

**Research Integrity Office**

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**Instructions for Consent & Authorization Forms**

**1. Start with the correct template form(s).**

You can browse [all consent and authorization templates](#), as well as other helpful forms, on the [IRB Forms Website](#). The table below summarizes the available templates and when they should be used:

**Specialized Templates**

<u><a href="#">OHSU Knight Cancer Institute Consent and Authorization Form</a></u>	Use for all studies that are cancer-related or that enroll primarily subjects with cancer.
<u><a href="#">Shriners Consent and Authorization Form</a></u>	Use for all studies conducted at Shriners Hospitals for Children.
<u><a href="#">Repository Only Consent and Authorization Form</a></u>	Use for studies involving the collection of data and/or specimens SOLELY for the purpose of storing them in a repository <sup>1</sup> for future research.
<u><a href="#">Treatment Use Consent Form</a></u>	Use for treatment use (NOT a research study) of an unapproved drug or device, or use of a Humanitarian Use Device (HUD). Note that HIPAA authorization is not required for treatment uses.

**General Templates – All Other Studies**

<u><a href="#">Clinical Research Consent and Authorization Form</a></u>	Use for studies that include clinical services <sup>2</sup> . This template has a barcode so that the form can be scanned into the subject's medical record.
<u><a href="#">Non-Clinical Research Consent and Authorization Form</a></u>	Use for studies that do not include clinical services; that is, studies where no information will be placed in the subject's medical record and no barcode is needed.
<u><a href="#">Information Sheet</a></u>	Use if you are requesting a waiver of documentation of consent so that subjects do not need to sign a consent form. This is usually only available for minimal risk studies. <sup>3</sup>

<sup>1</sup> For more information about repositories, please visit the IRB's [Repository Website](#).

<sup>2</sup> Clinical services are defined as any procedure, test, or exam performed by a licensed practitioner. This includes blood draws, imaging procedures, genetic tests performed by clinical laboratories, non-invasive exams, and dental work. For more information, please refer to OHSU Healthcare System Policy, [Research Documentation in the Integrated Health Record \(IHR\)](#). If you are not sure whether your study involves clinical services, use the clinical consent template.

<sup>3</sup> For guidance on modifying the consent process and requesting waivers, see the [IRB Help Sheet – Tips for Modifying the Consent Process](#).

**A note about HIPAA Research Authorizations:** Required HIPAA authorization language is integrated into the consent and authorization template. By signing the form, subjects document both their consent to participate in the research and their authorization for the use and disclosure of their Protected Health Information (PHI). **If**

**you need a standalone HIPAA authorization form for your study, please contact the IRB.** For more information about HIPAA, see the IRB's [HIPAA and Research Website](#).

For **complex study designs or studies with detailed sub-studies or optional components**, it may be helpful to use more than one consent form. Usually, this is your choice. However, if the IRB finds your consent form difficult to follow, it may require that you separate the required and optional components into different forms.

**2. Add supplemental language and create additional forms as applicable to your study.** These may include the following:

**If the study includes children:**

- **Ages 15-17** – Please see the [Consent Form Signature Templates](#) for guidance on how to structure the signature page.
- **Ages 7-14** – Please create an Assent Form. You may use the [Assent Form Template](#) or write your own, using language appropriate to your study population. **Note** that researchers do not sign or date assent forms.
- **Shriners Hospitals for Children** – if an Assent Form is needed for a study at Shriners, use the [Shriners Assent Template](#).

**If the study involves subjects with limited English proficiency**, you will need to translate the consent and authorization forms into the subjects' language or use one or more of the short consent forms posted on the [IRB Forms Website](#).

- Review the IRB policy on [Obtaining and Documenting Informed Consent from Subjects with Limited English Proficiency](#).
- See the [Instructions on Using the Short Consent Forms](#).

**If the study involves gene transfer**, see the IRB Help Sheet: [Consent Language – Gene Transfer Studies](#). Incorporate this language into your consent form as directed in the help sheet.

- 3. Instructions in italics are provided throughout the sample forms.** These instructions are for your information. Please **delete all instructions** before submitting to the IRB.
- 4. Include all required language from the template and delete all language that does not apply.** Language designated in the template as required may not be modified. Suggested language in the template must also be used unless the language is not consistent with the study. Consent forms containing modifications to required and suggested language may be returned to the submitter without review unless the modifications have been approved by the IRB prior to submission.
- 5. Consent forms must be written in language suitable for subjects who read at the eighth-grade level.**

For a glossary of lay equivalence of medical terms, check [here](#).

To check the Flesch-Kincaid reading grade level in Microsoft Word, follow the steps below. Note that because of medical terminology and some required OHSU

language, this system will generally indicate a higher reading level than is accurate.

- Click the **Microsoft Office Button**, and then click **Word Options**.
- Click **Proofing**.
- Make sure **Check grammar with spelling** is selected.
- Under **When correcting grammar in Word**, select the **Show readability statistics** check box.

**6. The IRB does not require co-investigators to be listed on the consent form. Only the PI is required.** You may list the co-investigators if you wish. However, the IRB discourages long lists of co-investigators. We recommend limiting the list to those investigators most likely to be conducting the consent discussion.