Institutional Review Board for Human Research Participant Protection (IRB)

PROCEDURE MANUAL

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C O N T E N T S

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I. INSTITUTIONAL RESPONSIBILITIES

A. The University of West Florida hereby gives assurance, as specified below, that it will comply with the Department of Health and Human Services, National Institutes of Health regulation 45 CFR 46, Protection of Human Subjects. It is the policy of The University of West Florida that all human participant research and research-related activities involving human participants conducted within or under the auspices of the University, by any faculty, student, or employee, whether or not supported by an external funding agency, be subject to the review and approval of the Institutional Review Board for Human Research Participant

Protection (IRB). Federal funds for which this Assurance applies may not be expended for research involving human participants until the requirements of this Assurance have been satisfied. The involvement of human participants in research covered by this Assurance will not be permitted until an appropriate IRB has reviewed and approved the research protocol and informed consent has been obtained from the participant and/or the participant's legal representative (see 46.111, 46.116, and 46.117 and Sections XII- XVI of this procedure manual).

B. Research covered by this procedure manual, which has been approved by the IRB, may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by the IRB.

C. The President, or designee, shall appoint members to serve on the IRB. Membership shall meet the criteria established in 46.107 and as outlined in Section VI of this manual.

II. OFFICE OF RESEARCH RESPONSIBILITIES

A. The Office of Research Administration & Engagement will provide investigators copies of regulation 45 CFR 46, Protection of Human Subjects, the institution's IRB procedure manual, the Belmont Report, the institution's Policy for Determination of Conflict of Interest, Policy for Information Security and Privacy Policy, and Export Control Policy.

B. The Office of Research Administration & Engagement will coordinate the review process of all proposals involving the use of human research participants, unless found to not be human subjects research under Section VII.A. of this procedure manual, including disseminating the proposals to the board for review, notifying the investigator of any changes required by the board to secure approval, and informing the investigators and funding agency of the board's final decision. Efforts will be made to relay IRB decisions and feedback to investigators within 10 to 12 working days from complete submission to the board (for exempt and expedited review) or after a convened meeting (for full board review). Longer review periods may be necessary for certain submissions, for example, those that are missing documentation or studies that are more than minimal risk.

C. The Office of Research Administration & Engagement's IRB office will review projects to determine the level of review under 46.101 and Section VII of this procedure manual. All exempt and expedited proposals will be forwarded to a designated IRB member for review. Proposals requiring full board review will be made available to all IRB members and added to the next convened meeting's agenda. All members of the IRB will be kept informed of research proposals that have been approved by the IRB since the last convened meeting.

D. Any proposal that is not exempt or does not qualify for expedited review will be sent to the IRB for full board review. A study that is originally categorized as exempt or expedited may be referred to the full board by its original designated reviewer.

E. Individual reviewers may not disapprove the research; disapproval requires a vote of the convened board. Expedited review of research activities will not be permitted where full board review is required.

F. The Office of Research Administration & Engagement will supply administrative support for the IRB in accordance with 46.115 including setting up meetings, recording minutes of meetings, maintaining a current file of all correspondence between the IRB and the investigators, all proposals reviewed, progress reports, any reports of injury, records of continuing review, maintaining a list of IRB members and qualifications, etc. All records will be maintained for a minimum of three years after completion of the research. All IRB records shall be accessible for inspection by authorized representatives of any Department or Agency.

G. The Office of Research Administration & Engagement will provide sufficient space, resources, and support for the IRB's review and record-keeping.

H. The Office of Research Administration & Engagement will provide appropriate training and educational opportunities for the IRB and UWF students, faculty, and staff.

I. The Office of Research Administration & Engagement will identify and analyze potential conflicts of interest and will prepare management plans as needed for investigators.

J. The Office of Research Administration & Engagement will promptly report to the IRB, appropriate institutional officials, the Office of Human Research Protection (OHRP), and any sponsoring agency any injuries to human research participants or other unanticipated problems involving risks to human research participants, any serious or continuing noncompliance with the regulations or requirements of the IRB, and any suspensions or termination of IRB approval for research.

III. INSTITUTIONAL REVIEW BOARD RESPONSIBILITIES

A. The IRB will review, and have the authority to approve, require modification in order to secure approval, or disapprove all research activities covered by 45 CFR 46 and this institutional procedure manual.

B. The IRB shall require that information given to research participants as part of informed consent is in accordance with 46.116 and Section XII-XVI of this procedure manual. The IRB may require that information, in addition to that specifically mentioned in 46.116 and Section XII-XVI of this procedure manual,

be given to the research participants when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of research participants.

C. The IRB shall require documentation of informed consent, or may waive documentation in accordance with 46.117 and Section XVI of this procedures manual.

D. The IRB will ensure effective input for all initial and continuing reviews of research involving the use of human participants. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

E. The IRB shall conduct a continuing review of research covered by this procedure manual at intervals appropriate to the degree of risk, but not less than once per year, and shall have the authority to observe or have a third party observe the consent process and the research.

F. When appropriate, the IRB will determine that adequate additional protections are ensured for fetuses, pregnant women, neonates, prisoners, and children as required by Subpart B, Subpart C, and Subpart D of 45 CFR 46.

G. In accordance with 46.113, the IRB will have the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to research participants. Any suspension or termination of approval shall include a statement of the reason for the IRB's action and shall be reported promptly to the investigator, appropriate University officials, and the Department or Agency head.

H. The Office of Research Administration & Engagement, in coordination with the IRB Chair or designee, will determine whether or not a proposed activity is exempt, qualifies for expedited review, or requires full IRB review and approval.

I. The IRB shall meet at least monthly in both Fall and Spring semesters and at least once during the Summer semester, or more frequently if deemed necessary by the Office of Research Administration & Engagement or the IRB Chair.

J. The IRB has the responsibility to review Conflict of Interest Information and management plans provided by the institution and request modifications to ensure protection of human participants as needed.

IV. INVESTIGATOR AND FACULTY ADVISOR RESPONSIBILITIES

A. Research investigators and faculty advisors of student investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research participants and for complying with all parts of 45 CFR 46, the UWF IRB Procedures Manual, and the decisions of the IRB.

   Research investigators are responsible for requesting and receiving approval from the IRB before initiating any research that involves the use of human participants. Investigators will submit a new project package on IRBNet.org in its entirety for IRB review. No research will be carried out until it is approved by the IRB. It is the responsibility of the investigator to apply to the IRB of any proposed research project for approval well in advance (4-6 weeks in advance) to allow adequate time for IRB review and approval.

B. Students are permitted to be designated as a Principal Investigator with a designated UWF faculty advisor listed as research personnel on their application. The IRB holds the Faculty Advisor(s) responsible for the overall management of an approved research protocol in conjunction with the student PI. Management of the research encompasses the administrative, ethical, fiscal, and applied elements of the project. Students must share their project with their Faculty Advisor in IRBNet and have them digitally sign the package electronically before submitting to acknowledge and accept their responsibility for protecting the rights and welfare of human research participants. Faculty advisors will have an up-to-date CITI training certificate in either the Social & Behavioral Research-Basic/Refresher course or the Biomedical Research- Basic/Refresher course.

C. The investigator will ensure that legally effective informed consent will be obtained and documented in a manner that meets the requirements of 46.116 and 46.117 and Section XII-XVI of this policy. The written consent form is to be approved by the IRB and signed by the research participant or the research participant's legally authorized representative. A copy shall be provided to the person consenting to the research. The copy provided to the participant can be paper or electronic and may be provided on an electronic storage device or via email. If the copy provided includes one or more hyperlinks to information on the internet, the hyperlinks should be maintained, and the information should be accessible until study completion.

D. The investigator will promptly respond, in writing, to any concerns expressed by the IRB regarding their protocol. Delays in responding will delay consideration of the protocol. **Extended delays (more than 90 days) may require resubmission of the project.** The investigator will comply with the requirements made by the IRB in order to secure approval of their protocol. Delays in responding to the board may result in a longer review process. Any protocol disapproved by the IRB cannot be conducted. Recruitment or data collection cannot occur without an approval letter from the board.

E. The investigator will promptly report any proposed changes in previously approved human participant research activities to the IRB through the submission of an amendment package in IRBNet. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the research participants. Such modifications may include changes in personnel, recruitment, consent, questionnaires, or procedures.

F. The investigator is responsible for reporting progress of approved research to the Office of Research Administration & Engagement as prescribed by the IRB, but not less than once per year.

G. The investigator will immediately report to the IRB any unanticipated problems involving risks to human research participants or incidents that harm or may harm human research participants. The Principal Investigator will complete the Serious Adverse Events or Unanticipated Problems Reporting Form and submit it in IRBNet as a new package.

H. Investigators are invited to attend the IRB meeting to discuss proposed projects. Faculty Advisors of student projects listed on an IRB meeting agenda are strongly encouraged to attend to assist their student in answering any questions the board may have, unless teaching responsibilities prevent them from doing so.

I. At the end of the IRB-approved time period for the project, the investigator is responsible for either requesting an extension of their expiration date or submitting their final report. Research Administration & Engagement will make efforts to remind investigators of upcoming expiration dates sixty, thirty, and seven days in advance through automated reminders in IRBNet. However, it is the responsibility of the investigator to know when projects expire and plan accordingly.

V. REQUIRED TRAINING

Research investigators, co-investigators, and faculty advisors (if applicable) who intend to use human research participants must complete a training course on the protection of human research participants. The required course is the CITI (Collaborative Institutional Training Initiative): Human Subjects Research Training Module. Investigators, co-investigators, and faculty advisors must take either the Behavioral/Social Research Basic Course or the Biomedical Research Basics course based on the research they will be conducting.

External investigators who do not have access to CITI Training may utilize OHRP's Human Research Protection Training. A printable completion certificate is available after the lesson so investigators can document completion for their

records. Note that OHRP does not collect information about who accesses or completes the training.

Research investigators will be knowledgeable of and comply with the following:

- The Belmont Report
- 45 CFR 46
- The UWF IRB Procedure Manual
- The UWF Policy for Determination of Conflict of Interest
- The UWF Policy and Procedures for Export Control
- The UWF Policy for Information Security and Privacy Policy

A. Additional Training for Clinical Trials: Good Clinical Practice Training

A clinical trial, as defined by the National Institute of Health (NIH), is a "research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes". The definition of a clinical trial includes both funded and unfunded research.

Good Clinical Practice (GCP) training pertains to the international ethical and scientific standard expected in the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials.

GCP training is intended for study staff who collect data through intervention or interaction with a participant or have access to private identifiable information. However, any member of a study team may be asked to take GCP training at the request of the IRB. GCP training certification is required before IRB approval.

Who must take GCP Training?

Good Clinical Practice (GCP) training is required for all investigators and staff involved in clinical trials as defined by NIH above. UWF offers GCP training online through www.citiprogram.org. Valid GCP training certification must have been completed within 5 calendar years of the submission of the new IRB protocol. Any of the following GCP programs will qualify:

- Collaborative Institutional Training Initiative (CITI);
- Academy of Physicians In Clinical Research (APCR)

B. Additional Training for Use of Protected Health Information (PHI): HIPAA Training

Health information refers to any information related to an individual's physical or mental health, health care provided to the individual, or payment for health care provided to the individual. **Identifiable health information** is any health information that is associated with personal identifiers (such as name, address, date of birth, or Social Security number). **Protected Health Information (PHI)**

refers to individually identifiable health information created, held, or transmitted by a covered entity or business associate of a covered entity. Covered entities include health care providers, health plans, and health clearinghouses. Although measures must be taken to protect the confidentiality of all identifiable health information that is accessed, reviewed, collected, analyzed, used, or disclosed for research purposes, PHI is subject to the Privacy Rule of the Health Insurance Portability and Affordability Act (HIPAA) of 1996 (US Department of Health and Human Services, 2022).

All principal investigators, co-investigators, and other personnel who have access to PHI must provide proof of HIPAA Training within the last three years. The HIPAA Training must be completed before initiating human subjects research and every three years thereafter.

VI. IRB MEMBERSHIP

A. Committee members will be recommended by the Provost/Vice President for Academic Affairs and appointed by the University President in accordance with 46.107. A minimum of five members will be appointed to the IRB. The board members will select one member to serve as Chair annually. Appointees will have varied backgrounds so as to promote a complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human research participants. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall, therefore, include persons knowledgeable in these areas. Consideration shall also be given to the inclusion of one or more individuals who have formal ethical training. The IRB may not entirely consist of members of one profession.

B. If the IRB regularly reviews research that involves a vulnerable category of research participants, such as children and minors, prisoners, pregnant women, fetuses, neonates, individuals with impaired decision-making capacity, and economically or educationally disadvantaged persons. Consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these research participants.

C. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

D. The IRB shall include at least one member who is not otherwise affiliated with the

institution and who is not part of the immediate family of a person who is affiliated with the institution.

E. No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest or active role, except to provide information requested by the IRB. Conflicting interests refer to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, a member's professional judgment in reviewing or evaluating a research project. All conflicting interests of an IRB committee member must be declared before review of any research under IRB jurisdiction.

F. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

VII. CRITERIA FOR IRB APPROVAL OF RESEARCH

In order to approve research covered by 45 CFR 46 and this procedure manual, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to research participants are minimized:

    a. by using procedures which are consistent with sound research design and which do not unnecessarily expose research participants to risk, and
    b. whenever appropriate, by using procedures already being performed on the research participants for diagnostic or treatment purposes.

2. Risks to research participants are reasonable in relation to anticipated benefits, if any, to research participants, and the importance of the knowledge that may be reasonably expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies research participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. The selection of research participants is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, and minors, prisoners, pregnant women, fetuses, neonates, individuals with impaired decision making capacity, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective research participant or

the research participant's legally authorized representative, in accordance with, and to the extent required by 46.116 and Section XII-XVI of this procedure manual.

5. Informed consent will be appropriately documented in accordance with, and to the extent required by 46.117 and Section XII-XVI of this procedures manual.

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

7. When appropriate, there are adequate provisions to protect the privacy of research participants and to maintain the confidentiality of data.

8. When some or all of the research participants are likely to be vulnerable to coercion or undue influence, such as children and minors, prisoners, pregnant women, fetuses, neonates, mentally disabled persons (including individuals with cognitive impairment that would affect decision making), or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these research participants.

A. Human Subjects Research Definition

1. A **human subject (or "participant")** is a living individual about whom an investigator conducting research:

   a. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

      - Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

      - Interaction includes communication or interpersonal contact between the investigator and the subject.

   b. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

      - Private information includes 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.

2. **Research** is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

   a. A "systematic investigation" is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

      Examples of systematic investigations include:
      - Surveys and questionnaires
      - Interviews and focus groups
      - Evaluations of social or educational programs
      - Analyses of existing human data or biological specimens
      - Epidemiological studies
      - Cognitive and perceptual experiments
      - Medical chart review studies

   b. “Generalizable Knowledge” is information expected to expand the knowledge base of a scientific discipline or other scholarly field of study and yield one or both of the following:
      - Results that apply to a larger population beyond the site of data collection or the specific participants studied
      - Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.

3. Research results do not have to be published or presented to qualify the investigation or data gathering as research. The intent to contribute to "generalizable (scholarly) knowledge" makes an experiment or data collection research, regardless of publication. Research that is never published is still research. Participants in research studies deserve protection, whether or not the research is published.

4. Thesis or dissertation projects involving human participants conducted to meet degree requirements are usually considered generalizable research and require IRB review and approval.

5. <u>Examples of activities that typically are not generalizable (not “research”) include:</u>

   a. Biographies

   b. Oral histories that are designed solely to create a record of specific

historical events

c. Service, program, or course evaluations, unless they can be generalized to other individuals

d. Services, programs, courses, or evaluations where it is not the intention to share the results beyond the UWF community

e. Quality assurance activities that are designed to continuously improve the quality or performance of a department or program, where it is not the intention to share the results beyond the UWF community.

6. Per federal regulations, the following activities are deemed not to be research:

a. 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.

b. 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).

c. 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.

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

B. Exempt Research

In accordance with 46.104(d), unless otherwise required by Department or Agency heads, research activities in which the only involvement of human research participants will be in one or more of the following seven categories will be categorized as exempt research. Although this category is called exempt, this type of research does require an IRB application submission and review. Individual investigators do not have the authority to determine that a research project qualifies as exempt.

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:

    a. most research on regular and special education instructional strategies, and

    b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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:

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

    b. Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' 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 participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

3.

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

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

        ii. Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' 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 participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

b. 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 participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the participants 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.

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

4. Secondary research for which consent is not required: Secondary research uses identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

a. The identifiable private information or identifiable biospecimens are publicly available;

b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants;

c. 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

d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research 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.

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.

    a. 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 participants.

6. Taste and food quality evaluation and consumer acceptance studies:
    a. If wholesome foods without additives are consumed, or

    b. 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.

Human subjects research that is classified as “exempt” means that the research qualifies as no risk or minimal risk to participants and is exempt from most of the requirements of the Federal Policy for the Protection of Human Subjects. Exempt

research is still considered research requiring an IRB review and approval.

These exempt categories do not, however, apply to research involving deception of participants (i.e., where the researcher deceives the participant with regard to the purpose of the research and/or the results of the participant's actions in the study), sensitive behavioral research, or to research targeting participant populations determined to be vulnerable.

All IRB members will be notified by the Research Administration & Engagement of all projects approved as exempt research. In reviewing the research, the reviewers may exercise all of the authority of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after full board review.

C. Expedited Review

In accordance with 46.110, research activities involving no more than minimal risk and in which the only involvement of human participants will be in one or more of the following categories (carried out through standard methods) may be reviewed by the IRB through the expedited review procedure:

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 increase the risks or decrease 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.

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 participants, 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 [2], considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these

participants, 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.

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

    a. hair and nail clippings in a non-disfiguring manner;

    b. deciduous teeth at the 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.

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 participant or an invasion of the participant'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.

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. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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

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. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

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 participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or

    b. where no participants have been enrolled and no additional risks have been identified; or

    c. where the remaining research activities are limited to data analysis.

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.

The IRB may use the expedited review procedure to review either or both of the following:

Some or all of the research appearing in D.1-9. above and found by the reviewer to

involve no more than minimal risk, and minor changes in previously approved research during the period of one year or less for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authority of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after full board review. All IRB members will be notified by the Research Administration and Engagement of all projects approved under the expedited review process.

D. Full Board Review

Any proposal that does not qualify for exempt or expedited IRB review shall be reviewed by the full IRB at a convened meeting in which a quorum (50% of the membership, including at least one member whose primary concerns are in non-scientific areas) is present. Only those members present at the meeting may vote on the proposal. No absentee or proxy votes will be allowed. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

Some examples of research reviewed by the full board are:

- Research projects involving more than minimal risk.
    - **"More than Minimal risk**" is: the probability and magnitude of harm or discomfort anticipated in the research is greater than those ordinarily encountered in the daily life of a typical person or during the performance of routine physical or psychological examinations or tests.
    - Risks include, but are not limited to, risks to information, psychological or emotional, social, physical risks or harms, legal, financial, and risk to genetic privacy.
- Research projects involving clinical trials and/or clinical interventions
- Research projects that involve vulnerable populations, which include but are not limited to:
    - children and minors, prisoners, pregnant women, fetuses, neonates, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons
- Research projects that involve the use of a medical device (in most cases) with Environmental Health & Safety approvals as applicable.
- Projects that involve possible coercion or undue influence that induce or entice consent (e.g., excessive compensation, inequitable relationship, etc.)
- Sensitive information is being gathered (e.g., child abuse, violence, sexual conduct/misconduct, physical/mental health status information, HIV status, substance abuse, illegal behavior, etc.)

- Projects involving significant deception (e.g., intentionally misleading participants about their status, giving false information about the researchers or the research purpose).

If you believe your IRB project will require full board review, plan to submit your application via IRBNet at least two weeks prior to the next IRB meeting.

E. Outcomes

There are four possible outcomes to a review:

1. Approved: No further action is required from the investigator prior to initiating the study.

2. Approved with Conditions: The IRB has conditionally approved this study. Conditions must be met and verified by an authorized member of the IRB prior to initiating research. Conditions may include:
    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 and, if applicable, subparts B, C, or D of 45 CFR part 46.

    With respect to research reviewed and approved with conditions by the IRB at a convened meeting, note that because the IRB is able to make all these determinations, the IRB may 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 further review by the IRB at a subsequent convened meeting would not be necessary.

    A study may not initially begin until the status is labeled as “Active” with a start date listed in IRBNet.org.

3. Modifications Required: Changes are required before the study may begin. Additional or revised information must be submitted to the IRB prior to approval. For studies reviewed at a convened meeting, a subsequent convened meeting will be necessary to review whether the required modifications have been met.

4. Not Approved: The proposed research, because of the level of risk involved, cannot be initiated. This determination can only be made at a convened meeting of the IRB.

VIII. AMENDMENTS

An amendment package must be created within your previously approved project in IRBNet.org and submitted for approval PRIOR to the modification of a previously approved project. Such modifications could include changes in:

- Study team members
- Principal Investigator
- Recruitment or recruitment materials
- Informed Consent documents
- Questionnaires or interview questions
- Study protocol or procedures

The amendment's review path (e.g., full board, expedited, exempt) depends on the nature and level of the change. Substantive changes to a project will be reviewed by its previous review path. Substantive changes to full board projects are subject to the IRB submission deadlines and committee meeting dates.

Minor amendments for projects previously reviewed at a convened meeting may be reviewed via an expedited review. Examples of minor amendments include, but are not limited to:

- Addition of procedures that do not increase risk
- Removal of procedures that result in reduced risk to participants
- Addition of, or changes to, recruitment materials or recruitment strategies that do not increase risk or coercion of participants

Examples of minor amendments that can be processed with an administrative review by the UWF IRB office include:

- Addition or deletion of study team members
- Document changes that do not modify the intent of the content (e.g., typographical error corrections, improvements for clarity)
- Addition of non-sensitive survey or interview questions

Once the IRB approves an amendment, the information, protocol, and documentation in the amendment become the record of the approved study.

IX. CONTINUING REVIEW

Approval of a human subject research proposal is in effect for one year. Federal regulations do not allow retrospective approval. If research involves extreme risk to participants, the IRB may review it more frequently or alternatively ask to be kept apprised of all research activity. In the event that the study continues longer than the initial approval period, the principal investigator is responsible for requesting an extension. As per HHS guidance, IRB review of a proposed change to a research project during the period for which approval is authorized does not constitute continuing review of the project as a whole, and thus does not extend the date by which continuing review must occur (e.g., beyond one

year from the effective date of the initial approval or the most recent continuing review approval).

To request an extension, the principal investigator is responsible for submitting a continuing review package that includes a continuing review form that includes:

1. A statement that there were no changes from the approved protocol.
2. A description of any adverse events or unanticipated problems involving risks to participants or others.
3. Any withdrawal of participants from the research or complaints about the research.
4. A copy of the actual informed consent document used in the research.
5. Were the actual risks and benefits as anticipated?
6. Was the IRB informed of any unforeseen problems or accidents that may have occurred?
7. Were the procedures agreed upon at the beginning of the research used?

If a project is not to be renewed, the PI is required to submit a final report form.

Continuing Review Reminders
IRBNet sends out courtesy project expiration reminders to the Principal Investigator (PI) before a study expires. However, it is ultimately the PI's responsibility to keep track of when the continuing review is due and to submit a continuing review request at least 2 weeks in advance for expedited applications and 4-6 weeks in advance for full board applications.

X. STUDY CLOSURES

When a research study no longer involves human participants, the study may be closed with the IRB by submitting a final report package in IRBNet. Research involves human participants, while the researcher:

- 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 biospecimens.

Once a study is closed, research personnel may continue to perform data analysis, manuscript preparation, and publication activities, so long as identifiable information is not being accessed.

All records produced or collected in connection with a research project must be retained for a minimum of three years after study closure, or longer if subject to federal regulation (including HIPAA) or sponsor requirements. If a study that is

closed or expired needs to be reopened for any reason, a new project submission will be required.

A. When a PI Leaves the University

When a PI leaves the University, they will need to either close the project by submitting a final report or submit an amendment to transfer the project to another active UWF PI. If a final report or amendment has not been received within a timely manner of the PI leaving the university, the project will be administratively closed. An administrative closure is not the equivalent of a study suspension or termination.

XI. SUSPENSION OR TERMINATION

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB policy and procedures, is not in compliance with federal regulations, or has been associated with unexpected serious harm to participants. Serious or continuing noncompliance with the determinations of the IRB may result in the IRB withdrawing approval for a study. Any letter of suspension or termination of approval to an investigator shall include a statement of the reasons for the IRB's action. The Investigator shall have an opportunity to respond in writing or in person to the letter of suspension or termination.

All suspensions or terminations of approval for cause must be promptly reported to the Institutional Official. The Institutional Official shall notify the relevant Department Head and the Dean of the Investigator's School.

Regulatory authorities such as OHRP, the FDA, NIH, or other federal sponsoring departments or agencies shall be promptly notified as required by the Associate Vice President of Research Administration & Engagement of any terminations or suspensions for cause.

The IRB chair or Research Compliance Officer may institute a suspension of IRB approval when, in the opinion of the IRB chair or Research Compliance Officer, participants may be at risk of adverse effects on their rights and welfare before action may be considered by the convened IRB. The Institutional Official, or designee, may institute a suspension of IRB approval or termination of IRB approval for any reason. Whenever possible, the Institutional Official or designee will follow the steps below and communicate with investigators orally and in writing.

1. Notify the investigator of the suspension or termination of IRB approval, along with the reasons for the decision.
2. Ask the investigator for a list of human participants currently involved in the research.

3. Ask the investigator whether any actions are required to protect those participants' rights and welfare or to eliminate an apparent immediate hazard. Consider whether any of the following additional actions are required to protect those or other participants' rights and welfare or to eliminate an apparent immediate hazard:

    - Transferring participants to another investigator.
    - Making arrangements for clinical care outside the research.
    - Allowing continuation of some research activities under the supervision of an independent monitor.
    - Requiring or permitting follow-up of participants for safety reasons.
    - Requiring adverse events or outcomes to be reported to the IRB and the sponsor.
    - Notification to current Human Participants.
    - Notification to former Human Participants. Refer to the IRB staff to place on the agenda for a convened IRB meeting in an IRB with appropriate scope as an item of Suspension of IRB Approval or Termination of IRB Approval.

4. The suspension or termination will be reviewed at the next convened meeting.

5. Complete and send to the investigator a suspension or termination letter.

XII. GENERAL REQUIREMENTS FOR INFORMED CONSENT

Except as provided in Section XVI of this procedure manual, no investigator may involve a human research participant unless the investigator has obtained the legally effective informed consent of the research participant or the research participant's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective research participant, or the representative, sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the research participant or the representative shall be in language understandable to the research participant or the representative. For instance, the adult informed consent form shall be written using plain language at an approximate 8th-grade reading level. No informed consent, whether oral or written, may include any exculpatory language through which the research participant or the representative is made to waive or appear to waive any of the research participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

A. The Informed Consent process generally consists of

1. Explaining the purpose of the study and the risks and benefits of participation to the prospective participant, or the legally authorized

representative, with sufficient opportunity to discuss and consider whether or not to participate

2. Securing the uncoerced, freely-given consent of a human research participant, documented in writing in language that is understandable and

3. Providing the participant with a written informed consent document that outlines the purpose, risks, and benefits of participation and provides details on how to contact the Principal Investigator (PI) and the UWF IRB.

B. In certain circumstances, the need for written consent may be waived, but the practice of informed consent applies to all research projects. Each UWF IRB application must include a copy of the informed consent document(s).

C. When researchers plan to enroll participants who are not proficient in English, they must create a plan for communicating with those participants at every phase of the research process, including enrollment, consent, data collection, and follow-up. Materials (including consent forms) must be submitted to the IRB in both English and the target language. The IRB also requests that researchers include the name and contact information of a UWF faculty/staff member, who is external to the research team, fluent in the target language and English, who might assist the IRB in evaluating the appropriateness of materials not in English.

D. Except as provided in Section XVI, the informed consent must include:

1. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. a description of any reasonably foreseeable risks or discomforts to the research participant;

3. a description of any benefits to the participant or to others which may reasonably be expected from the research;

4. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the research participant;

5. a statement describing the extent, if any, to which confidentiality of records identifying the research participant will be maintained;

6. for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained:

7. an explanation of whom to contact for answers to pertinent questions about the research and participants' rights, and whom to contact in the

event of a research-related injury to the participant; and

8. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the research participant is otherwise entitled, and the research participant may discontinue participation at any time without penalty or loss of benefits to which the research participant is otherwise entitled.

9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

    i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility; or

    ii. A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

E. When appropriate, one or more of the following elements of information shall also be provided to each research participant;

1. A statement that the particular treatment or procedure may involve risks to the research participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable;

2. Anticipated circumstances under which the research participant's participation may be terminated by the investigator without regard to the participant's or the legally authorized representative's consent;

3. Any additional costs to the research participant that may result from participation in the research;

4. The consequences of a research participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;

5. A statement that significant new findings developed during the course of the research that may relate to the research participant's willingness to continue participation will be provided to the participant;

6. The approximate number of participants involved in the study;

7. A statement that the research participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit;

8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to research participants, and if so, under what conditions; and

9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

F. **Child Assent**

Assent means a minor's (e.g., child, youth, adolescent under the age of 18) affirmative agreement to participate in research (45 CFR 46.402(b)). To assent, the minor must actively demonstrate a continued willingness to participate in the research, and not just comply with participation directions. The IRB may approve an assent process that is conducted verbally or in writing and tailored to the age or cognitive capacity of the individual. For older youth and adolescents, a written assent form is desirable. Researchers should consider the reading level of their participants when writing the assent form. In some instances, this may require researchers to define scientific jargon in simple terms. It may also require more concise explanations or the use of pictures to show study activities. A Child Assent Sample Form can be found within IRBNet. Multiple assent processes may be used within the same study. If the IRB has approved an assent process, then the child cannot be enrolled if they say "No" - regardless of whether the parent or legally authorized representative says, "Yes".

The legal age to consent varies by state and country. For example, the legal age of majority is 19 in Alabama and Nebraska. The PI is responsible for understanding and communicating to the IRB the laws around consenting for research in the state or country where the research will be conducted.

G. **Parental Consent**

Parental Consent forms provide a signature line labeled Parent / Guardian and a place for the date. The Board also requires a second signature line labeled 2nd Parent / Guardian with a place for the date. This is to accommodate parents with court-appointed joint custody. Because it is not the researcher's responsibility to become knowledgeable as to which children require joint permission, if a consent form is returned with only one parental signature, the researcher may assume this child's parents do not fall into that category.

Federal Regulations require the signature of both parents under the following circumstances:

- when research involves greater than minimal risk with no prospect of direct benefit to individual participants, but is likely to yield generalizable knowledge about the participant's disorder or condition;

- or when research, otherwise not approvable, presents an opportunity to

understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

XIII. PARTICIPANT COMPREHENSION ASSESSMENT

The responsibility of ensuring that a potential participant understands the research, risks, and benefits involved falls upon the investigator and not upon the potential participant. It is critical to the consent process that the Investigator not only field questions but also asks questions. Asking questions can further the discussion, elicit questions from the potential participant, prompt the potential participant to think more carefully about the study, and help the investigator decide whether the person has adequately understood the study. Useful questions will be open-ended and non-directive. Rather than asking for yes or no answers, they ask for explanations because these questions often can be answered in a variety of ways, and do not already contain the correct answer. Open-ended questions are often introduced with "what," "where," "how often," "when," and "please describe."

Examples of open-ended questions are:

- "Just so that I'm sure you understand what is expected of you, would you please explain to me what you think we're asking you to do?"
- "Describe in your own words the purpose of the study."
- "What more would you like to know?"
- "What is the possible benefit to you of participating in this study? What are the possible risks?"
- "Can you describe what the alternatives to participation in this study are?"

The IRB suggests that investigators use the decision-making capacity tool as needed to assess participant comprehension. In contrast, closed-ended questions do not further discussion and tend to bring it to a stop, so they should be avoided.

Examples of closed-ended questions are:

- "Do you understand?"
- "Do you have any questions?"
- "Do you see that there are some risks to taking this drug?"

If a researcher doubts the participant's consent comprehension, the participant cannot be enrolled in the study.

If a participant is legally blind or unable to read, allow sufficient time for questions to be asked and answered, both by the participant and by the person obtaining

consent, to ensure the participant comprehends the consent information. It is recommended that a witness, independent of the research, observe the consent process. Consider using a video/audio recording of the consent discussion as part of the documentation of informed consent. If the participant (or participant's legally authorized representative) verbally agrees to participate in the study:

- participant (if capable of doing so): Signs and personally dates the consent form. Illiterate participants may also mark an X to signify consent.
- Witness: Signs and personally dates the consent form. By doing so, the witness attests that the consent information was accurately explained and that the participant apparently understood the information, and informed consent was given freely.
- Person obtaining consent: Signs and dates the consent form.
- Give a signed copy to the participant.

XIV. DOCUMENTATION OF INFORMED CONSENT

A. Except as provided in Section XVI, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the research participant or the research participant's legally authorized representative. A copy shall be given to the person signing the form. The copy provided to the participant can be paper or electronic and may be provided on an electronic storage device or via email. If the copy provided includes one or more hyperlinks to information on the internet, the hyperlinks should be maintained, and the information should be accessible until study completion.

B. Once an individual has had all their questions answered and has agreed to participate in the study, the participant should sign and date the consent form.

C. If the IRB requires a HIPAA Research Authorization, this must also be signed and dated at the time written consent for participation in the study is obtained.

D. Researchers utilizing video and audio recording, or any other media recording, must prospectively inform participants that such recording will occur and be provided with information about the use, storage, confidentiality, and future use of the resulting recording. If the recording is not required as part of the research procedures, then the consent document must include a specific statement indicating that participation in the research study is not contingent upon agreeing to be recorded. The consent form should include dedicated places for the participant to specify consent to the recording or photography, and any other permissions or options.

   i. Please note that, under Zoom's terms, Zoom may have access to any audio or video recorded on its platform. Participants should be informed of this in the consent process.

E. The Investigator who has oriented and consented the participant also must sign and date the consent form. NOTE: The participant is not technically enrolled until both the participant and the Investigator have signed. It may be appropriate for the Investigator to sign after the participant if the Investigator needs to verify that basic eligibility criteria have been met. The Investigator's signature means that the informed consent process has taken place with the participant and that the participant:

   1. meets all study inclusion criteria;

   2. was appropriately consented (as described above);

   3. understands the requirements of the study; and

   4. has received a copy of the informed consent document.

F. Usually, the Investigator, participant and impartial witness (when required—see below) sign at the same time.

G. The Investigator's signature cannot predate the participant's signature.

H. The participant should always be provided with a copy of the consent form to use as a continual reference for items such as scheduling of procedures and for emergency contact information.

I. Observation of the consent process by a witness is required in the following situations:

   1. When using the IRB-approved foreign language short form process for participants who do not speak English;

   2. When obtaining informed consent from a participant (or the participant's parent/guardian or surrogate decision maker) who can understand and comprehend the language, but is physically unable to read, write, talk, or is blind.

J. The individual providing informed consent must be competent and able to indicate approval or disapproval by other means. The method by which the individual indicated consent must be noted on the consent form (blinking of eyes, raising arm, etc).

K. The witness must be impartial, such as an adult who is not a member of the study team (i.e., is not listed on the protocol narrative) and who is not a family member of the participant. The witness must sign and date the consent form attesting that the requirements for informed consent have been satisfied; that consent is voluntary and freely given by the participant, guardian, or surrogate, without any element of force, fraud, deceit, duress, coercion, or undue influence.

L. Except as provided in Section XVI, the consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent required by 46.116 and Part XII-XV of this procedure manual. This form may be read to the research participant or the research participant's legally authorized representative, but in any event, the investigator shall give either the research participant or the representative adequate opportunity to read it before it is signed; or

2. A short written consent document stating that the elements of informed consent required by 46.116 and Part XII-XV of this policy have been presented orally to the research participant or the research participant's legally authorized representative.

3. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the research participant or the representative. Only the short form itself is to be signed by the research participant or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the research participant or the representative, in addition to a copy of the short form.

M. **Key Information Section**: In response to the revised Common Rule, a Key Information section is <u>required for informed consent forms longer than 5 pages</u>. The key information should be at the beginning of the informed consent form to provide the prospective participant with enough information to determine whether they should participate in the study in a focused and concise manner. The Key Information section is designed to facilitate prospective participants' (or legally authorized representative's) understanding of the research study and the reasons why one might wish to participate, or not participate, in the study. The five required elements are:

1. That the prospective participant's consent is being sought for research, and that participation is voluntary;
2. The purpose(s)of the research, the expected duration of participation, the research procedures to be followed, and any other important information about the research;
3. The reasonably foreseeable risks or discomforts to the prospective participant;
4. The benefits to the prospective participant or others that may reasonably be expected;
5. Appropriate alternatives to the research, if any.

Key information provided to participants is not limited to these five elements. Researchers may include other types of information that they deem necessary

and appropriate to include in the key information.

XV. ELECTRONIC INFORMED CONSENT WITH SIGNATURE

As with the standard consent process for written consent, the electronic consent process has two parts:

1. Consent Discussion: Informing a participant using electronic means.
2. Consent Documentation: The individual indicates agreement to participate in the study by documenting consent using an electronic signature.

Before involving a person in research, an investigator needs to obtain and document the legally effective informed consent of that person (45CFR46.116). Historically, documenting consent would mean a written signature on a paper consent form stating that the person agreed to participate in the study. As technology has advanced, electronic (and digital) signatures have become acceptable for documenting legally effective informed consent if implemented correctly by the study team.

A. The Necessary Components of Electronic Informed Consent

- The participant must have adequate time to review the consent, and there must be a mechanism to allow the participant to ask questions of the study team.
- The participant needs to receive a copy of the signed consent, either a hard copy or an electronic file. For example, you could include instructions on how to print the consent form or provide a mechanism to email a copy of the consent form to the participant.
- The study team needs a mechanism to track consent versions and to re-consent participants as needed when the consent form changes. (All consent changes require IRB approval.)
- Appropriate technical security measures must be in place to protect the confidentiality of the participant's information.
- Document the participant's agreement through two separate consent fields:
    - A field to confirm that the person agrees to participate in the study.
    - A field to confirm that the person agrees to provide electronic consent.
- Unless a waiver for documentation of signature for consent has been requested and approved as per XV.B. below, document consent using an electronic signature application that meets the required UWF data security requirements.
- There should be a time stamp on the participant's signature.

B. Implementing Electronic Signatures

An electronic signature is defined as an electronic sound, symbol, or process, attached to or logically associated with an electronic record and used by a person with the intent to sign such a record. Unless the requirement for a

signature has been waived as per section XVI.B, an electronic signature may be used as legally effective documentation of consent. To be legally effective, the electronic signature needs to be attributable to a verified identity. (Note: This only applies to studies conducted in the United States. Consult the foreign country's laws regarding what constitutes a legal signature.)

Examples of how this could be accomplished include:

- Having the potential study participant write their signature on a digital screen when in the presence of a member of the study team (either physically present or remote via a video conferencing platform).
- Typing out their name to indicate an electronic signature when the potential study participant is signed into a password-protected system.
- The potential study participant could orally agree on a digital recording to provide their consent by electronic signature.
- Sending an email to a school email address or a text message to a phone number given by the potential participant with a link to access the electronic consent included in the message.

Frequently used applications for collecting electronic signatures include DocuSign, REDCap, and AdobeSign. These applications have developed processes for collecting electronic signatures that are connected to an individual's identity and are often a good choice for documenting legally effective consent signatures electronically. Applications such as Google Forms do not meet the level of security needed and should not be used for human subjects research. Qualtrics' electronic signature field does not meet the requirements for a legally effective signature in the state of Florida.

FDA-regulated studies require compliance with 21 CFR Part 11. This requires the use of Part 11 compliant software that provides additional elements for electronic signatures, including acceptable ways to confirm the participant's identity. This requirement applies to any study that is being performed under an Investigational New Drug (IND) application, an Investigational Device Exemption (IDE) application, a non-significant risk device (NSR) determination request, or that will submit data to the FDA for a marketing application or labeling change.

Please note that a participant clicking "I agree" after reading the informed consent does not constitute a legally effective documentation of informed consent. In this instance, an alteration of informed consent requirements would be sought. Always review your approved protocol to confirm whether documentation of a signature in the informed consent is required or has been waived. If the research poses more than minimal risk, then documentation of legally effective signatures on the consent form is required.

XVI. INFORMED CONSENT WAIVER OR ALTERATION

It is the preference of the University Institutional Review Board (IRB) that written informed consent is received from all research participants. However, the University recognizes that under certain circumstances, written consent is either impossible or impracticable to obtain. To obtain approval from the IRB for waiver of informed consent or waiver of documentation of informed consent (verbal consent), the researcher should review and follow the following guidelines:

A. Approval

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

1. the research involves no more than minimal risk to the participants;

2. the research could not practicably be carried out without the waiver or alteration; and

3. if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

4. the waiver or alteration will not adversely affect the rights and welfare of the research participants;

5. whenever appropriate, the research participants or legally authorized representatives will be provided with additional pertinent information after participation.

The informed consent requirements in this procedure are not intended to preempt any applicable Federal, State, or local laws that require additional information to be disclosed in order for informed consent to be legally effective.

Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

B. Waiver of Requirement for Signature

The UWF IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds either:

1. That the only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the

participant wants documentation linking the participant with the research, and the participant's wishes will govern; or

2. That the research presents no more than minimal risk of harm to participants, and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the UWF IRB requires the investigator to provide participants with a written information sheet regarding the research.

C. Verbal Consent

Verbal consent may be obtained when the IRB has approved a waiver of documentation of consent. Verbal consent requires that all of the information that is normally provided in written form be provided either orally or in writing, and the participant agrees to enroll verbally or behaviorally. In order to use verbal consent, the IRB must find that:

- The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves illegal activity or substance abuse). Each participant must be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern (i.e., the participant is from a culture that may punish the individual for participating) (THIS EXCEPTION IS NOT AVAILABLE FOR FDA FUNDED RESEARCH); or

- The research presents no more than a minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

The only difference in verbal consent is that there is no "consent form" for signature. The researcher is required to provide a proposed script for verbal informed consent with his or her IRB application, which should include all elements required in written informed consent. Verbal consent should be documented in either the written study record or included in any audio or video recordings. Participants should be provided with an information sheet as described below, except in cases where it is infeasible, such as phone surveys, or if possession of the information sheet would increase the individual's risk level of participating in the research. In the latter case, contact information for the investigator and IRB may be provided using a business card.

Information Sheets

When documentation of consent has been waived by the IRB, investigators are still expected to provide consent information to participants in writing through an information sheet or debriefing statement. Information sheets provide the same

information as would be required in an informed consent form, with the exception of a location for the participant's signature. Information sheets are commonly used as the front page of anonymous surveys.

D. Public Benefit or Service Program Studies

An IRB may approve a consent procedure that alters some or all of the elements of informed consent, or waive the requirement to obtain informed consent under HHS regulations at 45 CFR 46.116(c), provided that the IRB finds and documents that both of the following conditions are met:

1. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

    a. public benefit or service programs;

    b. procedures for obtaining benefits or services under those programs;

    c. possible changes in or alternatives to those programs or procedures; or

    d. possible changes in methods or levels of payment for benefits or services under those programs; and

2. the research could not practically be carried out without the waiver or alteration.

E. Educational Evaluation Practices

The UWF IRB will review requests for waivers of informed consent on a case-by-case basis. Frequently, IRB waivers are requested for standard educational evaluation practices. If you are requesting an informed consent waiver for an educational assessment, please answer the following questions in your request to the IRB:

- Will students be learning something different than the regular standard educational practice?
- Are there plans to publish or present the evaluation of this new educational procedure at a conference or publish it so that it can be accessed by other educators, researchers, or the public at large?
- What portions of their student work will be used for the research?

F. Research in Emergency Settings

The UWF IRB may also waive the requirement for obtaining informed consent if it finds and documents that the research meets the requirements of the HHS Secretarial waiver under 45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings.

G. Research with Protected Health Information

If you are accessing Protected Health Information in accordance with the Health Insurance Portability and Accountability Act, you must also apply for a waiver or alteration of HIPAA Authorization. In order to grant a waiver or alteration of HIPAA Authorization, the IRB must find:

1. There is an adequate plan to destroy identifiers at the earliest opportunity, absent a health or research justification or legal requirement to obtain them;
2. There is an adequate plan to protect health information identifiers from improper use or disclosure;
3. There are adequate written assurances that the PHI will not be used or disclosed to a third party except as required by law, for authorized oversight of the research study, or for other research uses and disclosures as permitted by the Privacy Rule;
4. The research could not practicably be conducted without the waiver or alteration; and
5. The research could not practicably be conducted without access to and use of PHI.

In order to obtain a waiver of informed consent, please see Appendix I Section IV: Obtaining a Waiver, Partial Waiver, or Alteration of Authorization.

XVII. RECRUITMENT

A. Emails Sent to Research Participants

1. A description of how email will be used to communicate with potential participants for recruitment purposes should be included in the IRB application, along with any other recruitment materials, including email templates that will be used to respond to initial inquiries about the study. The subject line and content of these emails should not contain any references to health information or request health information from the participant through email.
2. Email invitations to potential participants should include the same elements as a recruitment letter. If potential participants are asked to contact researchers by email, the invitations should also contain proper notification of the confidentiality issues associated with email communication, including appropriate HIPAA, FERPA, or other relevant disclosures.
3. The subject line of the email should clearly state that it is an advertisement for a research study, such as: "Seeking participants for a research study" or "Information about a Research Opportunity."

4. Emails sent to research participants must adhere to the UWF Electronic Communications Policy.

5. Researchers requesting access to UWF email addresses must seek approval based on the UWF Broadcast Distribution Standards.

6. Use of non-public email listservs and distribution lists may be used with permission of the listserv owner. This procedure must be detailed in the IRB application. Investigators are required to submit a copy of the listserv owner's permission with the IRB application, and should keep a copy of that permission on file with the study's research records and make it available upon request.

B. Social & Electronic Media

Research conducted using social media creates new challenges for both investigators and those responsible for maintaining protections for research participants. Examples of electronic and social media used for recruitment include advertising on a website, an electronic bulletin board, text messages, email solicitation, chat rooms, instant messaging, online gaming, banner ads, discussion forums, blogs, Amazon Mechanical Turk, YouTube and other social media sites (e.g., Facebook, Twitter, etc.) to name a few. Although technology grows swiftly, the requirements for research recruitment remain steadfast.

Recruitment procedures and materials used with social media must follow the IRB guidelines that apply to traditional media, such as recruitment letters and flyers. Procedures should consider strategies to avoid perceptions of undue influence and maintain participant privacy. Materials must be written in clear, direct lay terms, at a level likely to be readily understood by potential participants, be clearly presented as recruitment material, and cannot be published until they have received appropriate IRB review and approval.

Researchers must ensure safeguards are in place for screening children, prisoners, and other vulnerable populations, unless these populations are the intended participants of their study.

Recruitment announcements on websites should be clearly identified as a recruitment ad for a voluntary research study. Such ads and announcements cannot be located or positioned in such a way that they could be easily mistaken for, or confused with, something else. For example, an investigator wanting to recruit students might use a recruitment plan that involves instructors notifying their students of the research opportunity. Oftentimes, this is allowable so long as it is done so that the instructor is merely passing on the information while making it clear to students that the research is not related to the course, and interested students contact the investigator directly.

All recruitment materials to be conveyed via electronic media must be submitted

to and reviewed by the IRB, including any responses to said recruitment materials by potential participants. The applicant is required to deactivate any commenting or public responses to any recruitment materials on electronic media and may not use group texting or other methods that could result in the identification of a potential participant.

1. **UWF Social Media & Website(s).** UNIVERSITY-SPONSORED WEBSITES AND SOCIAL MEDIA SITES MAY NOT BE USED FOR RECRUITMENT OF RESEARCH PARTICIPANTS WITHOUT PRIOR APPROVAL FROM THE APPROPRIATE UWF DEPARTMENT COMMUNICATOR OR LIAISON. To find the contact information for your department's official social media communicator/liaison, please visit the University Marketing and Communications Contact Page**.** You must attach your IRB approval letter with your request.

   Large studies may even have their own websites. Such websites and pages may not be merged with an academic site without prior approval of the University's marketing department. This is to avoid confusion, particularly when participants are students or patients. Such websites should be written at a reading level appropriate to the potential participants.

2. **Private Groups and Forums.** When recruitment activities are conducted through internet forums or other web-based communities, investigators are expected to conduct their activities in accordance with that site's terms of use and/or privacy policy, or where such communities have a moderator or administrator, permission should be obtained in accordance with that community's requirements. These procedures should be detailed in the IRB application. Investigators are not required to submit a copy of a forum's or community's requirements, permissions, terms of use statements, or privacy policy with the IRB application. However, they should maintain such with their research records and make it available upon request. Additionally, depending on the specific circumstances of a particular research project, the IRB may require submission of such information in order to evaluate the proposed study.

C. Crowdsourcing Platforms (Ex: Amazon Mechanical Turk/ Prolific)

The use of Amazon Mechanical Turk, or analogous commercial recruitment method companies, as a recruitment method for human participant studies continues to grow. Online crowdsourcing platforms are advertised as a "marketplace for work," and individuals who take part in the activities called "HITS" on this site are referred to as "workers." The compensation for the tasks accomplished is typically very small, usually less than $1. The considerations for using this site for the recruitment of participants are the same as with any human participant research.

Additionally, the IRB suggests that investigators consider the following:

- Explicitly mention that the study is "research" and not a "job."
- Address whether or not the compensation is contingent upon certain

conditions.

- Ensure that the complexity of the task and the amount of time expected for completion are reasonable and communicated clearly in the consent process.
- Under MTurk's policy, you cannot ask workers for identifiable data such as their name or email address. Please see your platform's policy regarding identifiable data. However, participants may contact the PI.

Sample statement to include in the consent information: "This is an academic, not-for-profit research study. This form is designed to give you information about this study. We will describe this study to you and answer any of your questions."

Note: Researchers are advised to collect data using a third-party survey software, such as Qualtrics, with known policies for data security and anonymity.

D. Informed Consent Considerations

Consent for enrollment into a study should always be a process that is independent from the recruitment (e.g., before or as part of the survey process). It is generally not acceptable to provide information to participants about pertinent aspects of the study solely in the recruitment message and not in the informed consent as well.

An opt-out type of consent may be possible. For example, a participant informs friends that data posted on their site between certain dates will be available for research. Those not wanting their data included should inform them or refrain from posting. This waiver of consent should be acceptable for no more than minimal risk studies.

Researchers must clarify that the data are collected only when the participant accesses the survey site. In other words, no opportunistic data can be collected. For example, if an investigator sends a link to individuals to access a survey or an application, they may not collect information about the person if they click on the link to access the consent/survey or application. If data is collected in this manner, it would qualify as deception research and require debriefing and the ability of the unsuspecting participant to withdraw their data.

a. **Privacy Statements & Terms of Service**: It is the researcher's responsibility to check the privacy statement and terms of service of any site or app being used for research purposes. For example:

ii. Under Facebook's privacy policy, consent must be obtained for the use of any data from a Facebook user's page.

iii. Under Zoom's terms, Zoom may have access to any audio or video

recorded on its platform. Participants should be informed of this in the consent process.

iv. Under MTurk's policy, you cannot ask workers for identifiable data such as their name or email address.

XVIII. RESEARCH IN THE SCHOOL SETTING

A. Students as Research Participants

The following applies to a researcher using their own students, a research pool, or students of another faculty member at the University of West Florida. Students as research participants may be subject to coercion or undue influence if their decision to participate could affect their grades or class standing. Confidentiality may also be of concern to a potential student participant.

In order to gain approval to use your own students as research participants, you need to demonstrate to the IRB that there is no other practicable way to carry out the project. Preferred options to faculty utilizing their own students include but are not limited to: Recruiting students in another class, collecting and/or analyzing data after the class is over and grades are issued, or having a research assistant handle recruitment, informed consent, and data collection. If data will be accessed before grades are posted, a third party will need to collect the data. This will ensure the confidentiality of which students participated and which students selected the alternative assignment. When course credit or extra credit is given to students who participate in research as part of a course requirement, students are to be given a non-research alternative for earning an equivalent amount of extra credit. The informed consent must contain a statement that student participation in the research is voluntary and they can elect to withdraw at any time without affecting their class standing or grade.

B. Instructor Course-Related Student Research Proposals

The aim of these guidelines is to assist instructors who teach courses in research design or methods (e.g., Experimental Psychology) at the undergraduate or graduate level. Often in these courses, students are asked to develop and implement their own research projects as an important part of the required classwork. The IRB realizes that student research projects involving human research participants are valuable, "hands-on" educational experiences, but that it would be inefficient for the IRB to review each student proposal individually. Therefore, instructors teaching courses that require students to actually implement a brief study utilizing volunteer research participants are in the best position to approve or disapprove a proposal based on the protective guidelines described in this document.

Required: Instructors of research design and methods courses are responsible for individual student projects with respect to the ethical treatment and protection

of human research participants. Prior to allowing students to conduct research involving human research participants, instructors must:

1. Complete the IRB training requirements listed on the IRB website (appropriate documentation must be attached to the IRB proposal).

2. Submit an IRB proposal using standard IRB forms. The proposal should address all categories outlined in the IRB application.

   The proposal should include:

   a. Research Objectives: a general description of the proposed research projects. Include a list of student names, topics, and the research objective.
   b. Research Participant Recruitment: a general description of research participants and how participants will be selected.
   c. Syllabus for Class: to ensure the requirements below are included in the class.
   d. Confidentiality of Data: a brief description of how confidentiality of data will be addressed, and
   e. Informed Consent: a brief description of how research participants will be debriefed and given the opportunity to obtain the results of the study. Provide a consent form that the students plan to use. The instructor will be responsible for reviewing content before use.

All students must be required, pursuant to the syllabus of the class, to complete all required training listed on the IRB website. All student research projects should adhere to the ethical standards set forth in the IRB's procedure manual.

Students and faculty who wish to publish or present research results should seek separate approval from the class project application.

3. **This policy does not apply to the following and requires a separate IRB application:**
   a. Senior research projects conducted within the framework of the senior capstone experience
   b. Honors theses
   c. Master's theses
   d. Doctoral Dissertations
   e. OUR Projects and Symposium Posters
   f. Any research project whose results are to be used outside of class or will contribute to generalizable knowledge
   g. Research projects that allow access to Protected Health Information (as

defined by the HIPAA Act of 1996, as amended), Personally Identifiable Information (as defined by NIST Special Publication 800-122), or Educational Records (as defined by the FERPA Act of 1974, as amended);

h. Research projects that require invasive procedures or involve sensitive information, as defined below
i. Research projects involving participants that are potentially vulnerable to coercion or undue influence, or belong to traditionally protected populations, such as children and minors, prisoners, pregnant women, fetuses, neonates, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons
j. Research projects using significant deception of research participants, administration of licit or illicit drugs, nutritional supplements, and invasive data collection methods
k. Any research project that requires audio or video recording

4. **"Sensitive Information"** as used herein includes, but is not limited to:

    a. Information relating to an individual's psychological well-being or mental health
    b. Information relating to sexual attitudes, preferences, or practices
    c. Information relating to the use of alcohol or drugs
    d. Information relating to illegal behavior
    e. Information that, if released, could reasonably place the individual at risk of criminal or civil liability or be damaging to the individual's financial standing, employability, or reputation
    f. Information that would normally be recorded in a patient's medical record, and the disclosure could reasonably lead to discrimination, stigmatization, etc.

Students whose research involves any of the above-mentioned populations or conditions must submit separate IRB proposals for their projects following standard procedures.

Naturalistic observation studies are typically within the purview of student projects. Instructors should contact the IRB Chairperson with questions about particular student proposals when necessary, and ideally should steer students away from conducting moderate to high-risk research because these types of projects are not necessary in the context of class learning assignments.

C. Research in K-12 Schools

K-12 school-based research projects require special considerations beyond the federal regulations and University policy. In order to obtain permission from the Institutional Review Board for research in an elementary, middle, or high school, the researcher must provide additional information per the following guidelines:

1. Site permission

K-12 School sites are autonomous institutions that retain the right to approve/reject any human subjects research to be conducted on their site, in their facilities, or with their teachers, staff, or students. Therefore, for research in schools, the IRB requires site permission documentation from an appropriate authority at each school or district.

Each K-12 site may have different procedures for approving external research. It is the expectation of the IRB that researchers will contact the schools/districts/administrators to get permission from the appropriate authority. Depending on the specific site, permission may be granted by a superintendent, principal, or a committee at the district.

If a school or district uses a committee to review research proposals, it is important to plan additional time into the approval process since the study will be reviewed by both the UWF IRB and the school's review committee.

Often, K-12 school sites will require proof of IRB review prior to their approval. The IRB can provide conditional approval as evidence of that review to sites. However, final approval will not be granted until appropriate site permission has been submitted to the IRB.

As sites differ in their review and approval processes, the IRB sees many different types of site permission documentation. However, any letter of support/approval must indicate that the site understands the scope of the project. In addition, the IRB generally looks for the following to be included in site permission letters:

- Protocol title (or name of study);
- A scope of the research and/or activities to be conducted at the site;
- Person or entity providing permission (including title, contact information, and confirmation of appropriate authority to provide permission).
- Provided on school letterhead or an email sent from an official school email address

2. Engagement

If teachers are engaged in research activities taking place in their school or classroom, they must complete human subjects research training and be listed on the protocol application. The IRB defines engagement based on involvement in any research activities, including recruitment, consenting, data

collection, data analysis of identifiable information, answering questions about the project, etc. PLEASE NOTE THAT THE IRB DISCOURAGES USE OF TEACHERS IN RESEARCH ACTIVITIES DUE TO THE POTENTIAL FOR INFLUENCING PARTICIPATION. If the researcher is a student teacher, extra care must be given in any consent or assent documents provided to ensure that participation in the research is voluntary and will not affect the student's grade.

3. **Background checks**
   Some schools require research personnel to undergo background checks for members of the study team engaging in research activities in their district or with their students/staff. A researcher should provide those background checks to the school as soon as practicable.

4. **Use of instructional time for research purposes**
   Many school districts will not allow research activities to take place during normal class time. Please consider this as part of your research design.

5. **Consent/Assent**
   Parental consent is required for minors to be included as research participants. It is important to plan for an appropriate method to obtain consent from parents (i.e., send the study information and consent forms to parents for review, etc.). The researcher will need to plan for a method of distributing and collecting the forms from the parents, without engaging staff.

   Minor assent is also required prior to including minors as research participants. After parental consent has been obtained, consented students can be asked to provide assent. The assent process follows the consent process and should be similar in format/procedures. The assent document should be appropriate for the participant population (reading level, assent procedures, etc).

6. **Use of Video or Audio Recording**
   Many schools place limitations on the use of video or audio recording in classrooms. In addition, only consented and assented students should be captured on the recording. The school will want to see the researcher's video/audio recording procedure, and the IRB requires that it be included as part of your description of the scope of research to potential sites. Further, the researcher must provide additional consent for video or audio recording.

D. FERPA

The Family Educational Rights and Privacy Act (FERPA) is a federal law that protects the privacy of student education records maintained by schools. Educational records include class assignments, grades, GPA, attendance, disciplinary reports, individual student educational plans, etc.

A researcher who has natural access to student records as part of their employment cannot access those records for research purposes without appropriate consent. Parental consent is required for the release of FERPA-protected student records for minors.

All student data must be de-identified before presenting any research. Only aggregate, de-identified student data (consisting of a minimum of at least 10 students) may be published or presented. This is necessary to protect the identities of the students.

Education records may be released without consent under FERPA if all personally identifiable information has been removed by authorized UWF personnel, such as Institutional Research or the Registrar's Office, and are not members of the research team. Personally Identifiable Information includes:

- Student's name and other direct personal identifiers, such as the student's social security number or student number.
- Indirect identifiers, such as the name of the student's parent or other family members; the student's or family's address, and personal characteristics or other information that would make the student's identity easily traceable; date and place of birth, and mother's maiden name
- Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and
- Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student.
- Note: The US Department of Education indicates that "data that cannot be linked to a student by those reviewing and analyzing the data are not 'personally identifiable.' As such, the data are not 'directly related' to any students. Accordingly, a document containing only non-personally identifiable data, even when originally taken from a student's Education Record, is not a part of the student's Education Records for purposes of FERPA."

See FERPA and Student Records for further information.

XIX. PAYMENTS TO RESEARCH PARTICIPANTS

The following are the procedures to follow when making payments to research participants. Adherence to these procedures applies to research that is both funded and unfunded. Researchers frequently find it necessary to offer incentives in order to obtain sufficient participation. Incentives may be subject to tax reporting, and there are specific rules that must be followed in order for the university to remain in compliance.

1. Gift Cards
   The distribution of gift cards must be documented on the UWF Gift Card Log. Due to Florida's broad public records law, most records maintained by the University, including gift card logs, are considered public records and are subject to disclosure in the event a request is made.

2. Payments to UWF Employee Participants
   If the participant is a UWF employee, payment will be made through the university payroll system as additional pay. Taxes will be withheld, and the payments will be reported on the employee's form W-2. To pay a UWF employee, a personnel action form must be completed.

3. Taxation
   UWF is required to report payments equal to or greater than $600 on Form 1099-MISC. The reporting threshold is a cumulative amount in a year. For non-cash payments, such as gift certificates or gift cards, the value of the non-cash payments must be determined, and the $600 threshold applied.

4. IRB Approval for Patient Incentives
   The Institutional Review Board (IRB) should determine that the risks to participants are reasonable in relation to anticipated benefits [21 CFR 56.111(a)(2)] and that the consent document contains an adequate description of the study procedures, risks, and benefits [21 CFR 50.25(a)(1-3)]. It is not uncommon for participants to be paid for their participation in research, especially in the early phases of investigational drug, biologic, or device development. Payment to research participants for participation in studies is not considered a benefit; it is a recruitment incentive. The amount and schedule of all payments should be presented to the IRB at the time of initial review. The IRB should review both the amount of payment and the proposed method and timing of disbursement to assure that neither is coercive or presents undue influence [21 CFR 50.20].

   Any credit for payment should accrue as the study progresses and not be contingent upon the participant completing the entire study. Unless it creates undue inconvenience or a coercive practice, payment to participants who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn. For

example, in a study lasting only a few days, an IRB may find it permissible to allow a single payment date at the end of the study, even to participants who had withdrawn before that date.

While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable to the FDA, provided that such an incentive is not coercive. The IRB should determine that the amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn. All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document.

Any changes to payments, the amount, method, or timing must be reviewed and approved prior to the initiation of such changes via an amendment.

5. Incentive Drawings/Raffles/Lotteries
   Florida state law (Florida Statute Section 849.0935) prohibits drawings, raffles, or lotteries and should not be used as incentives for human subject research. This includes random selection drawings and predetermined winner drawings (Ex, the 10th enrollee or the first 25 enrollees are given a prize). Although Florida law allows certain nonprofit and charitable organizations to conduct drawings under specific situations, the context of human subject research would not be included in these situations.

XX. UNANTICIPATED PROBLEMS INVOLVING RISKS TO PARTICIPANTS OR OTHERS AND ADVERSE EVENTS

A. Reporting

Unanticipated problems are: 1) unexpected, 2) possibly, “more likely than not”, or definitely related to the research, and 3) indicate that participants or others are at an increased risk of harm than was previously known or recognized. Investigators must report the following unanticipated problems posing risks to participants or others to the reviewing IRB as soon as possible, but in all cases within 24 hours after the event has been made known to the investigator.

1. **Adverse events** that are unexpected and related to the research.
   - An adverse event is defined as **“unexpected”** when one or more participants participating in a research protocol, the nature, severity, or frequency of which is not consistent with either:
     - the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the

current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
    - the expected natural progression of any underlying disease, disorder, or condition of the participant(s) experiencing the adverse event and the participant's predisposing risk factor profile for the adverse event.

- An adverse event is **"related to the research procedures"** if it was *possibly related* to participation in the research. OHRP defines *possibly related* as follows: "There is a reasonable possibility that the adverse event may have been caused by the procedures involved in the research".

2. **Serious Adverse Event:**
   Any adverse event temporally associated with the subject's participation in research that meets any of the following criteria:
   - results in death
   - is life-threatening (places the subject at immediate risk of death from the event as it occurred)
   - requires inpatient hospitalization or prolongation of existing hospitalization;
   - results in a persistent or significant disability/incapacity
   - results in a congenital anomaly/birth defect
   - any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition

3. Serious problem that results in:
   - Substantive harm or damage (or risk of substantive harm or damage) to the safety, rights, or welfare of research participants, research staff, or others, or
   - An adverse event or problem in the research is also considered serious when a medical, surgical, behavioral, social, or other intervention is needed to prevent above #2.

4. Information that indicates a change to the risks or potential benefits of the research; for example:
   - An interim analysis indicates that the participants have a lower rate of response to treatment than initially expected.
   - Safety monitoring indicates that a particular side effect is more severe or more frequent than initially expected.
   - A paper is published from another study that shows that an arm of the research study is of no therapeutic value.

5. A breach of confidentiality

6. Information security incidents involving any unauthorized use, disclosure,

transmission, removal, theft, loss, or destruction of research-related protected health information.

7. Complaint from a participant when the complaint indicates an unexpected risk or cannot be resolved by the research team

8. Protocol violation (which is an accidental or unintentional change to the IRB-approved protocol) caused harm to participants or others, or indicates that the participants or others are at an increased risk of harm

9. Change to the protocol was taken without prior IRB review to eliminate an apparent immediate hazard to a research participant

10. An event that requires prompt reporting to the sponsor

11. Sponsor-imposed suspension for risk

12. Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol

13. Incarceration of a participant in a protocol not approved to enroll prisoners

14. Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application [including a supplementary plan or application], or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants)

The investigator must complete the Adverse Event/ Unanticipated Event Report form and attach any associated documents, medical record notations, and correspondence from the sponsor, etc.

The investigator is responsible for the documentation, investigation, and follow-up of unanticipated problems that occur at the site where the investigator is responsible for the conduct of the research. The UWF IRB will determine the unexpectedness, seriousness, and whether adverse events are “related to research.”

B. Review of the Event or Problem

The Research Compliance Officer will review the event or problem within 10 business days of receiving the event or problem. If appropriate to the event or problem, the IRB Chair and/or Institutional Official (IO) will also review. One of the following determinations will be made.

➢ The event is NOT an unanticipated problem involving risk to participants or others (because the event is either anticipated or does not indicate that the participants are at increased risk of harm).
- Take no action, document review, and put it on the IRB agenda for reporting purposes.

OR

➢ The event or problem is considered an unanticipated problem involving risks to participants or others because the problem (1) is unanticipated and (2) indicates that the participants are at increased risk of harm.

- The Research Compliance Officer, IRB chair, and/or IO may determine that immediate action is needed to ensure the participants' safety and request that the investigator suspend some or all of the research pending review of the event at the next convened IRB meeting. Suspensions will follow IRB procedures for suspension and termination.

<u>Actions that may be taken during or after the investigation of an adverse event or unanticipated problem include, but are not limited to:</u>

1. Modification of the research protocol
2. Modification of the information disclosed during the consent process
3. Additional information provided to past participants
4. Notification of current participants (required when such information may relate to participants' willingness to continue to take part in the research)
5. Requirement that current participants re-consent to participation
6. Modification of the continuing review schedule
7. Modification of the inclusion/exclusion criteria
8. Monitoring of the research
9. Implementation of additional procedures to monitor the participants
10. Monitoring of the consent
11. Suspension of the research
12. Termination of the research
13. Request for more information pending final decision
14. Refer to other organizational entities (e.g., legal counsel, institutional official), or

15. Other actions appropriate for the local study site

The determination will be reported in the minutes, and the investigator will be notified.

C. Notification

The investigator will be notified of the Research Compliance Officer, convened board, IRB chair's, and/or IO's determination and action(s). If the event is determined not to be an unanticipated problem involving risks to participants or others, no action will be required. If the event is determined to be an unanticipated problem involving risks to participants or others, the event will be reported to the appropriate individuals. A copy of this report will also be disseminated to the IRB members at the next convened IRB meeting.

Research sponsored by the Department of Energy (DOE)

Researchers must promptly (within 48 hours) report the following to DOE Human Subjects Protection Manager (HSP):

- Any significant adverse events, unanticipated risks, and complaints about the research, with a description of any corrective actions taken or to be taken
- Any suspension or termination of IRB approval of research
- Any significant non-compliance with HRPP procedures or other requirements
- Any compromise of personally identifiable information must be reported immediately (i.e., upon discovery).

OHRP Reporting Requirements

OHRP reporting requirements apply to nonexempt human subjects research that is conducted or supported by HHS or covered by a Federalwide Assurance (FWA), regardless of funding source. Incidents that are reportable include:

a. any unanticipated problems involving risks to participants or others;
b. any serious or continuing noncompliance with 45 CFR part 46;
c. any serious or continuing noncompliance with determinations of the IRB; and
d. any suspension or termination of IRB approval.

For studies that are HHS-supported and are also regulated by the FDA, additional reporting to the FDA may be required by FDA.

XXI. NON-COMPLIANCE AND PROTOCOL DEVIATIONS

A. Definitions

Noncompliance is defined as a failure (intentional or unintentional) to comply with applicable federal regulations, state or local laws, special conditions, or the requirements or determinations of the IRB, or university policy and procedures regarding research involving human participants. Noncompliance can also occur as a result of failing to act when required.

Serious Noncompliance which, in the judgment of the convened IRB, means a failure (intentional or unintentional) to follow state or federal regulations, or University policies and procedures, or determinations of the IRB for the protections of the rights and welfare of study participants and that, results in, or indicates a potential for (a) an increased risk to enrolled or potential participants or others, or (b) compromises the participants' rights or welfare, or (c) affects the integrity of the research/data or the human research protection program or the University.

- The IRB does not have to find that harm has occurred, or was likely to occur, to make a determination of serious noncompliance.
- Multiple instances of noncompliance that are deemed not serious individually may constitute serious noncompliance when considered collectively.
- The Board may consider mitigating factors, such as corrective action, that play a role in the determination of whether the event increased risk, decreased potential benefits, or negatively affected the integrity of the HRPP. However, if, despite these factors, the event's occurrence meets the definition of serious noncompliance, then the event should be categorized as such.

Examples provided by OHRP include, but are not limited to, non-exempt human subjects research conducted without IRB review and approval, or without appropriate informed consent, particularly if it is greater than minimal risk. Significant modifications to non-exempt IRB-approved research without IRB approval are considered serious.

Continuing Noncompliance: A pattern of non-compliance that indicates a lack of understanding or disregard for the regulations or institutional requirements that protect the rights and welfare of participants and others, compromises the scientific integrity of a study such that important conclusions can no longer be reached, suggests a likelihood that non-compliance will continue without intervention, or involves frequent instances of minor noncompliance. Continuing non-compliance may also include failure to respond to a request from the IRB to

resolve an episode of non-compliance or a pattern of minor non-compliance.

OHRP has advised that it considers noncompliance to be continuing if it persists after the investigator knew or should have known about it. In such cases, the UWF IRB holds a presumption of continuing noncompliance, placing the burden on the investigator to present compelling, mitigating circumstances. The period in which the continuing noncompliance occurred could be days or weeks (depending on the seriousness of the matter).

Protocol Deviation: Protocol deviation means an unapproved change, deviation, or departure from the study design or approved procedures and is under the investigator's control and has not been reviewed and approved by the IRB. Protocol deviations are divided into two categories: non-serious (minor) noncompliance or serious noncompliance. Noncompliance may also be continuing.

B. Reporting

The IRB will investigate and endeavor to resolve complaints and concerns from research participants and/or any individual lodging a complaint. All allegations, complaints, and concerns will be evaluated promptly, and any required investigation will occur in a timely manner.

Any UWF employee reporting a concern in good faith is protected against reprisals according to federal and state law (whistleblower protection). Deviations from an IRB-approved protocol as well as noncompliance with applicable University policies, regulatory requirements, and/or IRB determinations must be reported to the IRB. Such occurrences can have a negative impact on the research participants and the research study. Protocol deviations and noncompliances can alter the risk-benefit ratio for participants or otherwise jeopardize the safety, rights, and welfare of the participants. Nevertheless, there may be instances when it is necessary to deviate from an approved research plan to protect the research participants. These instances must either be made in consultation with the IRB Chair/Designee or Research Compliance Officer or reported to the IRB within 10 working days of initiation.

Reports made by the investigator: Protocol deviations and noncompliance should be reported to the IRB as soon as possible. An initial report should be made to the IRB office and/or IRB Chair within 1 week (7 calendar days) of when the investigator became aware of the event. A formal report should be submitted by the investigator within 2 weeks (14 calendar days) of when the investigator became aware of the event through IRBNet.

In some instances, reporting requirements may be met by submitting an initial report to the IRB and/or IRB Chair with a follow-up report submitted at a later date when more information is available. These determinations will be made on a case-by-case basis with the IRB Chair, Research Compliance Officer, and/or

other officials as appropriate. The primary consideration in making these judgements will be the need to take timely action to prevent any harm to the participants and others.

Reports made by other parties (Ex, research staff, research participants, general public, IRB members, and staff): The reporting party should use their judgment when determining if an event is reportable. If an individual is unsure of whether they should report an event, they may call the IRB office or the Research Compliance Officer to discuss the situation informally. Alternatively, individuals always have the option of making reports through the UWF anonymous hotline at (844) 858-1413 toll-free. Reports of possible protocol deviations or noncompliance should include a complete description as possible of the event and include sufficient detail to allow the IRB to make an assessment. If UWF is not the IRB of Record, reports must be submitted to the Reviewing IRB. The IRB of Record (or Reviewing IRB) will notify the UWF IRB when a determination of an anticipated problem, serious, and/or continuing noncompliance is made.

C. IRB Review and Actions:

The IRB will fully investigate and review reports of allegations, complaints, or concerns to determine if there were any possible protocol deviations and/or noncompliance. The IRB Chair reviews the potential noncompliance and may make a decision on the action to be taken, may convene an ad hoc committee to conduct an investigation, and/or ask the convened IRB to make a decision based upon the facts gathered. Incidents of potentially serious and/or continuing noncompliance will generally be referred to the convened IRB for deliberation and a final decision on the process and/or outcome. The ad hoc IRB committee (if appointed by the Chair) is responsible for reviewing the possible noncompliance and information gathered, conducting interviews as needed, reviewing pertinent data or findings of the investigation, deliberating, and making recommendations to the convened IRB as to a course of action. The convened IRB is responsible for reviewing information gathered about the possible noncompliance, reviewing pertinent data or findings of the investigation, deliberating, and determining a course of action for implementation by the investigator. The convened IRB may also make recommendations to the IO on a course of action following review of the noncompliance.

The IRB will determine if the reported information was (1) noncompliance, (2) an unanticipated problem involving risks to participants or others, (3) a non-serious (minor) noncompliance, (4) serious noncompliance, and/or (5) a continuing noncompliance.

1. If the IRB finds that no noncompliance occurred because: (1) the reported noncompliance was unsubstantiated, (2) the investigator deviated from the protocol in order to eliminate immediate and apparent risks of harm or hazards to the participants, or (3) the continued participation of enrolled participants in research for which approval has expired was necessary to

protect the best interest of the currently enrolled participants, actions by the IRB may include, but are not limited to:

- Requiring no further action.
- Requiring the submission of an amendment to the protocol or consent form(s).
- Requiring submission of a continuing review application.

2. If a non-serious (minor) noncompliance is found to have occurred, actions by the IRB Chair/Designee may include, but are not limited to:
   - Requiring no further action.
   - Requiring remedial training (e.g., online educational program, attendance at a workshop or seminar, one-on-one training).
   - Requiring re-consent of the participants.
   - Requiring the submission of an amendment to the protocol or consent form(s).

   Whenever appropriate, investigators will be assisted so they can achieve compliance without the need for sanctions. However, if the investigator fails to cooperate with the IRB's requests to correct a non-serious (minor) noncompliance, this inaction may be considered a continuing noncompliance.

3. If serious and/or continuing noncompliance is found to have occurred, actions by the IRB may include, but are not limited to:
   - Establishing a corrective action plan.
   - Requiring the investigator and/or research team to participate in and complete further training.
   - Requiring more frequent review of the project.
   - Limiting the investigator's human subject research privileges on the study.
   - Writing letters of censure.
   - Making recommendations of the Institutional Official (IO) for further sanctions, stipulations, or restrictions to the investigator's privilege to conduct human subjects research.
   - Sharing information of noncompliance with the faculty's supervisor, administration, and other institutional units (e.g., Conflict of Interest Committee, Research Integrity, Research Administration & Engagement, etc.) as deemed necessary.
   - Protocol suspension.

The IRB and, when appropriate, the institution will act promptly to ensure remedial action regarding any breach of regulatory or institutional human subject protection requirements. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies, procedures, with federal regulations, or deviates from the approved research.

All serious and/or continuing noncompliance must be reported promptly by the IRB to the AVP of Research (IO) and, for federally funded research, the appropriate department/university leadership (e.g., Research Administration & Engagement), agency head, and sponsor, where applicable. Reports will only be made to OHRP for research that is regulated by these oversight agencies per UWF's Federal-Wide Assurance (FWA).

XXII. EXTERNAL INVESTIGATORS

1. Requests from external researchers will be submitted to the IRB by submitting a project via IRBNet with their approved IRB application and approval letter from their institution

2. External researchers must designate a UWF liaison for their research project. The UWF liaison must be added to their application under "Additional Personnel" and sign the IRBNet package. If needed, the UWF Liaison will request Broadcast Distribution Standards Approval. Written approval will be included in the IRBNet package.

3. The IRB chairperson will review the request for the worthiness of the study and design, and the full board of the IRB will review the request for human participant protection compliance.

   If the request is determined by the full-board of the IRB to comply with 45 CFR Part 46, Protection of Human Research Participants and the UWF IRB for Human Research Participants Protection Procedure Manual, the researcher will be asked to provide an abstract of the research project and an e-mail or web link including the informed consent for UWF participants to use should they choose to participate in the research. A UWF full-time faculty or staff member from the selected department(s) will be responsible for sending emails to potential research participants with a link to the informed consent and survey questions. UWF will not divulge the names or other identifying information of UWF participants to the external researcher.

4. An external investigator's request to recruit UWF faculty, staff, or students cannot be approved if the project includes an informed consent waiver.

5. At any time, UWF Department Chairs and the Institutional Official have the right to refuse access to UWF students for the purposes of outside research.

XXIII. IRB RELIANCE REQUIREMENTS

Both OHRP and the FDA permit an IRB the option to rely on the review of another IRB. When this is the intention, the two institutions enter into an agreement referred to as an IRB Authorization Agreement or Individual Investigator Agreement. These agreements are executed between a Reviewing

IRB and one or more Relying Institutions and delineate the roles and responsibilities of the involved parties.

All federally funded cooperative human research projects receiving initial IRB approval on or after January 20, 2020, will be required to utilize Single IRB Review. That is, studies that involve more than one institution conducting research with human participants.

A. Requests for UWF to be the IRB of Record

When completing the IRB Application Wizard in IRBNet, you will be prompted to list external additional personnel who will be "engaged" in conducting human subject research on your research project.

- The Office for Human Research Protections states that an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the participants of the research through intervention or interaction with them; (2) identifiable private information about the participants of the research; or (3) the informed consent of human participants for the research.

For those external individuals who come from an institution with a Federalwide Assurance (FWA), their institution's IRB office will need to contact the UWF IRB Office to initiate a reliance agreement in order to rely upon the UWF IRB approval for non-exempt studies.

For those external individuals who do not come from an institution with an FWA, you will be prompted to attach an Individual Investigator Agreement for each individual.

B. Requests for UWF IRB to Rely Upon an External IRB

Generally, the following studies are eligible for ceding to an external IRB with a current FWA:

- Studies for which the use of a single IRB is a requirement of the sponsor or funding agency for participation in the study
- Domestic Multisite or collaborative, non-exempt research studies.

In order to request reliance on an external IRB, the UWF investigator must submit a project in IRBNet that includes the approved materials from the external IRB with a current FWA, including the IRB approval letter. The UWF IRB initial submission in IRBNet should mirror the IRB of Record approval. For full board projects that are requesting reliance on an external IRB, the request will be sent to the IRB chair for review.

The UWF IRB reserves the right to require changes to local documents, including the consent, recruitment materials, and other materials. The UWF IRB will work with the local investigators to make such changes, and then the local investigator

will need to seek IRB of Record approval of those changes.

All local investigators engaged in the research must be listed on the IRB application and complete the UWF required IRB training. The UWF IRB office will ensure all institutional requirements and state laws are met before placing a study open to enrollment when applicable.

When the IRB of Record will not review HIPAA waiver/alteration requests, or when the UWF IRB determines local review is necessary, the UWF IRB will review local HIPAA alteration and waiver requests. A local HIPAA waiver must be requested and approved to use this method, regardless of whether the IRB of Record approved a HIPAA waiver for screening, since local requirements must be followed.

Once the request is approved by the board, the PI will provide contact information for the external board and request that a reliance agreement be sent to irb@uwf.edu.

Post Approval:
The investigator must report the following documentation post-initial IRB approval:

1. The following changes approved by the central/single IRB must be submitted within 30 days of the approval date:
    - Local informed consent documents, including assent forms.
    - Protocol
    - Local recruitment materials
    - Local context changes requiring institutional reviews

2. Adverse Event/ Unanticipated Problem Report: Submit if required to be submitted to the central/single IRB. In addition, even if not required to be submitted to the central/single IRB, all local noncompliance and unanticipated problems must be submitted on an Adverse Event/Unanticipated Problem Report for local review within 5 business days as per Section XX of this manual.

3. IRB of Record Continuing Review: Prior to project expiration, submit the central/single IRB continuing review approval letter through a continuing review package. If a project is closing, an option is to instead submit the Completion/Withdrawal Report with the central/single IRB closure letter.

    - If the central/single IRB continuing review approval is not provided prior to the expiration date, the local study project status will be updated to “expired,” although the single/central IRB may still show active, and no local human subject research activities can occur until the approval has been provided.

4. Personnel Change Form: Submit all local personnel changes on the Amendment Form prior to an investigator participating in the study.

5. UWF IRB may place a study on hold in a closed-temporary status for delayed reporting until the issue can be resolved. Additional action may be taken, such as terminating the reliance agreement, if issues cannot be resolved.

6. UWF IRB, or designee, may conduct a site initiation visit prior to participant enrollment to ensure all processes are in place to successfully carry out the study. Notification in writing will be sent to the investigator if this is required. UWF IRB may also conduct post-approval monitoring when necessary.

7. Additional responsibilities are outlined in the study-specific Authorization Agreement.

XXIV. IRB REVIEW FEE SCHEDULE

The University of West Florida Institutional Review Board (UWF IRB) will assess review fees for commercial/for-profit funded research projects involving human participants. A project undergoing Full Board Review will be assessed a fee of $2,000, while a project undergoing Expedited review will be assessed a fee of $1,000.

Continuation review requests will be charged $1,000, and project amendments will be charged $500. This practice is consistent with the policies and fees incurred at peer institutions and will be used to support the administrative costs associated with reviewing human subject research projects.

Commercial/for-profit applications represent some of the most complex and resource-demanding research reviewed by the UWF IRB. The collected IRB fees will be used to continue staffing improvements, quality assurance efforts, and continuing education for staff and IRB Members.

- IRB Applications for research studies that are funded by non-business/non-industry sponsors (e.g., Federal, State, non-profit foundations, or internal funds) are not subject to the IRB Fee.
- When an IRB Application is received and is not designated as commercial/for-profit funded, but is later determined by the IRB to be commercial/for-profit funded, appropriate IRB Fees will be assessed.
- It is expected that Investigators or their staff incorporate applicable IRB Fees into the research proposal.

Frequently Asked Questions

Q. **Why are only commercial and for-profit funded projects being charged a fee?**

A. The costs incurred for reviewing IRB applications for non-commercially supported studies are included in the Facilities and Administrative (F&A)

rate, which is applied to those research projects. Commercial and for-profit funded projects reimburse the University for indirect costs at a rate that is lower than the federally negotiated rate. These projects are some of the more complex applications received and tend to be very demanding of IRB resources. The goal is to enhance the recovery for work expended on these studies and maintain a level of service that is acceptable to the research community.

Q. **How was the amount of the fee determined?**

A. The fee was determined by assessing the administrative costs of managing study review processes in RAE. The fee is consistent with the policies and fees at other peer research institutions.

Q. **Will potential contracts be affected by this new fee?**

A. An IRB Review Fee is standard practice for the University of West Florida's peer institutions, and business and industry sponsors are accustomed to paying a fee for review services. Research areas affected by this change should not see a difference in the attractiveness of the University of West Florida as a study site.

Q. **Why do some schools have such a fee and not others?**

A. Most of the University of West Florida's peers have seen an increase in commercial and for-profit funded research, and have started assessing a similar fee to cover the increasing costs of providing this service. The new fee helps the institution bridge that gap in funding to keep pace with the studies received.

Q. **What is to prevent the University from requiring researchers to pay this fee for reviewing IRB Applications for research that is supported by non-sponsored funding?**

A. The review of these projects is already supported by institutional funds. This fee will not be assessed on research that is funded from non-sponsored sources.

Q. **Is it ethical for an IRB to charge a potential sponsor a fee for the review of a proposal?**

A. The fee covers the cost of providing a specific service to the sponsor. IRB members do not consider any potential financial benefit of the study to the University when reviewing the application. Payment of the fee does not guarantee approval of the study protocol. The fee covers the cost of the service, which is why the fee must be paid even if the industry funding does not ultimately materialize.

Q. **For some commercial/for-profit funded projects, the IRB application is submitted before an agreement is reached on the final budget. Must the**

fee be paid at the time of IRB submission?

A. No, however, after the protocol is reviewed, the IRB will begin tracking the study to see when the industry-funded contract arrives. This is done by working closely with the Office of Research Administration & Engagement.

Q. **Will the IRB approval process be held up if the IRB Fee is not paid?**

A. Yes, the review process will remain on hold until the IRB Fee is paid in full. Exceptions include the situations in the above Q&A.

XXV. CLINICAL TRIALS BILLING

This procedure establishes uniform requirements for billing clinical services for participants who participate in research studies that may potentially generate claims to participants or third-party payers for any items or services designated as part of a research protocol. It seeks to ensure that UWF adheres to laws, regulations, and requirements governing research billing practice.

It is the policy of UWF that faculty investigators, academic departments, administrative units, healthcare entities, and associated staff members coordinate their activities to ensure that clinical services associated with research studies are billed appropriately and in compliance with relevant laws, regulations, and contractual obligations. UWF has developed processes to communicate information and train the relevant workforce on proper clinical research billing activities and to monitor and reconcile financial information. Individuals involved in the conduct of clinical research, registration of participants, ordering of research items and services, coding research services, and billing for research items and services will comply with this procedure and the roles, responsibilities, and procedures described herein. Corrective and disciplinary action may be taken for violations of this procedure, including, but not limited to, suspension of study activities.

Roles/Responsibilities

Principal Investigator (PI) and Research Staff

The PI (including research staff designated by the PI) is responsible for project budget development for each study and assuring that steps for accurate billing are taken in the manner described by this policy. The PI is responsible for the following specific steps:

1. Providing to the Office of Research Administration and Engagement (RAE) the study protocol (including amendments for addition or deletion of clinical items/services), proposed clinical trial agreement (CTA) (if any), proposed informed consent document (IC) (including amendments related to adding or deleting clinical items/services), schedule of events (i.e. clinical interventions/interactions and research activities designated by the protocol) with each event assigned to a standard treatment or research category to obtain a prospective coverage analysis of billable clinical

services, and a copy of the budget request page included in the application, if applicable;

2. Reviewing and accepting the billing matrix generated by RAE for the project, if applicable;
3. Communicating study and participant visit information to RAE and
4. Verifying claims for accuracy and processing payments.

The principal investigator and his/her designees are responsible for:

1. Accurately billing medical, technical, and professional research charges to the grant, the third-party payer, or the research participant;
2. Informing the research participant of the charges and how they will be allocated as part of the informed consent process;
3. Completing the required documentation to support charges for each research participant.

XXVI. VENIPUNCTURE/PHLEBOTOMY/BLOOD DRAW

This procedure provides standards for safely conducting blood draws and requirements for obtaining human blood and human blood products for human participant research purposes. This procedure applies to all University of West Florida employees, students, and participants in research projects that involve obtaining human blood and human blood products.

UWF requires that non-medically certified/licensed individuals must be trained and have their competency evaluated by an appropriate instructor (e.g., experienced faculty member, registered nurse) prior to performing blood draws. A UWF Venipuncture/Phlebotomy/Blood Draw Request Form, found within IRBNet, will be provided to a qualified faculty member for the determination of competency. Completion of this form by all persons who will perform blood draws in connection with a human participant research project is required prior to IRB consideration of the project.

APPENDIX I: STANDARD OPERATING PROCEDURES FOR HIPAA COMPLIANCE

1. GENERAL PROCEDURES AND DEFINITIONS

PURPOSE

To ensure that UWF researchers comply with the HIPAA laws regarding Protected

Health Information (PHI) obtained during research.

SCOPE

These procedures apply to all UWF researchers who obtain PHI for research purposes from covered entities.

RESPONSIBILITIES

UWF Researchers must ensure the safety and security of any PHI obtained or transmitted in furtherance of any research project. All requests for data that contains or potentially contains PHI must gain UWF approval prior to data acquisition.

DEFINITIONS

- **Covered Entity**: The Privacy Rule, as well as all the Administrative Simplification rules, apply to health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under HIPAA (the "covered entities"). For help in determining whether you are covered, use CMS's decision tool.

- **De-Identified (HIPAA Specific Definition):** All 18 identifiers from the defined HIPAA list (see below) have been removed, or the data has been certified as de-identified under the Expert Determination Method. The dataset is no longer considered to contain PHI.

- **Protected Health Information (PHI):** Any information in the medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment. HIPAA applies only to research that uses, creates, or discloses PHI that enters the medical record or is used for healthcare services, such as treatment, payment, or operations.

PROCEDURES

The Health Insurance Portability and Accountability Act ("HIPAA") and the Health Information Technology for Economic and Clinical Health ("HITECH Act"), collectively, the "Acts," create an obligation for Covered Entities (as defined by the Acts) to protect certain personal information of patients or customers ("Personal Health Information" or "PHI"). Covered entities include health care clearinghouses, health insurers, employer-sponsored health plans, and medical providers. 18 identifiers are defined in HIPAA as Protected Health Information. They are as follows:

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city,

county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;

3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including fingerprints and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

Federal statutes require, without exception, that the confidentiality of the protected health information be maintained throughout the research and thereafter. In proposing a research study, the Principal Investigator shall consider the nature, probability, and magnitude of harms that would be likely to result from a disclosure of collected information outside the research. The PI shall also evaluate the effectiveness of the proposed anonymizing techniques, coding systems, encryption methods, storage facilities, access limitations, and other relevant factors in determining the adequacy of confidentiality protections. The IRB requires that the IRB Proposal and consent documentation (if applicable, according to submission category) describe the extent to which confidentiality of records identifying the participant(s) will be maintained (or not maintained).

A UWF Researcher should review the “Evaluating a Research Study for HIPAA Compliance” Procedure below in order to determine whether PHI is required to perform his or her research. UWF encourages UWF Researchers to use de-identified data or limited data sets (as defined by the Acts and related regulations) in order to complete any research studies in order to eliminate or reduce the amount of PHI obtained by the UWF Researcher. Procedures for the use and

disclosure of de-identified data are contained in Section 7 of this Appendix I, and procedures for the use of Limited Data Sets are contained in Section VIII.

If it is determined that a researcher must use PHI, the following procedures must be followed:

1. A UWF Researcher seeking to use PHI for a research project must complete the HIPAA Training in addition to the standard CITI IRB Human Subject Training.

2. The UWF Researcher must contact the ITS Department to obtain a list of appropriate methods of storing and transferring PHI. The UWF Researcher will be required to include in any IRB submission a description of how the PHI will be stored and/or transferred, and that the method has been approved by the UWF ITS Department.

3. The UWF Researcher must obtain the necessary Authorizations, as applicable, outlined in the following sections:

    a. Use and Disclosure of PHI for Reviews Preparatory to Research
    b. Obtaining a waiver, partial waiver, or alteration of authorization
    c. Obtaining authorization to use PHI
    d. Use and Disclosure of Decedent PHI for Research Purposes

4. Submit the above documentation (CITI HIPAA training certificate, ITS approval, PHI Authorizations) to the UWF IRB for approval.

If there is a breach with regard to the handling or release of PHI, the UWF Researcher or any person who becomes aware of the mishandling or release of PHI in connection with a research study shall make a report via the UWF Integrity Hotline or directly to the Office of Research Administration & Engagement or the UWF Office of General Counsel as soon as possible.

2. EVALUATING A RESEARCH STUDY FOR HIPAA COMPLIANCE

PURPOSE

To provide guidance to UWF Researchers on evaluating the HIPAA implications of a proposed use/disclosure of health information for Research.

SCOPE

This procedure applies to UWF researchers who seek to comply with the requirements of HIPAA when using and disclosing Protected Health Information for research.

RESPONSIBILITIES

UWF researchers who intend to use health information in their research studies should apply the criteria outlined herein to evaluate whether the health information is Protected Health Information (“PHI”) and if so, which process for HIPAA compliance

(e.g., Authorization, Waiver, Partial Waiver, Review Preparatory to Research, etc.) will best serve the needs of the UWF Researcher while ensuring that the UWF Researcher's obligations under HIPAA are met.

PROCEDURES

The UWF Researcher should determine whether the health information to be used in a proposed research study is PHI.

1. Does the proposed research study use or reference Individually Identifiable Health Information about human participants (living or deceased) or health information that can be linked in any manner to the identity of the participant? (For guidance, please consult the General Procedures and Definitions Procedure).

    a. If yes, proceed to Question 2.

    b. If no, then the use is not subject to the Standard Operating Procedures Governing HIPAA Compliance.

2. Is the Individually Identifiable Health Information created, or maintained by, or received from a hospital or health care provider that engages in electronic billing transactions (physician; community clinic; social services agency; practitioner in psychology, psychotherapy, or social work), health insurer, Health Maintenance Organization (HMO), health plan, and/or health care clearinghouse?

    a. If yes, proceed to Question 3.

    b. If no, then the use is not subject to the Standard Operating Procedures governing HIPAA compliance.

3. The Individually Identifiable Health Information used in the study is PHI. As a recipient of PHI, a UWF Researcher may have certain responsibilities under HIPAA that are not governed by these Standard Operating Procedures. In order to ensure compliance with HIPAA, UWF researchers need to contact the privacy or compliance officer for the entity disclosing the information to determine whether that entity has any procedures or requirements for recipients of PHI. Failure to comply with the HIPAA procedures or requirements of the disclosing entity can result in the termination of your relationship with that entity as a recipient of their PHI.

Exceptions

The UWF Researcher should determine what, if any, exceptions apply to the fundamental requirement under HIPAA that participants' authorization must be obtained prior to use of their PHI for research purposes.

1. Can the research be conducted with de-identified data? For more information about de-identifying data sets, see "Guidance Regarding Methods for De-Identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule" at

https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/

- If yes, refer to Section 7 of this Appendix titled “Use and Disclosure of De-Identified Data for Research Purposes”.
- If not, can the research be conducted with the only identifying information linking the participant’s identity to the health information being one or all of the following: admission and discharge dates; birth dates; county, city, or state of residency; or zip codes? If yes, the PHI would constitute a Limited Data Set. Please consult Section 8 of this Appendix entitled “Limited Data Sets”.

2. Is the proposed use of PHI necessary for the purpose of preparing a research protocol or for a similar purpose associated with preparatory activities for research (e.g., reviewing the clinical and demographic information of a population to determine if it supports the development of a research question)?
   - If yes, refer to Section 3 of this Appendix titled “Use and Disclosure of PHI for Reviews Preparatory to Research”.
3. Is the review or use of the PHI primarily to recruit research participants from a population that does not consist of the UWF researcher’s own patients?
   - If yes, refer to Section 3.A. of this Appendix titled “Reviewing PHI for Recruitment purposes”.
4. Does the research involve PHI related only to deceased subjects where the focus of the research does not involve any living relative of the decedent?
   - If yes, refer to Section 6 of this Appendix titled “Use and Disclosure of Decedents’ PHI for Research Purposes”.
5. Is the use of the PHI necessary to the research study, yet will it be difficult or impossible to obtain the participants’ Authorizations?
   - If yes, will the use or disclosure of the participant’s PHI involve greater than minimal risk to the privacy of the subject? [NOTE: The research study must also be a minimal risk study where the IRB has agreed to waive the requirement of informed consent.]
     i. If yes, refer to Section 5 of this Appendix titled “Obtaining Authorizations to Use PHI”.
     ii. If no, you must apply to the UWF IRB to obtain a Waiver/Partial Waiver/Alteration of Authorization. UWF researchers who have questions regarding the process of evaluating a research study for HIPAA compliance should contact the UWF Office of Research Administration & Engagement.

3. USE AND DISCLOSURE OF PHI — PREPARATORY TO RESEARCH

PURPOSE

To define the procedures necessary to access Protected Health Information (PHI) for reviews preparatory to research. This request is made to obtain PHI solely as *preparation for research* (e.g., design a research study, or to prepare a grant application).

SCOPE

This procedure applies to all UWF researchers who desire access to PHI for reviews preparatory to research at the University of West Florida who use PHI for reviews preparatory to research.

RESPONSIBILITIES

All UWF researchers are responsible for following the procedures stated in this procedure manual. Before seeking access to PHI, UWF researchers must take reasonable steps to ensure that the procedures stated herein have been followed. The UWF IRB will evaluate and approve all requests for the use and disclosure of PHI for purposes “Preparatory to Research”

PROCEDURE

The UWF Researcher who needs to access PHI for purposes of preparatory research must complete and submit a Preparatory to Research Report request via the Office of Research Administration and Engagement. For more information on determining whether a proposed use of PHI qualifies as a “review preparatory to research,” refer to Appendix I, Section 2: Evaluating a Research Study for HIPAA Compliance. The Health Information Systems Preparatory to Research report request must include all of the following statements/information:

1. That you are preparing/considering a research protocol;
2. That in order to prepare or determine the feasibility of the research protocol, you require access to certain PHI;
3. That the particular PHI is necessary to prepare for the particular research;
4. That the extent of PHI sought is limited to only that which is essential to conduct the activity related to the preparation of the proposed protocol;
5. A complete list of the names of the individual(s) within the research team who will be reviewing the information being sought;
6. That at no time during the review will the information be removed from the provider’s premises;
7. That neither you nor your staff will contact patients about the proposed study or conduct any research until you submit and receive the approval for the human subject protocol from the UWF IRB or an IRB with which UWF has a reliance agreement;
8. That the review of PHI will commence on the date of approval of the Preparatory

to Research request and will expire on the date specified in the request. After the expiration date, you will no longer access the PHI for research preparation and will retain the PHI in accordance with the policies on human subject research, only if needed as part of a UWF IRB-approved research protocol. If no longer needed, you will destroy the PHI to ensure individual privacy and confidentiality rights.

The IRB verifies that the completed Preparatory to Research request is in compliance with this procedure manual. If changes are required, the IRB corresponds with the UWF Researcher. If no changes are required, the IRB approves the request.

A copy of the approved Preparatory to Research request must be maintained with the UWF Researcher's study documentation in the event a decision has been/is made to conduct the research study.

Upon notification of approval of a Preparatory to Research request, the UWF Researcher may have access to the identified PHI. The PHI may not be removed from the premises of the provider granting access.

A. Reviewing PHI for Recruitment Purposes

UWF researchers are not permitted to use PHI obtained pursuant to this procedure for the recruitment of study participants. UWF researchers must obtain a partial Waiver of Authorization from the UWF IRB pursuant to the procedures set forth in Appendix I, Section IV: Obtaining Waiver/Partial Waiver/Alteration of Authorization or supply the provider(s) with the appropriate informed consent(s) approved by the IRB to obtain the PHI.

The UWF Researcher must also consult that particular provider and follow the procedures that are in place for that provider.

Review of Psychotherapy Notes must have a participant's Authorization and may not be exempted from such pursuant to this Standard Operating Procedure.

4. OBTAINING A WAIVER, PARTIAL WAIVER, OR ALTERATION OF AUTHORIZATION

PURPOSE

To define the procedures necessary to obtain a waiver, partial waiver or alteration of individual research Authorizations to use or disclose Protected Health Information (PHI) in the research context.

SCOPE

This procedure applies to:

1. UWF researchers:
    - who intend to seek a waiver or partial waiver of the requirement to obtain

individual Authorization for the use of PHI in research activity, or
- who have the need to seek an alteration of the Authorization granted by the individual who is the subject of such PHI.

RESPONSIBILITIES

Prior to using PHI in the research context, UWF researchers must ensure that, in the absence of individual Authorization, the UWF IRB has approved a waiver or alteration of Authorization.

PROCEDURES

For qualifying research studies, UWF researchers may submit an application for waiver or alteration of the Authorization requirement to the UWF IRB. For more information on determining whether a research study qualifies for a waiver or partial waiver of the Authorization requirement, refer to Section 2 of this Appendix: Evaluating a Research Study for HIPAA Compliance.

The IRB is established to review and act upon waivers, partial waivers, and alterations of participant Authorizations upon reviewing the effect of a research protocol on the privacy rights and related interests of individual research participants.

IRB reviews and approves the requests for HIPAA Waivers, Partial HIPAA Waivers, and Alterations of Authorizations for those studies that are classified as Exempt and Expedited.

UWF researchers must obtain documentation that a Waiver, Partial Waiver, or Alteration of Authorization for release of PHI has been approved by the UWF IRB. This documentation must include all the elements stated herein.

The documentation required of the UWF IRB when granting approval of a Waiver, Partial Waiver, or Alteration of Authorization for the use/disclosure of PHI includes:

1. A statement identifying the UWF IRB that approved the action, and the date of such approval;

2. A statement that the UWF IRB has determined that the Waiver, Partial Waiver, or Alteration of Authorization satisfies all of the following criteria:

    a. The use or disclosure of an individual's PHI involves no more than minimal risk to the privacy of individuals, based on at least the following elements:

        - An adequate plan to protect an individual's identifying information from improper use or disclosure;
        - An adequate plan to destroy an individual's identifying information at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
        - Adequate written assurance that the particular PHI will not be reused or disclosed to (or shared with) any other person or entity, except as

required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the particular PHI would be specifically permitted under the Privacy Rule.

b. The research could not practicably be conducted without the Waiver or Alteration, and

c. The research could not practicably be conducted without access to and use of the PHI.

3. A brief description of PHI for which use or disclosure has been determined to be necessary by the UWF IRB.

Once the Waiver/Alteration application has been granted by the UWF IRB, the UWF Researcher will be notified.

If the UWF IRB needs additional information prior to granting the Waiver/Alteration, the UWF Researcher will be contacted by a representative of the UWF IRB and action on the application may be deferred or made conditional upon the receipt of the requested information.

Research involving the use or disclosure of Psychotherapy Notes must have a participant Authorization and does not qualify for a Waiver under this Standard Operating Procedure.

5. OBTAINING AUTHORIZATION TO USE PHI

PURPOSE

To define procedures necessary to obtain Authorizations to use and disclose Protected Health Information (PHI) in the research context.

SCOPE

This procedure applies to all UWF researchers who generate, collect, use or disclose PHI in Research conducted at the University of West Florida (UWF), or investigators utilizing the UWF Institutional Review Board (IRB) as their IRB of record, and who are required to seek participant Authorization.

RESPONSIBILITIES

It is the UWF Researcher's responsibility to obtain Authorization from human participants enrolled in research studies prior to using or disclosing their PHI in research.

PROCEDURES

The UWF Researcher must obtain written Authorizations from human participants enrolled in research studies that comply with HIPAA Privacy Rule Regulations. For additional information regarding HIPAA authorizations, please see HIPAA Authorization for Research.

The UWF IRB requires the HIPAA Authorization language to be compounded with the Informed Consent. The Authorization must include:

1. A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion;
2. The name of the Covered Entity, or class of entities or persons, authorized to make the requested use or disclosure;
3. The name of other specific identification of the person(s) or class of persons to whom the Covered Entity may make the requested use or disclosure;
4. Description of each purpose of the requested use or disclosure (e.g., a brief description of the clinical research study).
5. An expiration date. However, in Authorizations granted for research purposes, statements such as “end of the research study,” “none,” or similar language are sufficient;
6. Signature of the individual or the individual’s Legally Authorized Representative with a description of the Representative’s authority to act on behalf of the individual;
7. Date of granting the Authorization;
8. A statement in which the individual acknowledges the right to revoke the Authorization in writing, an explanation of the exceptions to the right to revoke, and a description of how the individual may revoke the Authorization;
9. A statement in which the individual acknowledges that information used or disclosed to any entity other than a health plan or health care provider may no longer be protected by the Privacy Regulations; and
10. Unless the Authorization is requested for clinical research that includes the delivery of health care, a statement that the Covered Entity will not condition treatment or payment on the individual’s provision of Authorization for the requested use or disclosure.

In the event a need arises to amend HIPAA authorizations already obtained, the UWF Researcher must submit an amendment with the proposed amended Authorization to the UWF IRB.

Revocation. A participant may revoke their authorization, in writing, at any time to a person on the research team. Covered entities may continue to use and disclose protected health information that was obtained prior to the time the individual revoked his or her authorization, as necessary to maintain the integrity of the research study. An individual may not revoke an authorization to the extent the covered entity has acted in reliance on the authorization. For research uses and disclosures, this reliance exception at 45 CFR 164.508(b)(5)(i) permits the continued use and disclosure of protected health information already obtained pursuant to a valid authorization to the extent necessary to preserve the integrity of the research

study. For example, the reliance exception would permit the continued use and disclosure of protected health information to account for a participant's withdrawal from the research study, as necessary to incorporate the information as part of a marketing application submitted to the Food and Drug Administration, to conduct investigations of scientific misconduct, or to report adverse events.

However, the reliance exception would not permit a covered entity to continue disclosing additional protected health information to a researcher or to use for its own research purposes information not already gathered at the time an individual withdraws his or her authorization.

6. USE AND DISCLOSURE OF DECEDENTS' PHI FOR RESEARCH PURPOSES

PURPOSE

To define procedures necessary for use or disclosure of decedents' Protected Health Information (PHI) for Research.

SCOPE

This procedure applies to all UWF researchers who use decedents' PHI for Research purposes.

RESPONSIBILITIES

All UWF researchers must follow the procedures stated herein as well as the HIPAA Privacy Rule. The UWF IRB will review and approve all requests for use and disclosure of decedents' PHI.

PROCEDURES

The UWF Researcher must submit to the IRB an attestation form prior to use and disclosure of decedents' PHI.

The written representations in the attestation must include the statements:

- That use or disclosure is sought solely for research on the PHI of decedents;
- That the subject of the PHI is actually deceased (must be willing to submit documentation to establish this fact);
- Representation that the PHI for which use or disclosure is sought is necessary for the research purposes.

The IRB will verify that the UWF Researcher's written representations are in compliance with this Standard Operating Procedure.

Notwithstanding any other provision in this Standard Operating Procedure, Psychotherapy Notes for decedents may not be used or disclosed without an Authorization signed by the decedent subject's Legally Authorized Representative

and must include a description of such individual's authority to act for the decedent.

7. USE AND DISCLOSURE OF DE-IDENTIFIED DATA FOR RESEARCH PURPOSES

PURPOSE

To define the procedures necessary to use and disclose de-identified data for research.

SCOPE

This procedure applies to all UWF researchers who use de-identified data in research.

RESPONSIBILITIES

Prior to giving UWF researchers or other entities access to health information categorized as de-identified data, providers must ensure that the procedures for the de-identification of Individually Identifiable Health Information pursuant to the Acts have been followed. The de-identification of data will require review and approval by the UWF IRB if the data is de-identified by an entity or person not directly affiliated with the covered entity data source.

PROCEDURES

Healthcare providers/Covered Entities who have access to Individually Identifiable Health Information for the purpose of treatment, payment or health care operations may de-identify Individually Identifiable Health Information in order to use and share information for Research or other appropriate functions at UWF in accordance with this procedure manual.

A Provider must provide a certification that patient health information is de-identified and cannot be used to identify an individual, and that either (1) or (2) below has occurred:

1. A statistician or other person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
    a. Has applied such principles and methods, and determined that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by a recipient of the information to identify the person whose information is being used; and
    b. Has documented the methods and results of the analysis that justify such a determination.

The Healthcare provider/Covered Entity is required to keep such documentation, in hardcopy or electronic format, for at least six (6) years from the date of the creation

of the de-identified data.

OR

2. The Provider has determined that:

    a. The following identifiers of the individual and the individual's relatives, employers, and household members are removed:

        i. Names;

        ii. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geo codes. However, the initial three digits of a zip code may remain on the information if, according to current publicly-available data from the Bureau of the Census, the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20, 000 people, and the initial three digits for all such geographic units containing 20,000 or fewer people is changed to 000;

        iii. All elements of dates (except year) for dates directly related to an individual, including birth date, dates of admission and discharge from a medical facility, and date of death; for persons age 89 and older, all elements of dates (including year) that would indicate such age must be removed, except that such ages and elements may be aggregated into a single category of "age 90 or older";

        iv. Telephone numbers;

        v. Fax numbers;

        vi. Electronic mail addresses;

        vii. Social security numbers;

        viii. Medical record numbers;

        ix. Health plan beneficiary numbers;

        x. Account numbers;

        xi. Certificate or license numbers;

        xii. Vehicle identifiers and serial numbers, including license plate numbers;

        xiii. Device identifiers and serial numbers;

        xiv. Web Universal Resource Locators (URLs);

        xv. Internet Protocol (IP) address numbers;

xvi. Biometric identifiers, including fingerprints and voiceprints;

xvii. Full face photographic images and any comparable images; and

xviii. Any other unique identifying number, characteristic, or code, except as permitted in this Standard Operating Procedure; and

b. The Provider has no actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information.

Re-identification of de-identified information:

The Provider may assign a code or other means of record identification to allow information de-identified under this policy to be re-identified by the Provider, provided that:

1. The code or other means of record identification is not derived from or related to information about the individual and cannot otherwise be translated to identify the individual; and
2. The code or other means of record identification is not disclosed for any other purpose; and
3. The mechanism for re-identification is not disclosed to anyone except the Provider.

8. LIMITED DATA SETS

PURPOSE

To define the procedures necessary to use and disclose Limited Data Sets for Research.

SCOPE

This procedure applies to all UWF researchers who use Limited Data Sets for Research

RESPONSIBILITIES

UWF researchers must adhere to the procedures stated herein prior to releasing Limited Data Sets for Research. All requests for use of limited data sets must be reviewed and approved by the UWF IRB. All data use agreements for faculty researchers are required to be reviewed and approved by the UWF Office of the General Counsel before signature.

PROCEDURES

Providers who have access to Individually Identifiable Health Information for treatment purposes may create and disclose a Limited Data Set only if:

1. The Limited Data Set meets the requirements set forth in this Standard Operating Procedure; and
2. A Data Use Agreement (approved by the UWF Office of General Counsel) has been executed with the recipient of the Limited Data Set, in accordance with this procedure manual.

A Provider may disclose Limited Data Sets in accordance with the other provisions of this Standard Operating Procedure and only for the purpose of research, public health, or health care operations.

No accounting is required for the disclosure of a Limited Data Set.

A Limited Data Set must exclude the following direct identifiers of the individual, and of the individual's relatives, employers, or household members:

1. Names;
2. Postal address information, other than town or city, state, and zip code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
6. Social Security Numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate/license numbers;
11. Vehicle identifiers and serial numbers, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URLs);
14. Internet protocol (IP) address numbers;
15. Biometric identifiers, including voice and fingerprints; and
16. Full face photographic images and any comparable images.

A Data Use Agreement between UWF and the recipient of the Limited Data Set must:

1. Specify the permitted use and disclosure of such information by the Limited Data Set recipient.

2. Specify who is permitted to use or receive the Limited Data Set; and

3. Specify that the Limited Data Set recipient will:

    a. Not use or further disclose the information other than as specified in the Data Use Agreement or as otherwise required by law;

    b. Use appropriate safeguards to prevent use or disclosure of the information other than as specified in the Data Use Agreement;

    c. Report to UWF if the recipient becomes aware of any use or disclosure of the information not specified in its Data Use Agreement with UWF;

    d. Ensure that any agents, including subcontractors, to whom it provides the Limited Data Set, agree to the same restrictions and conditions that apply to the Limited Data Set recipient with respect to such information; and

    e. Not identify the information or contact the individual(s) whose data is being disclosed.

9. ARCHIVAL DATA

Archival data are any data that are collected prior to the beginning of the research study but not for the original purpose of the research study. The data contains information that can be linked to individuals (though not necessarily to the individual's identity), otherwise, it is not considered human subjects research and does not qualify for IRB review. The data are also the primary source (versus a secondary source where the data was analyzed for another publication). The federal regulations allow for IRBs to exempt research using archival data when certain conditions exist, including stripping a participant's identity from the data. However, there are conditions where archival data is not considered exempt. In order for the Board to assess the risks to the participants through the use of archival data sources and make recommendations for ethical use of the data, they will need to know the following:

- How did you obtain access to the data? The Board will need to know if the data are publicly available or if there are restrictions for accessing the data. If the second is true, the Board will need to know how you obtained permission to access the data.
- What does the data consist of? The Board will need to know if you are using data sets, videotapes, audio tapes, journal entries, transcripts, etc. If you are using data sets, they will need to know what data fields you will use.
- Can the participants be linked to their data? The Board will need to know in what form you receive the data. Can the data be de-identified? Are the data linked and stripped of identifiers? Who prepared the data for you? Will you merge multiple

data sets?

Some research involving existing data sets and archives may not meet the definition of "human subjects" research requiring IRB review; some secondary data analysis may be exempt from the HHS regulations at 45 CFR 46; and some secondary data analysis may require IRB review.

Whether analysis of secondary data requires IRB review depends on whether the data is "identifiable" -- data may contain "direct" identifiers (such as individual's name, Social Security Number) or "indirect" identifiers (that is, a coding system in which codes (letters, numbers, symbols, or a combination of those) replace direct identifiers). The HHS Office for Human Research Protections (OHRP) has issued the following guidance on secondary analysis of data:

Under the definition of human subject at 45 CFR 46.102(f), obtaining identifiable private information or identifiable specimens for research purposes constitutes human subjects research. Obtaining identifiable private information or identifiable specimens includes, but is not limited to:

- using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that have been provided to investigators from any source; and
- using, studying, or analyzing for research purposes, identifiable private information or identifiable specimens that were already in the possession of the investigator.
- Private information must be individually identifiable (i.e., the identity of the participant 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 participants.

<u>Data is considered to be coded if:</u>

- identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and
- a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.
- In general, OHRP considers private information or specimens to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly, OR indirectly through coding systems. OHRP considers private information or specimens NOT to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

For example, OHRP does <u>not</u> consider research involving only coded private information or specimens to involve human subjects if the following conditions are met:

1. the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; AND
2. the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
    a. the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement); or
    b. there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
    c. there are other legal requirements prohibiting the release of the key to the investigators until the individuals are deceased.

For the full OHRP Guidance on Research Involving Coded Private Information or Biological Specimens, please see: Coded Private Information or Biospecimens Used in Research.