



Department	Title	Dates
Research Integrity and Protection	Engagement in Human Subject Research	Effective: 12/22/2017
		Approved: 12/18/2017
SOP ID		Last Revised: n/a
IRB-SOP-206		Expiration: n/a

PURPOSE

This document outlines the procedures used by Research Integrity and Protection for determining, documenting, and communicating whether Ascension Wisconsin (or other institutions) is engaged in a non-exempt human subjects research project.

SCOPE

This procedure applies to research conducted at Ascension Wisconsin and all researchers, study teams and RI&P staff.

DEFINITIONS

Engagement Ascension Wisconsin applies the definition of engagement provided on the website of the federal Office of Human Research Protections (OHRP) to all research, including FDA regulated research, regardless of the source of the research funding. The criteria defining engagement are outlined in the WORKSHEET: Engagement.

Employee or agent The concept of “employee or agent” is critical to the determination of engagement. It can include faculty members, staff, students, contractors, and volunteers, among others, regardless of whether the individual is being paid.

An “Employee or agent” refers to an individual who:

- Acts on behalf of an organization;
- Exercises institutional authority or responsibility; or
- Performs institutionally designated activities.

PROCEDURES

1. In general, the Ascension Wisconsin IRB reviews non-exempt human subjects research only when Ascension Wisconsin is engaged in the research, where “engagement” is defined as outlined in federal guidance.
2. An institution that is the direct (prime) recipient of federal funding for a research project is considered, by federal regulation, to be engaged in the entire research project, even when all activities involving human subjects are performed through subcontract or other arrangements by the employees or agents of other institutions. This means that the IRB of the prime awardee’s institution must review all aspects of the project, unless some or all of it has been deferred by formal agreement to another IRB.

3. The engagement of multiple institutions in a research project can result in duplicate or "dual" IRB review. Ascension Wisconsin is committed to reducing (as appropriate) duplicate reviews due to the engagement of multiple institutions, through the use of cooperative agreements, central IRBs, and study-specific agreements with IRBs at other institutions; see SOP: IRB Reliance.
 4. Institutions that fulfill the role of an overall coordinating center for a multi-site study, or a data coordinating center, may be engaged in the research. If they are engaged, they must obtain IRB review and approval from their own IRB or through arrangements between their own IRB and another IRB.
- 5. Engagement Determination**
- 5.1. The Ascension Wisconsin IRB must make determinations regarding institutional engagement.
 - 5.2. Engagement status is determined by designated IRB, or other Research Integrity and Protection staff, who may consult with the IRB Chair, Director or other experts on the decision, during the pre-review process, by referring to the WORKSHEET: Engagement.
 - 5.3. Any information gathered to support the decision is documented in Mentor. In addition, the "WORKSHEET: Engagement (WRK-311)" should be used at staff discretion.
 - 5.4. All determinations will be made in a timely manner in accordance with the applicable federal regulation and guidance.
 - 5.5. The determination will be documented and communicated to the researcher via Mentor.

REFERENCES

- OHRP "Guidance on Engagement of Institutions in Human Subjects Research", October 16, 2008.
- RI&P SOP: Research Covered by the HRPP
- IRB SOP: IRB Reliance.

RELATED MATERIAL

- WORKSHEET: Engagement

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	11/27/2017	New- Initial Integration Update	J. Blundon