Expedited Review

1.0 Purpose

To describe the policies and procedures for the Wright State University (WSU) IRB expedited review process.

2.0 Scope

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

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 WSU 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:

- 3.2.1 Obtains information or biospecimens through intervention or interaction with the individual and uses, studies or analyzes the information or biospecimens; or
- 3.2.2 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**:

- 3.10.1 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.
- 3.10.2 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).
- 3.10.3 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.

3.10.4 Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

4.0 Policy

The IRB may use an expedited review process to review proposed human subject research that involves no more than "minimal risk" and that meets one or more of the categories (see Section 5.1) defined by the Department of Health and Human Services (DHHS) and Food and Drug Administration regulations. Expedited review procedures allow one or more experienced IRB members to review and approve studies that meet the criteria without convening a meeting of the full board.

Expedited reviewers may only approve research that meets the federal criteria for approval as specified in 45 CFR 46.111 and 21 CFR 56.111. They must also ensure that the study's informed consent process and documentation meets the requirements as specified in 45 CFR 46.116 and 21 CFR 50.25 unless the IRB waives the requirements in accordance with federal regulations.

Expedited reviewers exercise all of the authority of the IRB except that the reviewers may not disapprove the research. Only the convened IRB is able to disapprove human subject research via procedures described in the DHHS and FDA regulations. Investigators cannot self-determine whether a study qualifies for expedited review. The IRB makes the final determination whether a study is eligible for expedited review.

5.0 Procedures

5.1 Expedited Categories

Applicability

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The categories in this list apply regardless of the source of funding, for example non-federally funded research.

The categories in this list apply regardless of the age of subjects, except as noted.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

The expedited review procedure may not be used for classified research involving human subjects.

The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

DHHS discourages the use of expedited review for research involving prisoners. However, if the IRB chooses to use expedited review for research involving prisoners, one of the designated reviewers must be the prisoner representative.

Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Category 1:
Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2:
Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week. *(NOTE: Children in Ohio are defined as individuals under the age of 18.)*

Category 3:
Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

a. Hair and nail clippings in a nondisfiguring manner;
b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
c. Permanent teeth if routine patient care indicates a need for extraction;
d. Excreta and external secretions (including sweat);
e. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
f. Placenta removed at delivery;
g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
h. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
j. Sputum collected after saline mist nebulization.

Category 4:
Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding

procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
b. Weighing or testing sensory acuity;
c. Magnetic resonance imaging;
d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5:
Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). *(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects.)*

Category 6:
Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 7:
Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. *(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects.)*

Category 8:
Continuing review of research previously approved by the convened IRB as follows:

a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
b. Where no subjects have been enrolled and no additional risks have been identified; or
c. Where the remaining research activities are limited to data analysis.

Category 9
Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

5.2 Initial Expedited Review

5.2.1 Submission and Screening

Once a PI's submission of a new study via the Human Subject Module in InfoED (InfoED) has completed routing approvals, IRB staff will make the determination as to whether the proposed research can be reviewed via the expedited process because it both meets the minimal risk definition and the interventions/interactions fall under one or more of the expedited categories.

To do this, IRB staff will begin by screening each new study submission for completeness. He/she will also be responsible for screening Health Insurance Portability and Accountability Act (HIPAA) authorization language included within the consent form to ensure that it is either one of the WSU-approved templates or that all required elements and statements are present via the highlighted version provided by the investigator, when applicable.

5.2.2 Assigning Reviewers

IRB staff will assign a new submission to an IRB member based on a member's experience, expertise and availability. This assigned reviewer must notify IRB staff within 48 business hours if he/she is not available to conduct the review within 7 business days or if he/she has a conflict of

interest. If there is an issue, the IRB staff will assign the submission to an alternate reviewer.

As part of the assigning process, IRB staff will alert the assigned IRB reviewer of any of the following: involvement of vulnerable subjects or federally mandated specific findings; waiver of informed consent/authorization or documentation; incomplete mandatory training; or need of additional consultant or prisoner representative review.

5.2.3 Study Reviews

Via InfoED, reviewers will have access to all documents and correspondence related to the study, including, but not limited to, the following:

- Initial Application
- Informed Consent/Assent Forms
- HIPAA authorization language
- Advertisements, data collection instruments, or other documents to be utilized during the study
- Vulnerable Population Checklists
- IRB staff comments/recommendations

Expedited reviewers will review all of the information in enough depth to be familiar with the protocol, to determine whether the research is eligible for expedited review, and to determine whether the research meets the regulatory criteria for approval. In addition, expedited reviewers must use the following criteria to review the proposed study in accordance with 45 CFR 46.111/21 CFR 56.111 and subparts B, C and D:

a. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
c. Selection of subjects is equitable.

d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46 46.116.
e. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
f. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
h. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as students, employees, children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

5.2.4 Determinations

After performing the review as described above, reviewers will recommend one of the following three determinations:

a. **Approved** – IRB reviewer has concluded that the research and consent forms meet federal criteria for approval. IRB staff will process the submission and send the investigator an approval letter and stamped the informed consent/assent/authorization letter, when applicable.
b. **Modifications Required** – IRB reviewer requires investigator to modify and/or add information and is responsible for providing IRB staff with a clear written description of the requested revisions. The IRB staff will send the investigator a letter describing the revisions requested by the IRB reviewer(s). The investigator will be required to respond to that request and submit response via InfoED. IRB staff will forward those responses back to IRB reviewer(s) for further review or administratively approve response if revisions only involve minor changes (i.e., spelling/wording changes).
c. **Refer to Full Board** – The IRB reviewer may determine that the study requires review by the IRB at a convened meeting because it represents more than minimal risk or because the reviewer believes study should be disapproved. IRB staff will then process the submission according to full board procedures.

The date the expedited reviewer signs off on final study approval is the date the approval period starts. IRB staff document the approval period dates in InfoED and in the approval letter to the investigator. The expiration date will be determined based on the requirements described in section 5.3.

5.3 Renewal of Research that Qualifies for Expedited Review

5.3.1 IRB Review of Continuing FDA-Regulated Research

In accordance with FDA regulations, FDA-regulated research that meets expedited criteria must receive continuing review not less than once per year. Therefore, investigators will be required to submit the Continuing Review/Administrative Update form and associated documents via the electronic submission system at least six weeks before the study expiration date.

For example, a clinical trial testing an FDA-regulated investigational drug in which any remaining activity is limited to data analysis would be eligible for expedited continuing review and a one-year renewal period.

The Continuing Review/Administrative Update form will receive IRB expedited review and be processed by the same procedures described in section 5.2 of this policy. Whenever possible the same expedited reviewer who conducted the initial approval will be assigned to conduct the continuing review.

5.3.2 Administrative Review of Continuing Non-FDA Regulated Research

Investigators conducting ongoing research that is eligible for expedited review and not subject to FDA regulations must submit the Continuing Review/Administrative Update form not less than once every two years from the initial or last continuing review approval date. IRB staff will review the update and if appropriate, will administratively approve the research for a subsequent 2-year period. IRB staff may consult with the IRB Chairperson or other IRB members, if needed during the course of their administrative review.

If the IRB Staff do not receive a Continuing Review/Administrative Update form within 30 days of the expiration date, the study will be administratively closed. Once a study is closed, submission of a new

application would be required to continue the study. Repeated failure to submit study closures may be considered non-compliance.

5.3.3 Other Required Submissions During the Approval Period

Investigators are required to submit and receive IRB review and approval of amendments (see Section 5.5) and reportable events during the conduct of the study for both FDA and non-FDA regulated research. When an expedited study is completed, the investigator is also responsible for promptly submitting a study closure form via the electronic submission system. Studies can be closed at any time during the approval period.

5.4 Expedited Review of Minor Changes/Amendments

Minor changes to more than minimal risks studies that have been previously approved can also receive expedited review and do not require review at a convened meeting. A minor change is a proposed change to research that does not significantly affect the risk and benefits of the study and does not substantially change the specific aims or design of the study. Examples of minor changes include, but are not limited to, the following:

a. An increase or decrease in proposed human research subjects' enrollment;
b. Narrowing the range of the inclusion criteria;
c. Broadening the range of the exclusion criteria;
d. Alterations in the dosage form (e.g., tablet to capsule or oral liquid) of an administered drug, provided the dose and route of administration remains constant;
e. Decreasing the number or volume of biological samples collections, provided that such a change does not affect the collection of information related to safety evaluations;
f. A decrease in the length of hospitalization or number of study visits, provided that such a decrease does not affect the collection of information related to safety evaluations;
g. Alternations in human research participant payment or alteration of the payment schedule with proper justification;
h. Changes to improve the clarity of statements or to correct typographical errors, provided that such a change does not alter the content or intent of the statement;
i. The addition or deletion of qualified investigators; or

j. The addition of study sites (which may require a Federal Wide Assurance (FWA) and appropriate IRB approval) or the deletion of study sites.

Examples of significant changes to a more than minimal risk study that would **not** qualify for expedited review may include, but are not limited to, the following:

a. Broadening the range of inclusion criteria;
b. Narrowing the range of exclusion criteria;
c. Alterations in the dosage or route of administration of an administered drug;
d. Extending substantially the duration of exposure to the test material or invention;
e. The deletion of laboratory tests, monitoring procedures, or study visits directed at the collection of information for safety evaluations;
f. The addition of serious unexpected adverse events or other significant risks to the Informed Consent Disclosure; or
g. Changes, which, in the opinion of the IRB Chairperson or his/her designee, do not meet the criteria or intent of a minor modification;
h. The addition of a qualified investigator with a disclosable conflict of interest.

To request review and approval of a minor change, investigators must submit an Amendment Form in InfoED. IRB staff will review the submission and determine if it meets the definition of a minor modification. If so, IRB staff will assign the submission to the IRB Chairperson or his/her designee for review. Determinations must be made in accordance with section 5.2.4 above. The approval date of the change will be the date of reviewer approval in InfoED. Approval of amendments does not affect the overall study expiration date.

5.5 Expedited Review of Amendments

Proposed changes to minimal risk studies that have been previously approved via expedited review must submitted for IRB review via the Amendment Form in InfoED. These submissions will be reviewed and processed by the same procedures described in section 5.2 of this policy. One IRB member will be assigned to review and approve these amendments. Whenever possible the same IRB reviewer who conducted the initial approval will be assigned to review the amendment.

If proposed changes to the study would make the study “more than minimal risk” the IRB reviewer must refer the study to the full board for review.

5.6 Expedited Review of Modifications Required by Convened Meeting

Expedited review of modifications required by the convened IRB will only be allowed when the IRB requires as a condition of approval that the investigator (a) make specified changes to the research protocol or informed consent document(s), (b) confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted, or (c) submit additional documents, such that, based on the assumption that the conditions are satisfied, the IRB is able to make all of the determinations required for approval under the HHS regulations at 45 CFR 46.111/21 CFR 56.111 and, if applicable, subparts B, C, or D of 45 CFR part 46.

The convened IRB will designate the IRB chairperson (and/or other individual(s) with appropriate expertise or qualifications) to review responsive materials from the investigator and determine that the conditions have been satisfied and that further review by the IRB at a subsequent convened meeting would not be necessary. The study approval date of the will be the date of reviewer approval in InfoED.

6.0 Responsibilities and Authorities

6.1 Investigators

All investigators must read and understand this policy and conduct expedited research in accordance with applicable regulations, institutional policies and procedures and scientific/ethical norms.

6.2 WSU IRB

The WSU IRB is responsible for maintaining this policy and ensuring the expedited review procedure is compliant and well supported.

7.0 Records

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

8.0 References

8.1 45 CFR 46.110
8.2 45 CFR 46.102(i)
8.3 21 CFR 56.110
8.4 21 CFR 56.102(i)
8.5 VHA Handbook
8.6 38 CFR 16