Exempt Review

1.0 Purpose

To describe the policies and procedures for the Wright State University (Wright State) exempt review process.

2.0 Scope

This policy applies to all human subject research that is conducted by Wright State faculty, staff and students and human subject research for which the Wright State Institutional Review Board (hereafter referred to as IRB) acts as the IRB of record for an external entity (e.g., Premier Health, Dayton VAMC).

Federal and institutional requirements do not allow Wright State investigators to rely on an exempt determination made by external IRB. Local exempt review and determination via this policy is required.

***This policy does not apply to exemptions granted prior to January 21, 2019. Those studies were determined to be exempt per 45 CFR 45.101(b) and 21 CFR 56.104(d) and relevant institutional policy.*

3.0 Definitions

3.1 **Investigator** means the Project Director/Principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposing of research, including persons who are subcontractors, collaborators, or consultants. At Wright State this definition includes, but is not limited to, the following roles: Principal investigator, co-investigators, research coordinators, research associates, collaborators, and consultants, and may include research assistants and students as identified by the PD/PI depending on their specific roles and responsibilities.

3.2 **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable specimens.

3.3 **Intervention** means both the physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

3.4 **Interaction** means communication or interpersonal contact between investigator and subject.

3.5 **Private information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

3.6 **Identifiable private information** means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information

3.7 **Identifiable biospecimen** means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

3.8 **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

3.9 **Written, or in writing** means writing on a tangible medium (*e.g.,* paper) or in an electronic format.

3.10 **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are **deemed not to be research**:

- Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify,

monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

3.11 **Federal Funded or supported** means any of the following:

- Funded by a direct federal grant
- Funded through a sub-award or pilot grant associated with federal dollars
- Includes personnel on a federally funded training grant
- Research conducted under a no-cost extension
- Data will be used to support an application for FDA approval or a grant application (e.g., data collection in response to a scored grant submission with plans to re-submit)
- Involves an FDA-regulated product or dietary supplement
- Involves data collection about FDA-regulated products
- Conducted under a contract that requires the investigator to adhere to federal human subjects' regulations (e.g., 45 CFR 46, 34 CFR 97 or other references to the HHS Common Rule)
- Involves any services that could be billed to a federal program

3.12 **Flexible IRB review** means a review and oversight process that applies human subjects' protections commensurate with risk while reducing administrative burdens for researchers and the IRB. Flexible IRB review allows abbreviated IRB applications and consent forms, streamlined review by IRB Chair or staff members and elimination of the continuing review requirement.

4.0 Policy

The Department of Health and Human Services (DHHS) and FDA regulations apply to research involving human subjects, but there are some categories of research that the regulations consider to be exempt from IRB review requirements. To qualify as an exempt study, the research must fall within one of the specific federal regulatory categories AND satisfy the other

regulatory and Wright State institutional requirements.

Investigators cannot self-determine whether a study is exempt. A determination of exemption must be made by the Wright State designee (e.g., IRB staff). To request a determination an investigator must complete and submit the Initial Review Request in the Wright State IRB electronic submission system.

Although the research may qualify as exempt from IRB review, it must still be conducted in accordance with the institutional ethical standards, including:

- Equitable selection of subjects;
- Adequate provisions to maintain confidentiality of any identifiable information collected;
- Adequate provisions to protect subject privacy;
- Present minimal risk to subjects; and
- Informed consent process.

Investigator activities that clearly **do not meet both** the definition of human subject and research as defined in Section 3.0 above are not required to be submitted for review under this policy. However, if an investigator is unsure or requires a written "Not Human Subjects Research" determination, he/she should consult with the Wright State IRB Office and/or submit an initial request for review.

5.0 Procedures

5.1 Exempt Categories

The DHHS exempt categories will be applied to proposed research regardless of funding source, unless one or more of the exceptions described in Section 5.2 apply. The categories defined in 45 CFR 46.104(d) are as follows:

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 most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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 §46.111(a)(7).

Category 3:

(i) 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**:

(A) 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;

(B) 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

(C) 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 §46.111(a)(7).

(ii) 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.

(iii) 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.

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, 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.

Category 5:
Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service

programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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).

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);
(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; 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.

5.2 Exceptions

5.2.1 Broad Consent

The use of broad consent as described in Category 7 (45 CFR 46.104(d)(7)) and Category 8 (45 CFR 46.104(d)(8)) is permissible only with prior consultation with the HRPP Director under this policy for research that does not involve data protected by the HIPAA privacy rule.

5.2.2 FDA-Regulated Research

Research is subject to FDA regulation if it involves a drug, medical device, food, or other product regulated by the FDA. The FDA only provides three types of exemption:

- Research which started before July 27, 1981, and either did not require FDA approval before that date, or was subject to requirements for IRB review prior to that date, and remains subject to review by an IRB which meets FDA requirements;
- Emergency use of a test article, provided any such use is reported to the IRB in accordance with the Emergency Use Policy
- The taste and food quality evaluation provided for above in category 6.

Any other research subject to FDA regulation cannot be exempt.

5.2.3 Prisoners

DHHS regulations and Wright State prohibit the conduct of research involving prisoners from receiving exempt review except for research aimed at involving a broader subject population that **only incidentally** includes prisoners.

5.2.4 Children

Research involving children (individuals less than 18 years of age) cannot be exempted under Category 2 (except for educational tests or observation of public

behavior when investigators do not participate in activities being observed) or Category 3. This does not mean that this type of research is prohibited. It means that it must receive IRB review and approval (i.e., expedited or convened review).

5.2.5 **Flexibility Provision**

Wright State University allows flexibility in its research protection program through limiting the scope of its Federalwide Assurance (FWA)_to federally funded or federally regulated research. Research projects outside the scope of these regulations will nonetheless be afforded equivalent protections. This Flexibility Provision is limited to studies involving no greater than minimal risk. This provision creates a new approval category not subject to federal regulations that applies to minimal risk research. Should a study approved under the Flexibility Provision obtain federal funding or should the risk level change, it is the responsibility of the Principal Investigator to notify the IRB. Application of this provision will be at the discretion of the of the Wright State IRB. This review process will reduce administrative and regulatory burden for minimal risk research that is not under federal purview.

Exclusions to Flexibility Provision:

- Federally funded studies
- Projects where a student is paid/supported from a federal training grant or otherwise paid/supported directly from the Faculty Advisor's federal funds
- Research conducted at the Dayton VA Medical Center
- Research otherwise regulated by a federal agency that has signed on to the Common Rule, including all agencies within the Department of Health and Human Services
- Classified research (research procedures and/or results are legally knowable only by individuals with United States government security clearance)
- Studies with FDA-regulated components
- Studies with contractual obligations or restrictions that preclude eligibility in this policy
- Collaborative studies requiring an institutional authorization agreement (IAA) that apply federal regulations to all research regardless of the funding source
- Studies using prisoners as subjects
- Studies seeking or obtaining Certificates of Confidentiality
- Studies required to register to ClinicalTrials.gov
- Studies targeting tribal members, military personnel, wards of the state, or cognitively impaired individuals.

Inclusions to Flexibility Provision:

- Normal educational practices in established or commonly accepted

educational settings that are not likely to adversely impact students' opportunity to learn required educational content, or the assessment of educators who provide instruction

- Surveys, interviews or focus groups with adults or children and covering benign topics.
- Minimal risk educational or behavioral tests, performance tasks, surveys, interviews or focus groups that involve participants with cognitive impairment, potentially sensitive topics, or use of videotaping if appropriate consenting and data protections are in place
- Observations of public behavior
- Benign research on perception, cognition, motivation, communication, social behavior, behavioral games, or minimal risk performance tasks.
- Studies of leadership traits of non-public, non-elected officials
- Studies involving oral histories, ethnographies, and autoethnographies
- Studies utilizing commercially available measurement technology such as eye-tracking
- Analysis of data or specimens may include:
    - Secondary research using identifiable information or specimens collected for non-research purposes
        - HIPAA requirements must be met (authorization or waiver of authorization)
        - Data storage and transfer (if any) must meet institutional security standards
    - Secondary research using identifiable information or specimens collected for research purposes
        - The new purpose for analysis must not be precluded by the original consent
        - HIPAA requirements must be met (authorization or waiver of authorization)
        - Data storage and transfer (if any) must meet institutional security standards
- Studies combining surveys with existing data that do not incur additional risk
- Studies utilizing incomplete disclosure
- Biomedical studies may include activities listed below provided participants are adults, research results are not clinically relevant; results are not placed in the participant's medical record; and results are not returned to participants.
    - Light to moderate exercise in healthy adult participants only
    - Non-invasive tests (body composition, blood pressure, pulse)
    - Non-invasive collection of biospecimens (nails, hair, saliva, etc.)

- Non-invasive procedures, such as ultrasound, doppler, EEGs, ECGs, eye tracking

Protected Categories Eligible for Flexibility Provision:

This provision may be applied to minimal-risk research involving pregnant women, prisoners, or children. The IRB confirms the research qualifies as minimal risk.

- Expansion of Research Involving Pregnant Women, Human Fetuses and Neonates
  - The 45 CFR 46 Subpart B regulations for pregnant women and fetuses are not applied when a pregnant adult subject is involved in minimal-risk research under the flexibility provision.
  - Neonates of uncertain viability and nonviable neonates may be in involved in retrospective medical chart reviews without requiring the legally effective informed consent of both parents as required at 45 CFR 46.205(b)(2) and (c)(5).
- Expansion of Research Involving Prisoners
  - The 45 CFR 46 Subpart C regulations for prisoners are not applied when a subject becomes incarcerated during the course of participation in research. The subject's continued participation is part of the investigator's overall responsibility to protect the rights and welfare of subjects. Individuals incarcerated during participation in research may continue participation in non-federally funded projects without an IRB re-review with the prisoner representative.
  - Research projects involving prisoners are subject to the same requirements for review as those at 45 CFR 46 subpart C, with the exception of the requirement for review by the Secretary of HHS cited at 45 CFR 46.306. Unfunded or non-federally funded research is not required to get approval from the Secretary at HHS.
  - The Wright State IRB will not consider persons in transitional custody whose liberty is restricted such as half-way houses, electronic monitoring, probation, or house arrest, to meet the federal definition of prisoner. For those individuals, the criteria at 45 CFR 46.111 offer sufficient protection for their level of vulnerability.
  - Data analysis of information collected from court records may be deemed exempt under the flexibility provision.
- Expansion of Research Involving Children
  - The 45 CFR 46 Subpart D regulations are not applied when a minor subject is involved in minimal-risk research under the flexibility provision.
  - Requirements for assent and parental permission may be altered or waived for reasons other than those outlined in 45 CFR 46.408.

- Research that would otherwise be subject to the requirements at 45 CFR 46.407 may be handled locally, not through the Secretary of HHS.
- Online surveys, in-person focus groups, and/or interviews can involve minors as long as the information collected does not place the individual at greater than minimal risk.
- Unfunded studies that involve children can be classified as Minimal Risk under Flexibility Provision at the discretion of the IRB.

5.3 Informed Consent, FERPA and HIPAA Authorization Requirements

Formal written informed consent is not required for research determined to be exempt from IRB review. However, the IRB encourages investigators to provide potential subjects with information about the study (e.g., informational letter) whenever feasible prior to engaging any subject in that research to support their voluntary participation. This ethical obligation exists for all research – exempt and non-exempt. Because formal written consent is not required for studies confirmed as meeting the criteria for exempt review, it allows PI's greater flexibility in the informed consent process.

While federal regulations do not require signed informed consent for participation in research under exempt review, investigators must be aware of other regulations or policies that may require documented/signed informed consent. Research involving educational records, or the use of student coursework/grades is likely subject to the Family Educational Rights and Privacy Act (FERPA). FERPA regulations typically do require that students (or parent/guardian) provide written consent for use of records or coursework for research regardless of the level of IRB review.

Other regulations such as the Health Insurance Portability and Accountability Act (HIPAA) and the General Data Protection Regulation (GDPR) may have additional authorization/consent, documentation, and/or notification requirements beyond those required by the IRB.

If the proposed exempt research involves utilization of Protected Health Information (PHI), HIPAA regulations apply. Investigators must indicate whether the research involves PHI as part of the initial request process and justify a waiver of authorization if written authorization will not be obtained from each subject in accordance with the Privacy Rule (see Human Subject Research Use and Disclosure of Protected Health Information Policy for more information about waivers).

5.4 Scientific Merit and Resource Feasibility Review

Scientific or scholarly merit and resource feasibility review **is not required** by the IRB for exempt human subject research projects, except for those funded by the

Department of Defense (See *Department of Defense* Guidance).

However, all Premier Health and Dayton VAMC studies must receive scientific review by the respective hospital's research committee regardless of whether the proposed research is exempt or not exempt from IRB review per their separate institutional requirements.

5.5 **Wright State IRB Office Review**

Wright State IRB staff members (IRB staff) are responsible for screening new studies to determine whether the proposed research requires IRB review or qualifies for an exempt determination. An IRB staff member has the authority to make an exempt determination (unless limited IRB is required) but may consult with the IRB Chair or Vice-Chair if needed.

The IRB staff will make one of the following review determinations:

- Certify the exemption; or
- Certify the exemption imposing mandatory changes to the research methods, consent process(es), privacy/confidentiality, and/or data security procedures. Upon receipt of the conditional certification, the researcher may either (a) accept and incorporate the mandatory changes, or (b) appeal the exempt review via e-mail; or
    - If the investigators accept and incorporate the mandatory conditions, the research may commence without further correspondence with the IRB Office. An appeal of the mandatory conditions may involve required modifications to the original submission.
    - Starting the study without incorporating the mandatory changes may be reviewed by the IRB as potential non-compliance in accordance with the *Human Subject Research Non-Compliance Policy.*
- Refer the submission for expedited or convened meeting review; or
- Require minor stipulations seeking clarification and/or changes to the research methods, consent process(es), privacy/confidentiality, and/or data security procedures of the original submission. The researcher will need to resubmit the submission for consideration for exempt certification.

After a study has been determined to be exempt, the IRB staff member will generate and send an exemption letter via the electronic submission system. This letter must document the date that exemption was made, the applicable exemption category or categories, and limited IRB review, when applicable.

5.6 Limited IRB Review

Limited IRB member review and approval of the proposed privacy and confidentiality provisions is required when research meets the exemption criteria defined for 45 CFR 46.104(d)(2)iii) or 45 CFR 46.104(d)(3)(i)C).

In such cases, where limited IRB is required, the IRB staff will assign a voting IRB member to review the submission in the electronic submission system. The IRB member's review is limited to the privacy and confidentiality provisions and does not include approval of all normal review criteria defined at 45 CFR 46.111.

Limited IRB review and approval must be documented in the exemption letter when applicable.

5.7 Administrative Check-In, Study Closure, and Required Modifications

Exempt determinations do not require continuing review and do not expire. An administrative check-in e-mail will be sent annually. The purpose of the check-in e-mail is to remind investigators to submit modifications, incidents, and/or closure submissions, as appropriate. No action is required to continue the project.

The principal investigator (PI) is responsible for formally closing a study when it is completed or discontinued regardless of whether it is exempt. For additional information regarding a study closure request, please refer to the Study Closure policy.

If the **exempt research involves protected health information** (PHI), the PI is required to submit a modification to his/her application via the electronic submission system prior to any study staff changes and/or study data collection changes (e.g., collection of additional data points, increase in number of subject records or biospecimens to be involved).

The IRB staff will review the modification and send a written letter approving the change via administrative review, if appropriate.

If the **exempt research does not involve PHI**, modifications are not required. However, the PI must consult with an IRB staff member prior to making any substantive changes to the initial research plan that received the exemption to determine whether the modified research plan remains exempt.

Substantive changes include, but are not limited to:

- Changes to study personnel (to review credentialing)
- Changes that involve protected health information (PHI)

- Changes that increase the risk to participants or change the risk: benefit ratio of the study
- Changes that affect a participant's willingness to participate in the study
- Changes to the study sponsor
- Changes to study procedures that are not covered by the Exemption Category determined for this study (listed above).

5.8 **Other Institutional Reviews**

Research that is determined to be exempt from IRB review, may still require other institutional reviews and approvals (e.g., affiliated hospital, department, etc.) before being allowed to commence. The investigator is responsible for identifying and completing all review requirements prior to the initiation of research.

6.0 Records

All records related to this process will be stored and maintained in accordance with any Wright State policy, federal regulations and sponsor requirements associated with the human subject research protocol under review.

7.0 References

- 45 CFR 46.104
- 21 CFR 56.104
- VHA Handbook
- 38 CFR 16