**Guidance on EXEMPT Review and Determination**

**Auburn University Human Research Protection Program (HRPP)**

**What is EXEMPT research?**

EXEMPT studies are so named because they are exempt from some federal regulations (refer to §46.104). However, EXEMPT studies are not exempt from state laws, institutional policies, or the requirements for ethical research. Auburn University policy requires review by an experienced reviewer for all research submitted as EXEMPT.

**1. Purpose**

1.1. The purpose of this policy is to provide: (1) information to investigators about what human research activities are considered EXEMPT; (2) a description of the responsibilities of the investigators in the ethical conduct of human participant research; (3) a description of the submission and determination process for EXEMPT research, (4) information about modifications to research determined to be EXEMPT, and (5) information regarding Principal Investigator (PI) eligibility.

**Policy**

2.1. The Auburn University Human Research Protection Program (AU HRPP) requires all research activities involving human subjects receive prior review, including human research activities that may qualify for EXEMPT determination.

2.2. Investigators must submit requests for EXEMPT review via irbsubmit@auburn.edu.

2.3. Research qualifies for EXEMPT determination if the proposed research activities involve no more than minimal risk to participants **and** the proposed activities fall within one or more of the EXEMPT categories listed in the federal regulations (DHHS).

 2.3.1. EXEMPT categories 7 and 8 require broad consent. The Auburn University IRB has

 determined that the regulatory requirements for legally effective broad consent are not

 feasible within the current institutional infrastructure. EXEMPT categories 7 and 8 will not

 be implemented at this time.

2.4. There may be restrictions on the involvement of vulnerable populations in EXEMPT research which are as follows:

2.4.1. **Fetuses, Pregnant Women, and Human in Vitro Fertilization** (Subpart B 45 CFR 46.104 (b)(1)): Each of the EXEMPT categories may be applied if the conditions of the exemption are met.

2.4.2. **Prisoners** (Subpart C 45 CFR 46.104 (b)(2)): EXEMPT determination categories do not apply to research targetingprisoners. If the broader participant population only incidentally includes prisoners who are not targeted, EXEMPT determination categories are applicable.

2.4.3. **Children** (Subpart D 45 CFR 46.104 (b)(3)**:** EXEMPT categories (1), (2), (4), (5), and (6) are applicable to research involving children. Category 2 can only be applied when research activities are limited to educational tests or observation of public behavior (when the investigator is NOT participating in the activities being observed). Category 3 does not apply if the activity involves children. Research which occurs out of the United States and targets minors as participants is not eligible for EXEMPT review.

2.5. Research that is subject to FDA regulations may be EXEMPT only under category 6.

2.6. Research using deception or incomplete disclosure regarding the nature or purposes of the research is eligible for EXEMPT determination, if it meets criteria for EXEMPT determination as described in this policy **and** participants authorize the deception through a prospective agreement. Limited IRB is required for EXEMPT research meeting criteria for EXEMPT determination.

 2.6.1. For research using deception, the process to de-brief participants must be described

 and the debriefing script must be included in the EXEMPT application.

2.7. All research activities involved must be eligible for at least one of the EXEMPT categories in order to be determined EXEMPT. If any research activity is not eligible for an EXEMPT category, then the study will be reviewed by the IRB through expedited or full board review.

2.8. Determination regarding whether research subject to the revised Common Rule qualifies for EXEMPT status will be made by the HRPP Manager or designee.

2.9. Research that is EXEMPT from federal (DHHS) regulation may not be EXEMPT from other federal regulations, laws, codes, and guidance. Applicable federal laws may include Family Education Rights and Privacy Act (FERPA) and Health Insurance Portability and Accountability Act (HIPAA).

2.10. EXEMPT research must meet the same ethical standards as other human subjects research, including adequate provisions, when warranted, to protect vulnerable participants, maintain the confidentiality of the data and the privacy interests of participants and as articulated in codes of professional conduct.

2.11. The HRPP Manager, designee, and IRB Chair(s) are authorized to conduct institutional ethical evaluation of EXEMPT research.

2.12. When research requires limited IRB review or a HIPAA determination (waiver or alterations of the requirement for HIPAA authorization), the review will be conducted using expedited review procedures and will be reviewed by the IRB Chair(s). As with other research subject to IRB review requirements, when conducting limited IRB review, the IRB or designated member of the IRB have authority to approve, require modification to secure approval, or disapprove all research activities.

2.13. For EXEMPT categories 2(iii) and 3(iii), the IRB may approve the research when it is determined there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

2.14. If approved research later becomes funded, supported, or regulated, the change must be reported immediately to the IRB via Modification.

 2.14.1. Human subjects research activities may not continue until review and approval of

 the modification describing funding is issued by the IRB.

 2.14.2. Participants must be informed of sponsor support, including any potential conflict

 of interest by members of the research team, that study data may be shared with the

 sponsor(s), and other changes that directly and/or indirectly affect participants.

2.15. All changes/modifications to approved EXEMPT research requires review and approval of the changes/modifications by the IRB in advance of those changes/modifications being implemented. While the modification process occurs, previously approved procedures can continue; however, no new procedures may begin until IRB approval of the modification request is issued.

2.17. Continuing review is not generally required for EXEMPT research even when subject to limited IRB review. No expiration date is assigned for most EXEMPT research. However, the IRB may determine continuing review is required for a particular study that is subject to limited IRB review, in which case the reason(s) for continuing review will be documented and communicated in the IRB memorandum.

2.18. When all study procedures from recruitment to data analysis are completed, the Principal Investigator must formally close the study. A Final Report submission is required.

2.19. Complaints, concerns, and unanticipated events or problems which involve risks related to the research must be reported promptly to the IRB.