HUMAN RESEARCH PROTECTION PROGRAM POLICY AND PROCEDURE

1.3 EXEMPT REVIEW OF RESEARCH

RESPONSIBLE OFFICE: Human Research Protection Program Department (HRPPD) **EFFECTIVE DATE: JUNE 7, 2021**

I. POLICY STATEMENT

A. Research that meets the categories set forth by the federal regulations [45 CFR 46.104(d); 21 CFR 56.104(d); 32 CFR 219.101(b)] may qualify for exemption. This procedure documents the requirements for determining an exemption from human subjects research regulations

B. Exempt research is exempt from IRB review; therefore, requests for exemption may be reviewed by a Designated Reviewer (an experienced HRPPD staff member designated by the IRB Director) or by a member of the IRB designated by the IRB Chair.

C. Exemption determinations may not be made by researchers

D. Research is exempt from the human research protection regulations

E. Ethical Principles Relevant to Exempt Research. The principles of respect of persons, beneficence and justice are applied to all research conducted at the UTSW including human research that has been determined to be exempt.

F. Exemption #2(i) and (ii) for research involving survey or interview procedures or observations of public behavior does not apply to research in children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. Exemption #2(iii), where identifiable information is obtained and the IRB conducts a limited IRB review, is NOT applicable to research in children. Exemption #3 does NOT apply to research involving children.

G. Exemptions do not apply to research with prisoners EXCEPT for research aimed at involving a broader subject population that only incidentally includes prisoners.

II. SCOPE

A. This policy and procedure applies to all Investigators, the Human Research Protection Program Department and IRB.

III. PROCEDURES FOR POLICY IMPLEMENTATION

A. Submission and Screening

1. The PI makes a preliminary determination to submit a study for exempt review based on an assessment of the protocol establishing that it falls into one or more of the categories specified in the federal regulations.
2. The PI submits a completed Exemption Application to the HRPPD via eIRB. Instructions for preparing the application are available on the IRB website. The investigator may call the HRPPD with questions.

3. Upon receipt of the application, the study is in-processed and reviewed for completeness and accuracy per the 1.1 Receiving, Routing and Administrative Review of Submission Policy and Procedure.
4. The HRPPD staff will route the application to a designated reviewer of the IRB
5. If it is clear to the HRPPD staff that the application does not meet the criteria for exempt review, the HRPPD staff contacts the PI and recommends resubmitting either a non-research, non-human research, expedited or full board application. An IRB Expedited Reviewer is generally consulted.

B. HRPPD Exempt Review

1. The Designated Reviewer (DR) receives the exempt application materials.
2. The Designated Reviewer is responsible for reviewing the application to determine that all of the research procedures fit one or more of the exemption categories specified in the federal regulations. The DR may request additional information from the PI to aid in providing clarifications where necessary. The DR ensures that the research meets ethical principles and standards for protecting research subjects. The Reviewer uses eIRB to note the results of the review.
3. To be determined exempt, all of the following must be true. The research must:
    a. Present no more than minimal risk, and
    b. For research funded by HHS or DoD, it must not involve prisoners as participants, and
    c. Not be subject to FDA regulations ("FDA regulated research") – category 1 – 5 only, and
    d. For research funded by HHS, DoD or ED, it must not involve children under category 2(i or ii) unless the research involves education tests or observations of public behavior and the investigators do not participate in the activities being observed. Children may not be involved in category 2(iii) or category 3.
4. The research must also fall within one or more of the categories below:
    a. **Category 1 -** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes:
        i. Most research on regular and special education instructional strategies, or
        ii. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
    b. **Category 2** - Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
        i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an **IRB conducts a limited IRB review** to make the determination required by 45 CFR §46.111(a)(7): *"When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."*

c. **Category 3** - Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an **IRB conducts a limited IRB** review to make the determination required by 45 CFR §46.111(a)(7): *"When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."*

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

d. **Category 4** - Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
   i. The identifiable private information or identifiable biospecimens are publicly available;
   ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
   iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 ['HIPAA'], subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); **or**
   iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

e. **Category 5** - Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   i. The projects conducted pursuant to specific federal statutory authority such as programs under the Social Security Act, or other federal statutory public benefit or services programs;
   ii. Procedures for obtaining benefits or services under those programs;
   iii. Possible changes in or alternatives to those programs or procedures; or
   iv. Possible changes in methods or levels of payment for benefits or services under those programs.
   v. Projects for which there is no statutory requirement for IRB review;
   vi. Projects that do not involve significant physical invasions or intrusions upon the privacy interests of subjects;
   vii. Authorization or concurrence by funding agencies that exemption from IRB review is acceptable.

f. **Category 6** - Taste and food quality evaluation and consumer acceptance studies:
   i. If wholesome foods without additives are consumed; or
   ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: Exempt categories 7 & 8 always require limited IRB review and are only available when broad consent will be (or has been) obtained. The UT Southwestern IRB may limit or constrain the use of broad consent as appropriate. Any determination where broad consent is not allowed or limited will be communicated as per 8.2 REPORTING POLICY AND PROCEDURE.

g. **Category 7** - Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR §46.111(a)(8):
   i. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of 45 CFR §46.116(a)(1) – (4), (a)(6), and (d) (See Sections 8.1 and 8.3);
   ii. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with 45 CFR §46.117 (See Sections 8.6 and 8.7); **and**
   iii. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

h. **Category 8** - Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
   i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR §46.116(a)(1) through (4), (a)(6), and (d) (See Sections 8.1 and 8.3);
   ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR §46.117 (See Sections 8.6 and 8.7);
   iii. An IRB conducts a limited IRB review and makes the determination required by 45 CFR §46.111(a)(7): *"When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data"* and makes the determination that the

research to be conducted is within the scope of the broad consent referenced in 8.i above; **and**

iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

5. Criteria used to determine that participants are protected in Exempt Research
    a. **Criteria 1**: All of the proposed research procedures fit one or more of the exemption categories above
    b. **Criteria 2**: Selection of participants is equitable (as applicable).
    c. **Criteria 3**: If there is recording of non-sensitive, identifiable information, there are adequate provisions to maintain the confidentiality of the data.
    d. **Criteria 4**: If there are interactions with participants, there will be a consent process that will disclose the following information (as applicable):
        1) That the activity involves research.
        2) A description of the procedures.
        3) Risks and benefits.
        4) That participation is voluntary.
        5) How information will be protected to maintain confidentiality.
        6) Name and contact information for the investigator.
    e. **Criteria** 5: There are adequate provisions to maintain the privacy interest of participants.
6. For exempt research subject to limited IRB review, the following criteria for IRB approval shall be applied:
    a. For exempt categories 2 and 3, the IRB may approve the research when it determines that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data [45 CFR §46.104(2)(iii) and (3)(iii)]
    b. For exempt category 7, the IRB may approve the research when it determines that the following criteria are satisfied:
        i. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained [45 CFR §46.116(a)(1) - (4), (a)(6), and (d)]
        ii. Broad consent is appropriately documented or waiver of documentation is appropriate [45 CFR §46.117]; and
        iii. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
    c. For exempt category 8, the IRB may approve the research when it determines that the following criteria are satisfied:

i. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and
ii. The research to be conducted is within the scope of the broad consent obtained from subjects.

7. The Designated Reviewer or HRPPD staff contacts the PI for any revisions needed to qualify the study for exempt status.
8. The PI is responsible for responding to the Designated Reviewer's issues in a timely manner. Once received, the Designated Reviewer determines whether the revisions are sufficient for determination of exempt status.
9. The Designated Reviewer makes the final determination and notes the appropriate category(ies) in eIRB.

C. Review Outcome(s)

1. The Designated Reviewer makes one of the following decisions:
    a. Determination that the research does not qualify for exempt status.
        1) The rationale for the determination and recommendations for submission of non-research, non-human research, expedited or full review application will be communicated to the PI where applicable;
        2) If the Designated Reviewer determines the research does not qualify for exempt status, the PI may request that the proposal be reviewed by Expedited Review or the Convened IRB who may determine the exemption applies. Alternately, the PI may submit the research proposal as an expedited study if the study meets the criteria for an expedited review. If the study does not meet the criteria for an expedited review, the PI submits a full board review application and requests that the HRPPD schedule a full board review.
    b. Changes Requested: Indicates that the Designated Reviewer requires minor revisions . The HRPPD staff or DR sends the investigator a summary of the requested changes via eIRB. The PI responds to revisions requested via eIRB. The DR may HRPPD request additional information from the investigator or acknowledge the response to issue an exempt determination.
    c. Accepted as Exempt: If ready for implementation, the HRPPD staff notifies the PI of the decision per the HRPP Reporting Policy and Procedure.
2. Appeals - If the PI has concerns regarding the Designated Reviewer or IRB decision/recommendations for changes in the study, he/she may submit the concerns to the IRB in writing, including a justification for changing the IRB decision. The PI may send the request to the reviewer and/or the IRB Director or IRB Chair for final resolution. If the investigator is still dissatisfied with decision, he/she may send the study to the full IRB for review.
3. IRB records for all exempt determinations include the citation of the specific category justifying the exempt status.

4. When a research study has been determined to be exempt, continuing reviews are not required. The HRPP office will periodically request status updates to determine whether the study should be closed in the eIRB system.

D. Changes in ongoing Exempt research

1. Any changes to the research activities should be reviewed by an HRPPD staff member (who may or may not be a Designated Reviewer) prior to implementing.
2. The PI should submit the proposed changes, and any revised documents to the HRPPD via eIRB.
3. The HRPPD staff reviewer will determine whether the change alters the exemption determination.
4. If the changes do not affect the exempt determination and are acceptable, the reviewer documents the determination in the eIRB record . The PI is then notified.
5. If the changes do affect the exempt determination such that the study will no longer be eligible for exempt status, the reviewer contacts the PI and develops a plan to modify the study via eIRB.

IV. DEFINITIONS

SEE GLOSSARY OF HUMAN RESEARCH TERMS

V. REFERENCES

Resource
21 CFR 50 – PROTECTION OF HUMAN SUBJECTS
45 CFR 46 – PROTECTION OF HUMAN SUBJECTS
45 CFR 164 – SECURITY AND PRIVACY (HIPAA PRIVACY RULE)
21 CFR 56 – INSTITUTIONAL REVIEW BOARDS

VI. REVISION AND REVIEW HISTORY

Revision Date	Author	Description
June 2021	HRPP	Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.
January 2019	HRPP	Updated for Revised Common Rule
August 2017	HRPP	New Policy Development
March 2012	IRB Office	IRB Written Procedures

VII.