Department	**Title**	**Dates**
Institutional Review Board	IRB Review of Contracts and Funding Agreements	Effective: 10/23/2017
		Approved: 4/11/2017
SOP ID		Last Revised: 12/6/2017
IRB-SOP-305		Expiration: n/a

SOP

PURPOSE

IRB review of contracts and funding agreements contributes to the protection of research participants in sponsored research and meets the federal regulations that require IRB review of grants for federally-supported human subject research.

SCOPE

This document describes the Ascension Wisconsin IRB's review of a grant, contract or other type of award that an investigator has identified as providing support for a research activity.

DEFINITIONS

None

PROCESS

1. **Review**
   - **1.1.** The purpose of this review is to:
     - Ensure consistency between the funding proposal and materials submitted to the IRB with respect to issues relevant to the criteria for IRB approval or exempt status.
     - Provide the IRB with information that is helpful in applying the criteria for IRB approval or exempt status.
     - Ensure compliance with any funding agency requirements that funds for human subject research are not released until the investigator obtains IRB approval or exempt status.
   - **1.2.** Research Integrity and Protections staff ensures the Ascension Wisconsin required language is in the contract or funding agreements and is consistent with the information in the IRB application and consent document, including but not limited to the following:
     - Details of subject remuneration.
     - Sponsor agrees to provide payment for medical care for research participants with a research-related injury.
     - Sponsor will promptly report any findings from monitoring activities that could affect the rights or safety of subjects.
     - Sponsor will provide data and safety monitoring reports to the PI and IRB, when appropriate.
     - After study closure, the Sponsor will provide any result information that could affect the rights or safety of subjects.
     - Plans for disseminating findings; PI and Sponsor role in publication/disclosure of results.
   - **1.3.** This is typically assessed through the Investigator attestation in the IRB application and direct review of the agreement or contract.
   - **1.4.** This review is neither an assessment of the adequacy of the budget or resources, nor whether specific human subjects-related costs are included in the budget.

1.5. Discrepancies between the grant and the IRB application must be resolved and the resolution documented as described below, prior to granting IRB approval or exempt status for human subject research proposals.

2. Federally Supported Human Research Studies

2.1. Federal regulations require that each application or scope of work for federally-supported human subjects research has been reviewed and approved by an Institutional Review Board (IRB) before the work begins.
Ascension Wisconsin applies this requirement to all human subjects research activities supported by a funding award of any type, except for funding support provided by a grant that does not contain a description of the specific research project (for example, because significant pre-human subjects development work is required).

2.2. The Ascension Wisconsin IRB requires a copy of any application or proposal that provides funding or other support for the research, including but not necessarily limited to sections that address the following topics. If this information is not provided in the funding application, the researcher is not asked to create a document with the information.

- Research aims
- Research plan (including all procedures)
- Resources and facilities
- Members of the research team: identification, qualifications, institutional affiliation, and activities that each will conduct or oversee
- Performance sites: identification, and activities that will be conducted by or at each site
- Protections and issues related to human subjects
- Investigator's response to the funder's review (if there was a re-submission)
- Some research is supported by an award from a training grant, program or center grant, or similar type of grant that itself makes awards for projects. In these cases, the researcher is not required to provide a copy of the "parent" training, program, or center grant. Instead, the researcher should provide only a copy of the proposal submitted in order to obtain the specific award funding the project.

2.3. A federal grant should be provided to the IRB once awarded, either at the time of initial review or, if the IRB already has approved the research study, the addition of the grant should be submitted to the IRB as an amendment.

REFERNCES

- 45 CFR 46.103(f)
- OHRP Guidance, "IRB Review of Application for HHS Support", 2000

RELATED MATERIAL

- IRB SOP: IRB Pre-Review
- IRB SOP: Submission Requirements for Human Subject Research Review

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	4/11/2017	New- Initial Integration Update	J. Blundon
02	10/23/17	Addition of Related Materials, References and Revision History sections minor clarification to 1.2. and 1.3.	J. Blundon
03	12/6/2018	Chang SOP number from 205 to 305.	J. Blundon