Federal Criteria for the Approval of Human Subjects Research

The UW Institutional Review Board (IRB) follows federal requirements for approving research. In order to approve human subjects research, the IRB must determine that the research meets all eight federal criteria that are listed in 45 CFR 46.111.

The committee's requests for changes should be clearly related to the federal approval criteria or to institutional policy.

Federal Approval Criteria	Ethical Principles	Study Factors to Consider/Applicable Sections of the Protocol Template
Risks to subjects are minimized through sound design and through re-use of clinical data, when possible	Beneficence	• Background and rationale • Study design: setting, study intervention, timelines, procedures involved, comparison with usual care and study procedures, withdrawal of participants, risks to participants • Study objectives and endpoints • Resources available; Multi-site Research
Risks to subjects are reasonable in relation to anticipated benefits	Beneficence	• Study design, procedures involved • Potential benefits to participants • Risks to participants (risks may be physical, psychological, social, economic or legal)
Selection of subjects is equitable and non-coercive	Justice	• Number of participants • Inclusion/Exclusion criteria • Recruitment methods • Compensation • Economic burden to participants • Resources available
Informed consent will be sought	Respect for persons	• Consent/assent process, • Format and clarity of consent documents • Withdrawal of participants

Informed consent will be appropriately documented	Respect for persons	• Process to document consent in writing • Waiver of consent if applicable
Provisions for safety monitoring are adequate	Beneficence	• Provisions to monitor the data to ensure the safety of participants • Sharing of results • Study analysis • Resources available
Privacy and confidentiality will be maintained	Respect for persons	• Data management and confidentiality, • Provisions to protect the privacy interests of participants • Data and specimen banking • Multi-site research

Vulnerable populations will be protected	Respect for persons, justice	• Special populations
		  ○ Children or emancipated minors
		  ○ Pregnant persons
		  ○ Non-viable neonates or neonates with uncertain viability
		  ○ Prisoners
		  ○ Adults with impaired decision-making capacity
		  ○ Non-English speakers
		  ○ Illiterate/low literacy participants
		  ○ Visual or hearing impairments
		  ○ Status relationships with PI/study team members
		  ○ Individuals treated for mental illness/developmental disability/alcohol-drug abuse
		  ○ Veterans/military personnel
		  ○ Socioeconomically, educationally or otherwise disadvantaged
		• Consider legal protections, safeguards such as parental permission, surrogates, ancillary review requirements