SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	Human Subject Research Exempt from IRB Review	Effective: 1/21/2019
		Approved: 2/19/2018
SOP ID		Last Revised: 12/4/2018
IRB-SOP-302		Expiration: n/a

PURPOSE

This document outlines the procedures used by Ascension Wisconsin Research Integrity and Protection to review and evaluate submissions for exempt human subject research status.

SCOPE

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

DEFINITIONS

None

PROCEDURES

1. **Criteria for Exemption**
   - **1.1.** Exempt research is human subject research that involves very little, if any, associated risk and falls within the defined categories outlined at 45 CFR 46.101(b) & 102(d) and (f) (pre-2018 Common Rule)/ 45 CFR 46.104(d)(2018 Common Rule) and 21 CFR 56.104.).
   - **1.2.** Research may not qualify for exemption from IRB review if the research is FDA regulated.

2. **Submission for Determination of Exempt Status**
   - **2.1.** Researchers may not self-determine research to qualify for exemption from IRB review.
   - **2.2.** Researchers must submit an application requesting exempt human subject research review and approval through Mentor prior to beginning the research.
   - **2.3.** Researchers are expected to use the forms and guidance provided and to provide sufficient information to RI&P so that specific required determinations can be made and it can be determined, as appropriate, the kind of review is required and whether the applicable criteria for IRB approval have been met. This may be achieved by submitting study materials such as a protocol, consent form (if applicable), data collection tools, etc.

3. **Determination of Exemption**
   - **3.1.** RI&P staff determines if the research project meets eligibility requirements for exemption from IRB review and may consult with the IRB Chair, designated reviewer or Director as needed.
   - **3.2.** For Exempt categories requiring limited IRB review, under 45 CFR 46.104(d) (2018 Common Rule), IRB staff assign an IRB reviewer to conducts a limited IRB review using Mentor.
   - **3.3.** Questions about the application will be sent to the investigator for response.
   - **3.4.** If the exemption is granted, the investigator will be notified.
   - **3.5.** If the exemption is not granted, the investigator will be notified that the submission does not meet the criteria and will be advised about how to proceed.

4. Additional Requirements and Oversight

4.1. Compliance with this SOP also requires compliance with state or local laws or regulations which provide additional protections for human subjects.

4.2. Researchers are responsible for ensuring full and continuing compliance with all Institutional and IRB policies in the conduct of their research and all Institutional and ancillary review requirements apply. For example, IRB SOP: Use and Disclosure of Protected Health Information for Research, IRB SOP and Guidance: Ancillary Review Requirements.

4.3. Research activities may not commence until the Researcher receives a written notice of exemption from RI&P.

4.4. Once a study has been determined to qualify for exempt status, no further oversight of the IRB is normally necessary, except for the following:

4.4.1. If revisions are made to the study as originally approved for exempt status, the Researcher must submit the so that R&IP staff can verify that the project remains eligible for exemption from IRB review.

4.4.2. Notification of study completion or closure (applicable only for studies initially approved on or after 1/1/2019).

REFERENCES

- 45 CFR 46.104(d)
- 21 CFR 56.104, 21 CFR 56.105
- OHRP Decision Charts for guidance on the regulatory eligibility for exemption from IRB review
- IRB SOP: Materials for IRB Review (SOP-105)
- IRB SOP: Use/Disclosure of Protected Health Information for Research (SOP-701)
- IRB SOP: Ancillary Review Requirements (SOP-304)

RELATED MATERIALS

- IRB Guidance: Exempt Research
- IRB Guidance: Exempt Study Submission Guide
- IRB Guidance: Ancillary Review Requirements

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	2/13/2018	New- Initial Integration Update	J. Blundon
02	12/4/2018	Effective 1/21/2019- Updates due to revised common rule; addition of closure notification requirement.	J. Blundon-Kirchen