Convened Institutional Review Board Review

1.0 Purpose

The purpose of this policy is to define the procedures and requirements for convened meeting review by the Wright State University Institutional Review Board. This includes, but is not limited to, meeting scheduling, IRB member review requirements, formal determinations/findings, and content of minutes.

2.0 Scope

This policy applies to all human subject research that is conducted by Wright State University 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 Health, Dayton VAMC).

3.0 Definitions

3.1 **Alternate IRB Member** means an individual appointed to the IRB to serve in the same capacity as the specific IRB member(s) for whom the alternate is named, who substitutes for the member at convened meetings when the member is not in attendance. If both the member and alternate member are present at a convened meeting, only one will count for quorum and will be allowed to vote.

3.2 **Director** means a member of the HRPP Office who directs, manages, implements and administers policies and procedures related to research involving human subjects. The Director provides for all compliance and regulatory functions of the IRB ensuring adherence to all federal, state, and local regulations and policies governing research involving human subjects including the Belmont Report and the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations.

3.3 **Financial Conflict of Interest** means a monetary interest of an individual (or his/her immediate family) in the design, conduct, or reporting of the human subject research or other interest that competes with an IRB member's (or consultant's) obligation to protect research participants and potentially

compromises the objectivity and credibility of the research review process.

3.4 **Human Research Protection Program (HRPP)** means a multi-tiered program involving the University administration, the Wright State Institutional Official, the Wright State Institutional Review Board, HRPP Office, other research administrative and compliance offices, and investigators.

3.5 **Informed consent** means an individual's voluntary agreement, based upon adequate knowledge and understanding of the relevant information, to participate in research.

3.6 **Institutional Review Board (IRB)** means a committee established to review and approve research involving human subjects. The purpose of the IRB is to ensure that all human subject research be conducted in accordance with all federal, institutional, and ethical guidelines.

3.7 **IRB Member** means an individual appointed as a member of the IRB with the right to act as an expedited reviewer and the right to vote and count in determining quorum at a convened meeting.

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 **Non-affiliated IRB member** means an individual who is not affiliated with Wright State and who is not part of the immediate family of someone who is affiliated with Wright State. This individual must not have or had have an employments or other relationship with Wright State. One or more non-affiliated members are expected to attend at least fifty percent of convened meetings.

3.10 **Non-financial conflict of interest** means an interest other than monetary of an individual (or his/her immediate family) in the design, conduct, or reporting of the human subject research or other interest that competes with an IRB member's (or consultant's) obligation to protect research participants and potentially compromises the objectivity and credibility of the research review process.

3.11 **Non-scientist member** means an individual appointed by the IRB who can review research activities from the viewpoint of someone outside the scientific or scholarly discipline of the IRB on which he/she serves due to his/her training, background or occupation.

3.12 **Office of Human Research Protections (OHRP)** means the administrative agency that oversees the United States' system for protecting volunteers in research conducted or supported by the U.S. Department of Health and Human Services (DHHS).

3.13 **Principal Investigator (PI)** means the primary individual responsible for the preparation, conduct, and administration of a human subject research study.

3.14 **Quorum** means the majority of the voting members. In the case of the Institutional Review Board (IRB), a quorum will consist of at least 51% of the voting IRB members and must include at least one non-scientific and one unaffiliated member. All members present have equal voting power. At meetings of the IRB, a quorum must be established and maintained throughout the entire meeting. A member with a conflict of interest cannot contribute to a quorum. For Food and Drug Administration-regulated research, a licensed physician must be present during the review, deliberation and voting to satisfy the quorum requirement under Code of Federal Regulations Title 21 CFR 56.108(c).

3.15 **Sponsor** means any person or entity that takes responsibility for, initiates, or funds a study. The sponsor may be an individual, pharmaceutical company, device manufacturer, governmental agency, academic institution, private organization, or other organization.

4.0 Policy

This policy is based on the essential principles established in the Belmont Report: respect for persons, beneficence, and justice, and is in accordance with both the Department of Health and Human Services (45 CFR 46) and the Food and Drug Administration (21 CFR 50 and 56) regulations that require convened IRB review of certain research.

The Wright State University IRB (hereafter referred to as IRB) reviews all non-exempt

research at a convened meeting (i.e., full board review) unless the research is eligible for expedited review. This includes reportable events, the initial and continuing review of research that is determined to be greater than minimal risk, and any other continuing review, amendment, or other submission that the Chairperson (Chair) or other IRB member requests receive full board review. Research involving vulnerable populations such as children, the cognitively impaired, and the educationally or economically disadvantaged may require full board review and approval, as well.

All convened meetings will be documented via written minutes. Minutes will comply with applicable federal regulatory and guidance requirements. The convened IRB will review and approve minutes from the previous meeting at its next convened meeting. Minutes may not be altered by anyone including a higher authority once approved by the IRB.

5.0 **Procedures**

5.1 Meeting Schedule

Whenever possible, the HRPP Office will schedule convened meetings at least 90 days in advance. Scheduled meetings will occur at appropriate intervals to permit adequate progress of pending and approved research. Special meetings may be called at any time by the Chair or HRPP Director. The schedule for IRB meetings will be posted on the Human Research Protection Program (HRPP) website.

Investigator submission deadlines for each meeting will be set at least two weeks prior to each scheduled meeting date. The meeting schedule and submission deadlines will be posted on the HRPP website.

5.2 Submission Pre-Review and Meeting Assignment

An HRPP staff member will perform a preliminary review of all protocol materials submitted to the HRPP Office for determination of completeness and accuracy. Initial pre-review sent from HRPP staff to the principal investigator (PI) may include clarifying questions; requests for missing documents, letters of support or permission; discrepancies and inconsistencies; missing sections or elements in sections of the documents; missing training; and clear regulatory or policy issues.

Only complete submissions will be placed on the IRB agenda for review. The investigator will be informed in writing of missing materials.

Submissions (i.e., initial, continuing, amendments) requiring convened IRB review and approval will be assigned by the HRPP Office to the next scheduled meeting agenda subject to the availability of IRB committee members with appropriate expertise. Submissions will not be assigned to a meeting agenda until a complete application package is received from the PI.

5.3 Reviewer Assignment

After a submission has been placed on a convened meeting agenda, the HRPP Office will assign it to IRB Member reviewers (reviewers) paying close attention to the scientific content of the protocol, and the potential reviewer's area of expertise and representation for vulnerable populations involved in the research. Reviewers are assigned to all study submissions requiring initial review, continuing review, amendments, and reportable events.

For initial review, at least two IRB members will serve as primary reviewers. For other submissions, studies will be assigned at least one primary reviewer. For research involving primarily biomedical intervention(s), the primary reviewer will be a physician or health care practitioner with appropriate expertise.

For research involving primarily social-behavioral interventions, the primary reviewer will be a scientific member with adequate expertise in that area of the research. For the review of research involving prisoners that requires convened IRB Committee review (see *Vulnerable Populations Policy* for more information), a prisoner representative must be assigned as a primary reviewer and must be present (in person or via approved remote/virtual mechanisms) at the meeting during the discussion and vote of the proposed research study or the study cannot be reviewed or approved.

Reviewers may contact the PI, co-investigators, other IRB members, or outside sources as necessary to facilitate a thorough evaluation of risks and benefits of the proposed research. IRB Members who have a conflict of interest with a protocol must recuse themselves from a review assignment.

5.4 Meeting Materials and IRB Member Review Responsibilities

Approximately five business days prior to each convened meeting, the HRPP Office will make the agenda, continuing education/training materials, the Notice to Committee containing items reviewed via Expedited review, minutes from previous meeting(s) and all new and previously approved documents related to each full board submission available to all voting IRB members, ex officio members and other institutional administrators via the electronic submission system. This includes, but is not limited to,

5.4.1 IRB application;
5.4.2 Local protocol;
5.4.3 Proposed consent / Parental permission / Assent form(s);
5.4.4 Recruitment materials;
5.4.5 Data collection instruments;
5.4.6 Investigator's brochure;
5.4.7 Letters of support or permission from external sites;
5.4.8 Other documents submitted by the PI for review.

The IRB members who are assigned as reviewers are responsible for conducting an in-depth review of their assigned submissions. All IRB members are responsible for reviewing all full board submissions listed on the agenda (including those protocols for which the IRB member is not an assigned reviewer) to be familiar with the protocol, to be prepared to discuss the protocol at the meeting, and to be prepared to determine whether the research meets all relevant criteria for approval. An absent primary reviewer may submit their written comments for presentation at the convened meeting by the Chair/Designee.

When the IRB is presented with a study that may be outside of the knowledge base or representative capacity of the IRB members, a consultant will be sought. Protocols for which appropriate expertise cannot be obtained for a given meeting will be deferred to another meeting when appropriate expertise can be achieved.

5.5 Conduct of Convened Meetings

5.5.1 Quorum and Conflict of Interest Recusal

A majority of the voting IRB members (or their designated alternates), including at least one member whose primary concerns are in non-scientific areas, must be present to conduct a convened meeting. When FDA-regulated research is reviewed, there must be at least one member in attendance who is a licensed physician.

The IRB does not consider ex officio members or consultants to establish quorum.

Members or consultants with a conflict of interest must leave the room during the vote and only participate in the review by providing information.

If quorum is lost during a meeting (e.g., loss of a majority through excused members with conflicting interests or departure of voting members or absence of a non-scientist member), the IRB will not take any further protocol actions that require a vote unless or until the quorum is restored.

The Chair/Designee, with assistance of HRPP Staff, will confirm that quorum is present before calling the meeting to order. The HRPP staff will document, in the minutes, the time of arrival and departure for all IRB members and notify the IRB Chair if a quorum is lost.

Quorum includes those participating in the meeting via approved remote mechanisms (e.g., teleconference, web conferencing or other virtual mechanisms). IRB members present via remote mechanisms are noted as such in the meeting minutes or when applicable, the minutes will reflect that the meeting itself was conducted solely via a remote mechanism. Review responsibilities and document access will not vary from Section 5.4 when convened review is conducted by remote mechanisms.

To ensure the presence of a quorum, alternate IRB members may be requested to participate to review proposed research. IRB minutes will

indicate if the member present at the meeting is an alternate, as well as the IRB member for whom the alternate is substituting.

5.5.2 IRB Member Education and Policy/Procedure Review

Education and training activities at the convened meeting will normally be conducted at the start of most meetings. HRPP staff (in conjunction with the Chair) are responsible for preparing continuing education topics/materials.

At convened meetings, the Chair will encourage discussion with regards to continuing education/training information and/or current related events. Education and training activities will be documented in the minutes, including the review of any new/revised policy or procedures.

5.5.3 Review of Submissions Approved Via Expedited Review

Prior to the meeting all IRB members will be provided with a list of submissions (i.e. Notice to Committee) approved via expedited review since the last convened meeting. As part of the review of the Notice to Committee, the Chair will ask if any member has a concern with any of the submissions approved in this manner.

If concerns/questions are expressed, the Chair and/or HRPP Staff will work with any member to address those concerns/questions outside the convened meeting. The discussion and acceptance of the notification must be documented in the minutes.

5.5.4 Review of Meeting Minutes from Prior Meeting

The IRB will review and discuss the IRB minutes from the prior meeting and determine if there are any revisions or corrections to be made. If there are no changes to be made, the minutes will be accepted as presented and considered final. If it is determined that revisions or corrections are necessary, the minutes will be amended. If the revisions are minor (e.g., typographical errors, revised language provided by members present), then the minutes will be considered approved after the HRPP staff makes the changes. If the revisions are major, they will be

presented again at the following IRB meeting for a second review and vote.

5.6 Study Submission Reviews at Convened Meetings

Each study submission requiring review and approval by the full board will be addressed separately at the convened meeting.

The reviewer(s) for each submission will lead the discussion of the study at the IRB meeting. During the discussion IRB members will discuss whether the submission meets the federal criteria for approval as specified in 45 CFR 46.111 or 21 CFR 56.111 and the following, as applicable:

5.6.1 Frequency of Continuing Review

During the convened meeting, the IRB will determine the approval period, as appropriate to the degree of risk but not less frequently than once per year for research that is more than minimal risk or FDA regulated. The IRB may set a shorter period for high risk protocols or protocols with high risk/low potential benefit ratios. This determination will be documented in the minutes by HRPP Staff.

Research determined by the convened board to be minimal risk and that meets one or more expedited categories is subject to the continuing review procedures described in the *Expedited Review Policy*.

5.6.2 Risk Level

When considering risks, the IRB will consider physical, psychological, social, economic and legal risks. IRB members will be polled by the Chair to determine the risk level (minimal, greater than minimal) of the proposed research. This determination will be documented in the minutes by HRPP Staff.

5.6.3 Required Findings

Certain types of research require additional regulatory findings by the IRB beyond 45 CFR 46.111/21 CFR 56.111. When applicable, the minutes and

approval letter sent to PI for each submission will document that the IRB found that the research met the regulatory requirements for the following determinations:

- Research Involving Children (45 CFR 45 Subpart D)
- Research Involving Pregnant Women, Fetuses, Neonates (45 CFR 46 Subpart B)
- Research Involving Prisoners (45 CFR 46 Subpart C)
- Use of Legally Authorized Representative (LAR)
- Waiver of HIPAA Authorization
- Partial Waiver of HIPAA Authorization for Recruitment
- Waiver of Informed Consent
- Waiver of Signed Informed Consent
- Non-Significant Risk Device Determination

In addition, the minutes will include protocol specific findings justifying those determinations.

5.6.4 Require Notification of New Information

During the convened meeting review of a submission, the IRB may determine that currently enrolled subjects need to be notified of new information or significant new findings that alter the risk benefit ratio and may affect their willingness to continue study participation. The IRB may require that that new information be presented to subjects via an addendum to the consent form or a modified consent form.

Any determination by the IRB that subject(s) must be notified of new information will be documented in the minutes.

5.6.5 Verification from Other Sources

Protecting the rights and welfare of subjects sometimes requires that the IRB during the convened meeting decide that independent verification, utilizing sources other than the PI, is necessary to determine that no material changes occurred during the IRB-designated approval period. Additional sources may include audit by the Office of the Vice Provost for Research, as well as, information from research staff, subjects, families,

sponsors and others.

Criteria for determination if verification is required will include, but not be limited to:

- Complex protocols involving unusual levels or types of risks to subjects;
- Protocols conducted by investigators who previously failed to comply with federal regulations, Wright State policy, or IRB requirements/determinations.
- Protocols where concern about the possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.

Any determination by the IRB that independent verification is required will be documented in the minutes.

5.6.6 Informed Consent Monitoring

For research determined to be greater than minimal risk or involving a conflict of interest or potential coercion, the IRB members may request during the convened meeting that random monitoring of the informed consent process be undertaken by the Office of Research Compliance or University Compliance.

Any determination by the IRB that informed consent monitoring is required will be documented in the minutes.

5.7 Submission Review Determination and Voting

At the completion of the open discussion regarding the submission, the Chair/Designee will summarize the findings determined per Section 5.6.3 of this policy and recommend one of the following review determinations:

5.7.1 Approve

This determination means that the IRB has concluded that the research

and consent forms meet the federal criteria for approval and Wright State policies. IRB approval verifies the IRB agrees with the assessment of the submission and/or specific findings as described by the PI in the application. The investigator may initiate the research immediately upon receipt of the written notification of full approval to conduct the research.

5.7.2 Requires Modifications

Conduct of the research can be granted full approval by the IRB pending PI concurrence with specific revisions stipulated by the convened IRB. The PI may not initiate the research until such time that s/he has modified the research protocol and/or informed consent document(s) to comply with the specific revisions stipulated by the IRB; such revisions have been reviewed and approved by the IRB Chair or designated individual; and the principal investigator has received written notification of full approval to conduct the research.

5.7.3 Table

Insufficient information is available to review the proposed research in an adequate manner. Approval to conduct the research requires substantive clarifications or modifications of the research design or procedures or substantive revisions of the informed consent document(s).

The PI must respond to the identified concerns, clarifications, modifications or revisions and resubmit the revised research and/or informed consent document(s) for full-board IRB review.

The proposed research may also be tabled due to loss of quorum or lack of appropriate expertise present at the meeting.

5.7.4 Disapprove

The proposed research has fundamental design problems and/or presents significant ethical or safety concerns to involved human subjects. This determination means that the IRB disapproved the protocol from further consideration of approval. Disapproval usually occurs when

the IRB determines that the risk of the procedures outweighs any benefit to be gained or if the research does not meet the federal criteria for IRB approval. To request future IRB review of the proposed research, the PI must undertake a major revision of the research which usually involves submission of a separate new application.

After the recommendation, the Chair will then call for a motion, another IRB member will second the motion, and then the convened IRB members will vote for, against, or abstain. IRB members in attendance at the full board meeting, but absent from the meeting during the discussion of the research submission and the vote; will not be counted in the committee vote.

The absence of members due to a conflict during the discussion of the research protocol and the vote will be documented in the minutes including the reason for their absence (e.g., listed investigator on study, financial or other conflict).

IRB members who provide written comments regarding the proposed research, but who are not present at the meeting, will not be counted in the committee vote.

If both the IRB member and his/her alternate are present at the meeting, only one member's vote is counted. The IRB minutes will indicate the name of the voting member and his/her alternate.

HRPP staff will be responsible for properly documenting the vote in the minutes.

5.8 Meeting Minutes

The minutes of a convened meeting will contain the relevant information as stipulated by federal regulations (45 CR 46.115(a)(2); 21 CFR 56.115(a)(2)), including sufficient detail to show the presence of a quorum throughout the meeting. The attendance list will include those members present at the beginning of the meeting. The minutes will also indicate by name, those IRB members who enter or leave during the meeting.

Minutes of each IRB meeting will document the separate deliberations, actions, and votes for each submission. The minutes must be sufficient in detail to demonstrate the following:

5.8.1 Actions taken by the IRB (e.g., approve, requires modifications, table and disapprove).
5.8.2 The discussion of any controverted issues and their resolutions.
5.8.3 Documentation of a consultant's findings, if applicable.
5.8.4 If the IRB reviews research that involves categories of subjects that are vulnerable to coercion or undue influence, one or more individuals who are knowledgeable about or experienced in working with such subjects are present.
5.8.5 The basis for requiring changes to submission, when applicable.
5.8.6 The basis for disapproving the submission, when applicable.
5.8.7 The level of risk involved in the research (i.e., minimal or greater than minimal risk).
5.8.8 The approval period for initial and continuing review.
5.8.9 The vote on the submissions including the number of voting "For, Against and Abstaining." The votes will be recorded in the following format: Total=xx For=xx Against=xx and Abstained=xx (see Section 5.7 for more information).
5.8.10 Determinations required by federal regulations (see Section 5.6.3) and protocol specific findings justifying those determinations.
5.8.11 Justification for deletion or substantive modification concerning risks or alternative procedures contained in any DHHS-approved sample informed consent document, when applicable.
5.8.12 Documentation of the discussion on whether to allow for continued treatment of enrolled subjects when suspension of an approval of an approved protocol is considered.

6.0 **Records**

IRB records for research that is subject to DHHS or FDA regulations, including meeting minutes, must be retained for at least three years after completion of the research that is the subject of the review and must be accessible for inspection and copying by authorized representatives from OHRP and/or FDA at reasonable times and in a reasonable manner (45 CFR 46.115(b); 21 CFR 56.115(b)).

The minutes will have records of review of multiple studies. Relevant portions of the minutes must be retained until the regulatory retention period for each study is satisfied.

All records other records related to this policy will be stored and maintained in

accordance with any Wright State policy, federal regulations, and sponsor requirements associated with the human subject research under review.

7.0 References

7.1 45 CFR 46, Subpart B, C, and D
7.2 21 CFR 50
7.3 21 CFR 56