# PURPOSE

## This document describes the procedure for the IRB to follow when it wishes to obtain an ethics consultation during the review process.

## Examples of situations for which an ethics consultation might be useful include (but are not limited to):

### Research with novel technologies

### Research with a population of subjects not often involved in research

### Questions about study design (e.g., use of a placebo)

### Concerns about inclusion and exclusion criteria

### Identifying and assessing risks and potential benefits

### Concerns about the relationship between researchers and subjects

### Concerns about the relationship or distinction between the research and clinical care

### The behavior of enrolled subjects

### Unexpected research findings

### The disclosure of interim findings on subjects

# POLICIES

## The UW provides its IRBs with the opportunity to obtain consultation on ethical issues during the review process. Even when a study meets regulatory requirements, ethical issues and concerns can remain for which research ethics consultation may be useful.

## Initial consultation is provided by a member of HSD Leadership. In some circumstances, the IRB (or HSD Leadership) may choose to obtain an ethics consultation from outside HSD about the specific issue or study.

# DEFINITIONS

## None.

# PROCEDURES

## The request. The IRB sends a written request for consultation to any member of the HSD Leadership team. The request should contain:

### The identifying information for the study

### The issue of concern, described as specifically as possible

### Whether the IRB wishes a consult in person, by phone, or in writing

### Any time constraints

## Identification of consult service. The member of HSD Leadership who receives the request determines the appropriate consultation service. In most cases, this will be the Research Bioethics Consult service offered by the Institute for Translational Sciences (ITHS; see reference below). Other possibilities may include:

### Consultation from Seattle Children’s

### Consultation from an individual UW faculty member with expertise in a particular area. For example, faculty members from the following academic units might be helpful:

#### Department of Bioethics and Humanities

#### Department of Philosophy

#### UW Law School

#### UW I School

#### UW School of Social Work

## Initiation of consultation. The member of HSD Leadership contacts the consultant or service, and arranges for the consultation. The arrangement may require some negotiation with the IRB concerning the method and timing of the consultation, as well as providing supporting materials.

## Consultation documentation. Documentation of the consultation, including any materials provided by the consultant, becomes part of the IRB file for the study.

## Appreciation for consultation. The member of HSD Leadership is responsible for sending the consultant a suitable expression of appreciation and gratitude.

# MATERIALS

## None

# REFERENCES

## ITHS Research Bioethics Consult website <https://www.iths.org/investigators/services/bioethics/>

# Key Words: Ethical principles; Pre-review