SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	Determination of Human Subjects Research	Effective: 7/26/2017
		Approved: 7/25/2017
SOP ID		Last Revised: 12/6/2017
IRB-SOP-207		Expiration: n/a

PURPOSE

Ascension Wisconsin defines human subject research as any research activity that involves human subjects as defined by Department of Health and Human Services (DHHS) regulations or Food and Drug Administration (FDA) regulations.

SCOPE

The IRB will evaluate projects conducted at Ascension Wisconsin, by Ascension Wisconsin staff or that otherwise qualifies as covered research, as described in SOP Research Covered by the HRPP to determine whether or not the projects involve the use of human participants.

DEFINITIONS

Research is defined in 45 CFR 46.102(d) as a systematic investigation, including research development, and testing and evaluation, designed to develop or contribute to generalizable knowledge. 21 CFR 50.3(c) defines research as an experiment that involves a test article and one or more human subjects.

Human Subject is defined in 45 CFR 46.102(f) as an individual about whom an investigator conducting research obtains data through intervention or interaction with individual or identifiable private information. 21 CFR 50.3(g) defines human subject as an individual who is or becomes a participant in research, either as a recipient of a test article or as a control.

Intervention or Interaction includes physical procedures performed on an individual, manipulation, communication or interpersonal contact with an individual or manipulation of an individual's environment.

Private information includes information that an individual can reasonably expect will not be made public, and information about behavior that an individual can reasonably expect will not be observed or recorded.

Identifiable means that the identity of the individual is or may be readily ascertained by the investigator or associated with the information.

Test Article 21 CFR 50.3(j) defines test article as any drug (including a biological product for human use), medical device for human use, human food additive, color, additive, electronic product, or any other article subject to regulation under the jurisdiction of the FDA.

PROCEDURES

1. **Process for Determining Whether an Activity Constitutes Human Subject Research**
   1.1. In some cases, the IRB must make the determination about whether or not projects meet the regulatory definition of human subject research. There are limited types of non-research that may be initiated without prior submission to the IRB. These activities include:
   - Training/education exercises where individuals are taught job-related responsibilities.

- Many Quality Improvement projects, as long as you will not require an IRB determination for publication.
- Case studies involving no more than three (3) separate cases, provided that the case studies are void of private identifiable information. However, a HIPAA review and determination may be required in these cases; the IRB serves as the HIPAA privacy board for research.

1.2. Researchers who feel that their proposal does not meet the regulatory definition for human subject research should submit the project to the IRB for review.

1.3. The determinations are made by designated IRB, or other Research Integrity and Protection staff who may consult with the IRB Chair, Director or other experts on the decisions. All determinations will be made in a timely manner in accordance with the applicable federal regulation and guidance. Each determination and its basis will be documented and communicated to the researcher via the electronic IRB system or email.

1.4. If the staff determines that the project does meet the regulatory definition of human subject research, the researcher will be guided to submit an application for a new study review.

2. Other Applicable Standards for Projects that are Not Human Subject Research

2.1. All projects conducted at Ascension Wisconsin are subject to the same ethical standards as IRB-approved projects and other reviews required, as determined by institutional policy and/or procedure.

2.2. Any change to a research project that was initially deemed not-human participant or non-research shall be resubmitted to the IRB for review to determine whether the change alters the original determination that the project is not research or is not human subject research.

3. Protocols Lacking Definite Plans for Human Involvement

3.1. Certain types of activities are planned and written with the knowledge that human subjects may be involved, but without definite plans for such involvement. A common examples is when a research has received an external grant for the development of a research protocol and the granting agency requires IRB review to receive the funds.

3.2. In these instances, researchers must submit the protocol to the IRB like a new study submission and include as much information as is available. The protocol must include assurances that additional information will be submitted when developed.

3.3. The IRB staff or Director may provide a letter of support with the understanding that the specific research protocol will be submitted to them once it has been developed. The letter of support does not imply approval of the IRB for these projects.

REFERNCES

- 45 CFR 46.102, 45 CFR 46.118
- 21 CFR 50
- IRB SOP: Intake and Processing of Submitted Items

RELATED MATERIAL

- WORKSHEET: Determination of Human Subject Research

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01		New- Initial Integration Update	J. Blundon
02	7/26/2017	Minor formatting, grammar corrections	J. Blundon
03	10/23/2017	Addition of Related Material, References and Revision History sections.	J. Blundon
04	12/6/2017	Change SOP number from 202 to 207	J. Blundon