**1. PURPOSE**
The procedure describes the research process, review, and determinations for claims of exemption.

**2. PROCEDURE**
Research activities in which the only involvement of human subjects will be in one or more specific categories listed in 45 CFR 46.101, 45 CFR 46.104, 21 CFR 50.23, 21 CFR 50.24, 21 CFR 56.104, 21 CFR 56.105, and which are listed on the Exempt & Limited IRB Review Checklist, must be submitted to the IRB for review and approval.

All research including in the exempt categories must meet, at a minimum, the principles outlined in the regulations and meet Avera ethical standards. Determination of exemption will be documented by the IRB on an appropriate checklist.

**3. SPECIFIC PROCEDURES**
**3.1 Exempt Project Submission Requirements**
Research activities that meet the requirements for one or more exempt research categories must be reviewed by the IRB in order for an IRB letter to be generated, which documents the exempt determination.

The Principal Investigator (PI) must complete the appropriate electronic submission and submit the protocol (or plan) along with (if appropriate):

- Questionnaires, surveys, assessments, interview questions, tools;
- Consent statements, informed consents, waiver of informed consent;
- Research HIPAA authorization or waiver of HIPAA; and/or
- Advertisements, letters of permission.

**3.2 Exemption Categories and Determinations**
Research activities in which the only involvement of human subjects will be in one or more of the exempt categories can be approved as exempt. The Chair, designee or manager will complete the Exempt & Limited IRB Review Checklist to review the project and make a determination.

The review of the research will also include:

- Assessing whether the research meets the ethical standards of Avera; and
- Ensuring there is minimal risk to the subject.

The reviewer may require additional protections to meet the principles, including a level of informed consent appropriate to the research, or review by the full IRB.

**3.3 Approval Period**
Studies receiving an exemption by the IRB will not receive an expiration date and do not need to submit an annual continuing review. Even when research is excused from continuing review, the PI is responsible for ensuring any changes to the protocol are submitted and approved by the IRB prior to implementation, reporting any unanticipated problems, noncompliance, or new information to the IRB.

The PI may close the study when data collection has ended or contact with the subject is complete. The manager may close the study administratively if they are not able to contact the PI after multiple attempts.

**3.4 Documentation of Exempt Review**
If the study qualifies for exempt review, the reviewer will complete the Exempt & Limited IRB Review Checklist, and the checklist will be used as documentation.

**3.5 PI and IRB members Notification**
The PI will be notified via a formal IRB letter of the exempt determination.

**4. RESPONSIBILITY**
Chair, designee, or the manager is responsible for review of the project to determine if the research qualifies for exemption.

Chair, designee, or manager is responsible for providing guidance to the reviewer as needed.

Manager or IRB staff is responsible for sending out approval correspondence to the PI and reporting exemption to IRB members via IRB meeting agenda.

**5. APPLICABLE REGULATIONS AND GUIDELINES**
45 CFR 46.101
45 CFR 46.104
21 CFR 50.23-24
21 CFR 56. 104-105

**6. REFERENCED DOCUMENTS**
Exempt & Limited IRB Review Checklist

| Revision Number | Version Date | Approved By | Date Approved |
|---|---|---|---|
| 2.0 | 8/27/2019 | Avera Institutional Official | 9/27/19 |
| • Under the revised 2018 Common Rule, some research may be recorded and still qualify as Exempt Research, per 45 CFR 46.104(d).<br>• Research project must be submitted in the IRB electronic system in order for an IRB letter determination to be completed.<br>• Changed the "Exemption Checklist" to the revised, current IRB reviewer checklist: HRP-312 Exempt & Limited IRB Review Checklist.<br>• Updated the applicable regulations. | | | |
| 1.0 | August 2016 | Director HSRP / August 2016 | |