SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	Review Standards for Research Not Covered by Federalwide Assurance-Flexibility Policy and Procedures	Effective: 1/21/19
		Approved: 2/19/2018
Policy ID		Last Revised: 12/4/2018
IRB-SOP-208		Expiration: n/a

PURPOSE

Ascension Wisconsin's Federal-wide Assurance (FWA) is limited to federally funded research, which allows an appropriate level of flexibility for research involving no greater than minimal risk. Non-federally supported research projects outside the scope of the FWA and reviewed under the flexibility policy will be provided protections equivalent to those found in the Common Rule (45 CFR 46), while also reducing administrative burden for researchers, IRB members and staff.

SCOPE

This policy applies to research conducted at Ascension Wisconsin.

DEFINITIONS

Common Rule: OHRP regulations for human research protection at 46 CFR 46.

Federalwide Assurance (FWA): A written assurance of compliance with federal human subject regulations that is provided by an institution conducting federally-supported, non-exempt, human subjects research. Through the FWA, an institution commits to federal agencies that it will comply with the federal -regulations and requirements.
Institutions conducting human subjects research that is supported by any component of the federal Department of Defense (DOD) are required to have a DOD Addendum to the FWA.

Federal Regulations: As used throughout this document to refer to the regulations described at 45 CFR 46, unless otherwise specified.

Federally supported: In this policy, means that the research is supported by federal funding or other type of federal involvement. RI&P/ IRB rely upon the information provided by the researcher, except when the provided information is inconsistent or ambiguous about federal support. If there is no indication of federal support, the researcher is not asked for confirmation that there is no federal support. "Federal support" includes any of the following:

- Funding from any federal agency. This means:
  - Awards made to directly support the research;
  - No-cost extensions of awards made to support the research;
  - "Flow through" federal funds that are awarded to a non-Ascension WI institution and then awarded to the through a subcontract.
  - Federal funds that may be indirectly supporting the research such as: Federally-funded training grants; Federal scholarships, fellowships, or other training awards such as "K" grants; Federally-funded program project grants.
- Involvement of federal personnel (including VA employees);
- Use of federal equipment or materials;
- Use of federal facilities (including VA facilities);

- Any research team member (including students) whose time on the research is paid or supported (whether directly or indirectly) by any federal award.

PROCESS

1. Applicability

1.1. Ascension Wisconsin chooses to apply the federal regulations to all federally- supported and non-federally-supported research, except as described in this document. These exceptions are referred to as the Flexibility Policy.

1.2. The Flexibility Policy allows for greater flexibility in the oversight of research for which federal regulations might not be appropriate or optimal. It also reduces unnecessary administrative burdens upon researchers, IRB members, and Research Integrity and Protection staff.

1.3. The Flexibility Policy applies only to human subjects research reviewed by the Ascension Wisconsin IRB that meets all of the following criteria:

- The research is not subject to the regulations of the Food and Drug Administration (FDA), and data are intended to be used to support applications to the FDA; and
- The study does not include and clinical interventions; and
- The research is not federally supported by a federal agency that signed the relevant Subparts of the federal human subjects regulations (45 CFR 46); and
- There is no contractual obligations or restrictions that preclude eligibility in this policy; and
- There is no NIH-issued Certificate of Confidentiality; and
- Meets other specific application criteria outlined below.

1.4. The applicability of the Flexibility Policy to a specific study is at the discretion of the Research Integrity and Protection staff or Ascension Wisconsin IRB, within the limits described in this document.

1.5. All human subject research remains subject to Ascension Wisconsin IRB policies and review, whether or not it qualifies for the Flexibility Policy.

1.6. For research that is eligible for any of the flexibility options described here, the Ascension Wisconsin provides equivalent protections to those provided by the federal regulations, when applicable.

2. Specific Applications of the Flexibility Policy

2.1. Documentation of Informed Consent

When the IRB determines that documentation of informed consent can be waived under the criteria outlined at 45 CFR 46.117(c)(1), "that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality", the IRB may determine that the researcher does NOT need to ask each participant whether the participant wants documentation linking the participant with the research.

2.2. Posting of clinical trial consent form.

§ .116(H) one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site. Ascension Wisconsin applies this requirement, as outlined in the regulation, only to clinical trials conducted or supported by a Federal department or agency.

2.3. Expansion of Expedited Review

Research projects involving no greater than minimal risk that do not otherwise fall under the expedited categories at 45 CFR 46 may be reviewed through the established expedited review process by the IRB Chair(s) or designees.

2.3.1. Activities determined to be "non-invasive": non-invasive collection of biospecimens/ data may be expanded to include skin biopsy (without sutures); ionizing radiation (<100 mrem/yr [1 Sv]); blood draws via indwelling catheter (regardless of frequency); blood draw 5 mL/kg/day or 9.5 mL/kg/8 weeks; additional collection of blood, cerebrospinal fluid, bone marrow during a clinically indicated procedure; additional endoscopic gastro-intestinal biopsies.

2.3.2. Research Involving Vulnerable Populations

2.3.2.1. Children: Research projects involving children are subject to the regulations and tiered review standards at 45 CFR 46 Sub Part D. Requirements for assent and parental permission are consistent with the federally funded research standards, though the IRB may, at its discretion, determine that consent from one parent is sufficient. Research that would otherwise be subject to the requirements at 45 CFR 46.407 may be handled locally, not through the Secretary of HHS.

2.3.2.2. Prisoners: Research projects involving prisoners are subject to the same requirements for review and protections as those at 45 CFR 46 Sub Part C, with the exception of the following requirements: OHRP certification and concurrence; HHS Secretarial consultation; Prohibition against exempt status. In addition, if a research participant incidentally becomes incarcerated after enrolling in projects eligible for flexible review and oversight, prisoner research regulations (45 CFR 46 Subpart C) do not apply, review does not need to include a prisoner representative.

2.3.2.3. Pregnant Women, Human Fetuses and non-viable Neonates: Research projects eligible for flexible review and oversight involving pregnant women, fetuses and neonates are subject to the federal requirements at 45 CFR 46 Subpart B with the exception of the requirement at 45 CFR 46.204(d) which requires the research develop "important biomedical knowledge."

2.4. Reporting Requirements

Research projects that fall out of the scope of the FWA are not subject to the same reporting requirements as federally funded projects for reporting of serious or continuing non-compliance, suspensions or terminations, or reporting of unanticipated problems involving risk to subjects or others. Ascension Wisconsin does not report those matters to the federal agencies but follows internal reporting requirements. All other procedures and requirements involving these determinations and actions remain the same, including the requirement for the researcher to report them to the IRB and the management, determination, and review procedures followed RI&P and the IRB.

2.5. Multicenter Research

Multicenter or multisite research projects involving other "engaged" institutions that are funded outside the federal funding stream are not subject to the same formal inter-institutional agreements or assurance requirements as are federally funded projects. Other forms of communication documenting collaborations are sufficient.

3. Equivalent Subject Protections for Research Reviewed Under the Flexibility Policy

3.1. The research is reviewed using the same procedures for research to which the Common Rule applies.

3.2. All subject protections and ethical standards apply to all research.

3.3. All forms, checklists, documentation and reporting requirements outlined in other policies and procedures apply to all research, including post approval quality reviews.

REFERENCES

n/a

RELATED MATERIAL

n/a

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	2/13/2018	New- Initial Integration Update	J. Blundon
02	12/4/2019	Modifications to implement revised common rule	J. Blundon-Kirchen