

**CONSENT FORMS:** Consent forms are required for most research involving human subjects. Please see the instructions for consent forms in the IRB Handbook, Section 6, found on the University of Puget Sound Institutional Review Board website:

<https://www.pugetsound.edu/gateways/faculty-staff/institutional-review-board/>

Because consent forms must be representative of each project, below is a general checklist. Each Principal Investigator (PI) must ensure that the consent form(s) submitted for IRB review are a complete and accurate description of the research project that allows a potential subject to give voluntary informed consent.

**Procedural Details:**

- \_\_\_\_\_ a. Page 1 is on appropriate institution letterhead.
- \_\_\_\_\_ b. Project title (identical title used on consent form and protocol).
- \_\_\_\_\_ c. Pages numbered (protocol and consent form numbered separately).
- \_\_\_\_\_ d. List all investigators, email addresses, and business telephone numbers (personal numbers, e.g., cell phone numbers may not be used).
- \_\_\_\_\_ e. If consent form is longer than 1 page, line for subject's initials appears in lower right corner of each page of consent form.
- \_\_\_\_\_ f. Signature lines for all that apply to a specific study, e.g., subject, witness, parent, corroborator.

Consent forms are required for all individuals who need to consent. Separate consent forms are required for individuals who experience different levels of the study. For example, adults in a treatment group, the control group, parents/guardians all require separate consent forms. Children require assent scripts/forms dependent on age and purpose of study. Additional consent forms may be needed given a specific study's design.

**Content:**

- \_\_\_\_\_ Description of study written in non-technical language no greater than 8<sup>th</sup> grade reading level
- \_\_\_\_\_ Risks/benefits clearly described
- \_\_\_\_\_ Alternative treatments, if applicable
- \_\_\_\_\_ Costs and payments, if applicable
- \_\_\_\_\_ Confidentiality and use of protected health information
- \_\_\_\_\_ Phone number for Associate Dean's Office
- \_\_\_\_\_ Right to refuse or end participation
- \_\_\_\_\_ No compensation for injury, if applicable
- \_\_\_\_\_ Voluntary consent
- \_\_\_\_\_ Acknowledgment of parent, if applicable
- \_\_\_\_\_ Investigator's certification