SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	IRB Fees	Effective: 10/23/17
		Approved: 7/25/17
Policy ID		Last Revised: 10/23/17
IRB-SOP-103		Expiration: n/a

PURPOSE

This policy describes the circumstances in which the Ascension Wisconsin IRB will bill for IRB, administrative or compliance reviews of human subject research and outlines the requirements for assessing IRB review fees.

SCOPE

This policy applies to research overseen by the Ascension Wisconsin IRB that is funded by an Industry Sponsor; IRB fees do not apply to federally funded studies or investigator initiated studies where the Principal Investigator is an Ascension Wisconsin associate, medical staff or other affiliate.

DEFINITIONS

Industry Sponsored: A clinical research study is industry sponsored when a commercial entity contributes to the design or conduct of the study (as evidenced by a sponsor's protocol, investigator's brochure, provision of drug/device supplies, etc.); or coordinates the study as a multi-center trial; reimburses the Institution for costs associated with conducting the clinical trial; or will have access to, or publish or present data gained from conducting the trial.

PROCESS

1. **Background**

   The IRB operates in a highly specialized and regulated manner to ensure all human subject research conducted under the auspices of Ascension Wisconsin meets rigorous ethical standards and all applicable State and Federal laws, and local Policies and Procedures for the protection of research participants. Industry sponsored clinical research study submissions represent some of the most complex and resource demanding research reviewed by the IRB. The fees collected from industry sponsored clinical research studies provide support for the human subject research protection and IRB operations otherwise not recovered by traditional indirect cost rate and overhead assessment.

   1.1 Uses of IRB fees include, but are not limited to, the following:
   - Subsidizing IRB Committee membership, staff support and training and continuing education requirements.
   - Promoting Research Quality Improvement Unit services to Ascension Wisconsin Associates and Employed Physicians who conduct human subject clinical research studies.
   - Supplying informatics and technology related to the HRPP.

2. **Assessment of Fees**

   2.1. The IRB will charge for initial and continuing review, review of changes, exemption determinations, not human subject determinations and study closure. The IRB will also asses an

administrative/compliance review fee for studies that are requesting to use an external or commercial IRB. This fee is in addition to any fee assessed by the IRB of record.

2.2. The Director of Research Integrity and Protection is responsible for the management and conduct of the IRB research review fee policy and procedures. The fee structure may be reviewed annually and is subject to change.

2.3. The IRB fee schedule is available on the IRB website and/or by contacting the IRB office.

2.4. The Director of Research Integrity and Protection, in collaboration with the Compliance and Legal Counsel, may decide to administratively withdraw IRB approval for any research study fees that are over 90 days past due.

3. Criteria for Assessment of IRB Fees

3.1. The IRB assesses a fee for initial review of all business-and-industry sponsored clinical trials.

3.2. When an IRB submission is received and is not designated as industry-supported, but is later determined to be industry-supported, the fee will be assessed.

3.3. IRB fees do not apply to the following:

- Research dependent on state, federal, non-profit foundations or organizations.
- Investigator-initiated studies that are internally supported.
- There is no charge for modifications not initiated by the Sponsor (e.g., the only change is to study personnel) or submission of reportable events (i.e., unanticipated problems, adverse event (AE) or serious AE, protocol deviation).

4. Budget Preparation, Invoicing, Collection and Accounting

4.1. It is expected that AWRI Research Grants, Contracts and Finance Administration shall include the IRB research review fees in all industry-sponsored budgets or payment schedules. The IRB fee is in addition to any separate budget item negotiated for IRB preparation and submission.

4.2. The IRB will prepare a monthly list of activity meeting the Criteria for fee assessment. AWRI Research Grants, Contracts and Finance Administration staff is responsible for the appropriate invoicing, collection and accounting of IRB research review fees charged in accordance with this policy and procedure.

4.3. AWRI Research Grants, Contracts and Finance Administration completes these responsibilities as outlined in the AWRI Research Grants, Contracts and Finance Administration SOPs.

REFERNCES

None

RELATED MATERIAL

IRB Fee Schedule (available on R&P website or by contacting the IRB office)

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	4/11/2017	New- Initial Integration Update	J. Blundon
02	7/26/2017	Minor formatting, grammar, clarification updates	J. Blundon
03	10/23/17	Addition of Related Material, References and Revision History sections.	J. Blundon