking people. Describe how information will be translated and by whom. You may wait until the consent approved in English before having it translated.

**For a decisionally impaired person**, a legally authorized representative (LAR) must provide written permission. Provide signature and date spaces for the LAR and the participant, if the latter is capable of consent.

**State whether the subjects and data are anonymous or confidential.** If subjects are anonymous, no one, *including the researcher*, knows the identity of those who participated in the study or which data they provided. If the information is confidential, the identity of participants and the data is known, but is kept in strict confidence within legal limits. Coding identities and storing data in locked files are methods of preventing private information about subjects from being revealed.

Once the informed consent or **Informed Consent and Health Information Use and Disclosure Authorization** has been approved in its final form, HSRP will stamp it and include the IRB tracking number and the dates the consent is valid. **Copies of this original stamped version MUST be used to recruit participants.** No changes to the authorization are permitted without prior approval and a new authorized version by HSRP.

**A copy of the consent must be given to every participant.** The PI retains the original signed statement. The investigator must retain these documents for at least three years past the completion of the research activity.

**In case of audit**, the investigator will be required to provide documentation that appropriate signed and dated consent was obtained by each participant on the approved consent document.