EXEMPTION DETERMINATIONS AND EXPEDITED REVIEW POLICY

All proposed research involving human subjects must be submitted to the IRB for review. IRB staff members are responsible for screening new submissions to confirm that the proposed research meets the definition of human subject research (see below) prior to initiating IRB review.

If an investigator is unsure whether or not his/her proposed research meets the definition, he/she should consult with an IRB staff member prior to submitting his/her research to the IRB.

The purpose of this policy is to describe the process by which exemption determinations and expedited review are conducted at Wright State University.

1.0 Definitions

**Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)).

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

1. data through intervention or interaction with the individual, or
2. identifiable private information. 45 CFR 46.102(f)

**Intervention** means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

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

**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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
Minimal Risk means 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.

2.0 Exempt Determinations

Investigators do not have the authority to make an independent determination that research involving human subjects is exempt. IRB staff members are responsible for screening new studies to determine whether or not the proposed research requires IRB review or qualifies for an exempt determination.

The reviewing IRB staff member has the authority to make an exempt determination, but may consult with the IRB Chair or an IRB member if he/she needs assistance in determining whether or not the proposed research meets an exemption category listed below.

FDA-regulated research does not qualify for an exemption unless it falls under the FDA’s emergency use provision for the use of a test article (21 CFR 56.104(c)) or Taste and Food Quality Evaluations and Consumer Acceptance Studies Exempt Category 6(21 CFR 56.104(d)).

There are exemption restrictions for research involving children (see 45 CFR 46, Subpart D); and research involving prisoners will not qualify as exempt research (see 45 CFR 46, Subpart C). In addition, any HHS-funded research using newborn dried blood spots collected on or after March 18, 2015 will also not qualify as exempt research: (see NOT-OD-12-127 Preliminary Guidance Related to Informed Consent for Research on Dried Blood Spots Obtained Through Newborn Screening).

After the review is complete, the study’s PI/faculty advisor will be notified in writing if his/her study has been determined to be exempt from IRB review. The exemption letter must document the date that exemption was made and the applicable exemption category or categories.

Human subject research that is exempt from IRB review does not require continuing review. However, the PI/faculty advisor must consult with an IRB staff member prior to making any substantive changes to the initial research plan to determine whether the modified research plan remains exempt or requires IRB review. IRB records for exemption determinations will be maintained for a minimum of three years.

IRB Notification of Exemptions

At each convened meeting, the IRB will review the monthly Report of Administrative Actions that includes a list of all studies that were determined to be exempt (including
exemption category) during the previous month. The IRB will make the determination whether to accept exemptions listed on the report. If the IRB votes not to accept any of the exemptions, then the studies must be brought to a subsequent convened meeting for additional review and discussion. If no additional review is requested at the convened meeting, the IRB will vote to approve the written notification and the Report will be appended to the meeting minutes as documentation of this approval.

**Exempt Categories: 45 CFR 46.101(b) (1-6); 45 CFR 46.401(b); 21 CFR 56.104(d)**

Exempt Category 1

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

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

Exempt Category 2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
- Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. NOTE: The Department of Veteran’s Affairs (VA) also includes loss of insurability in this category.

Exempt Category 3

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

- The human subjects are elected or appointed public officials or candidates for public office; or
- Federal statute(s) require(s) without exception that the confidentiality of the
personally identifiable information will be maintained throughout the research and thereafter.

Exempt Category 4

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Exempt Category 5

Research and demonstration projects which are conducted by or subject to the approval of federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine (i) public benefit or service 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 program.

Exempt Category 6

Taste and food quality evaluation and consumer acceptance studies,

- If wholesome foods without additives are consumed; or
- 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.

Informed Consent and HIPAA Authorization Requirements

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 as a way to support their voluntary participation.

If the proposed research involves utilization of Protected Health Information (PHI), HIPAA regulations still apply, even if the IRB staff member has determined that the research is exempt. Investigators must indicate whether the research involves PHI as part of the initial application process and apply for a waiver of authorization if written authorization will not be obtained from each subject in accordance with the Privacy Rule.
3.0 Expedited Review

Federal regulations (45 CFR 46.110(b) and 21 CFR 56.110(b)) allow for certain kinds of research involving no more than minimal risk, and for minor changes to approved research to be reviewed using the expedited review procedure.

Initial and continuing reviews and amendment requests are initially reviewed by an IRB staff member, in consultation with the IRB Chair as needed, to determine if the proposed research meets the regulatory criteria for expedited review.

The activities listed in the Expedited Review Categories section below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list only 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.

Other provisions that apply to the expedited review procedure include:

- The categories in the expedited 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.
- Categories 1 through 7 pertain to both initial and continuing IRB review.

**Expedited Review Categories**

Research may be reviewed and approved via expedited review if that research a) presents no more than minimal risk to participants; and b) involves only procedures listed in one or more of the categories listed below; or c) qualifies as a minor modification, in accordance with the definition of minor modification/change as described in P8 “Modifications (amendments) to previously approved research.”

**Category 1- Drugs and Devices**

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 – Blood Samples

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

a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amount drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than two times per week; or,

b) From other adults and children, considering 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. From such 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 two times per week.

Category 3 – Biological Specimens

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 – Non-Invasive Data Collection

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- Data Collected for Non-Research Purposes

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).

Category 6 – Data from Recordings

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

Category 7 – Behavioral Research

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.)

Category 8 – Continuing Review
Continuing review of research previously approved by the convened IRB where:

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

Category 9 - Continuing Review of Research Reviewed at Convened Meeting

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.

** Expedited Review Procedures **

Expedited review must be conducted by the IRB Chair or by one or more experienced IRB members designated by the Chair. The criteria for determining whether an IRB member is experienced to perform an expedited review is based on the following: They must have a minimum of one year’s experience as an IRB member and have attended more than fifty percent of their scheduled convened meetings; show a high level of understanding of the human research protection regulations and an ability to appropriately apply them to human subjects’ research; and routinely contribute to the discussions and resolution of controversial issues related to IRB reviews.

In addition to determining and documenting the appropriate expedited review category above, the expedited reviewer(s) must use the following criteria to review the proposed study:

1.0 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.
2.0 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.
3.0 Selection of subjects is equitable.
4.0 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 §46.116.
5.0 Informed consent will be appropriately documented, in accordance with, and to the extent required by
extent required by §46.117.

6.0 When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7.0 When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8.0 When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as 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.

The study’s PI/faculty advisor will be notified in writing if his/her study has been approved via expedited review. The expedited approval letter must document the study approval date, study expiration date, expedited review category, any informed consent or HIPAA authorization waivers, and any required findings with regard to vulnerable populations (e.g., children, pregnant women, prisoners, etc.…).

**IRB Notification of Expedited Reviews**

At each convened meeting, the IRB will review the monthly Report of Administrative Actions that includes a list of all studies that were reviewed using expedited procedures (including the applicable expedited category) during the previous month. The IRB will make the determination whether to accept expedited reviews listed on the report. If the IRB votes not to accept any of the expedited reviews, then the studies must be brought to a subsequent convened meeting for additional review and discussion. If no additional review is requested at the convened meeting, the IRB will vote to approve the written notification and the Report will be appended to the meeting minutes as documentation of this approval.

Note: If a research study is not exempt or cannot be reviewed under the expedited review process, it must be reviewed and approved at a convened meeting of the IRB (i.e., Full Board Review) before the proposed human subject research can begin.