Institutional Review Board for
Human Research Participant Protection (IRB)

PRACTICE AND PROCEDURES MANUAL

Last modified 11.03.21

C O N T E N T S

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 Part IX- XII of this policy).

B. Research covered by this policy, that 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 Part V of this policy.

II. OFFICE OF RESEARCH RESPONSIBILITIES

A. The Office of Research will provide investigators copies of regulation 45 CFR 46, Protection of Human Subjects, the institution's IRB policy and procedures, the Belmont Report, the institution's Policy for Determination of Conflict of Interest, and Policy for Information Security and Privacy Policy.

B. The Office of Research will coordinate the review process of all proposals involving the use of human research participants, unless found to not be human subjects research under Part VI.B. of this policy, including disseminating the proposals to the board for review, notifying the investigator of any changes required by the board in order 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, but longer review periods may be necessary for certain submissions.

C. The Office of Research and the IRB Chair will review projects to determine if they qualify for exemption under 46.101 and Part VI.C. of this policy. Notice of concurrence for all exempt research will be promptly conveyed in writing to the investigator (within 5 working days) and reported to the full IRB at the next scheduled meeting. All nonexempt research will be forwarded to the IRB either for expedited review or full board review. All members of the IRB will be kept informed of research proposals that have been found to be exempt from IRB review.

D. The Office of Research Administration & Engagement and the IRB Chair will review projects to determine if they qualify for expedited review under 46.110 and Part VI.D. of this policy. If a project qualifies for expedited review, the Chair, or one or more experienced reviewers designated by the chairperson, will review the project and promptly (within 10 working days) notify the Office of Research, in writing, of their decision to approve or require modification in order to secure approval. These reviewers may not disapprove the research; disapproval requires a vote of the full board. Expedited review of research activities will not be permitted where full board review is required. All members of the IRB will be kept informed of research proposals that have been approved under the expedited review procedure.

E. Any proposal that is not exempt from IRB review or does not qualify for expedited review will be sent to the IRB for full board review.

F. The Office of Research 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 will identify and analyze potential conflicts of interests and will prepare management plans as needed for investigators.

J. The Office of Research 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 policy.

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

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 policy at intervals appropriate to the degree of risk, but not less than once per year, and shall

have 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 IRB chair or designee, in coordination with the Office of Research Administration & Engagement , 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 if a quorum is present, or more frequently if required by the IRB on the basis of degree of risks to research participants. A meeting of the IRB may be requested by any member of the IRB during a proposal review or at any time the member is concerned with rights and welfare of human participants being used in research.

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

IV. INVESTIGATOR RESPONSIBILITIES

A. Research 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 Policy and Procedures, and the decisions of the IRB.

Research investigators are responsible for notifying the IRB of any projects planned which involve the use of human participants in research. Investigators will complete the IRB Application available on IRBNet.org in its entirety prior to beginning the proposed research. No research will be carried out until it is approved by the IRB. It is the responsibility of the investigator to notify the IRB of any proposed research project 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 Principal Investigator, but must have a faculty advisor who shares the responsibility for the conduct of the research. Students must share their project with their Faculty Advisor in IRBNet and have them “sign” the package electronically before submitting. Faculty advisors will have an up to date CITI training certificate in either 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 Part IX-XII 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 given to the person signing the form. The copy provided to the subject 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 hyper links to information on the internet, the hyperlinks should be maintained and information should be accessible until study completion.

D. The investigator will promptly respond, in writing (within 5 business days), to any concerns expressed by the IRB regarding his/her protocol and 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.

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 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 Primary 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.

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 thirty days in advance through automated

reminders in IRBNet. However, it is the responsibility of the investigator to know when projects expire and plan accordingly.

J. **Required Training**

Research investigators and co-investigators 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 and Co-Investigators 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 at the conclusion of the lesson so investigators can document completion for their records. Note that OHRP does not collect information about who accesses or completes the training.

K. Research investigators will be knowledgeable of and comply with the following:
- The Belmont Report
- 45 CFR 46
- The UWF IRB Policies & Procedures
- 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

L. **Additional Training for Clinical Trials: Good Clinical Practice Training**

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

Who must take GCP Training?

Good Clinical Practice (GCP) training is required for all investigators and staff involved in clinical trials. Investigators and staff on new studies and any new staff on ongoing studies meeting the NIH definition of a clinical trial (definition below) must complete GCP training.

NIH Definition of "Clinical Trial"

A clinical trial is a "research study in which one or more human subjects 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.

GCP training is intended for study staff who collect data through intervention or interaction with a subject 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 prior to IRB approval.

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)

M. Additional Training for use of Protected Health Information (PHI): **HIPAA Training**

The UWF HIPAA policy extends directly or indirectly to any researcher who is conducting research using Protected Health Information (PHI), whether the researcher's primary appointment is with a UWF Covered Component or not.

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. It is a requirement of the IRB that the IRB Proposal and consent documentation (if applicable, according to submission category) describe the extent to which confidentiality of records identifying the subject(s) will be maintained (or not maintained).

All principal investigators, co-investigators and other personnel who have access to PHI must complete the CITI UWF HIPAA Training. The HIPAA Training must be completed prior to initiating human subjects research and every three years thereafter.

V. IRB MEMBERSHIP

A. The Associate Vice President for Research will recommend candidates, and the President of the University will, in accordance with 46.107, appoint no less than five members to the IRB. The board members will select one member to serve as Chair. Appointees will have varied backgrounds so as to promote 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 ethical training.

B. If the IRB regularly reviews research that involves a vulnerable category of research participants, such as children, prisoners, pregnant women, or handicapped or mentally disabled 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. Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB may not consist entirely of members of one profession.

D. 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.

E. 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.

F. 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 in, except to provide information requested by the IRB. Conflicting interests refers 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.

G. 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.

VI. CRITERIA FOR IRB APPROVAL OF RESEARCH

A. In order to approve research covered by 45 CFR 46 and this institutional policy, 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 reasonably be 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. 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, prisoners, pregnant women, mentally disabled persons, 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 Part IX-XII of this policy.

5. Informed consent will be appropriately documented in accordance with, and to the extent required by 46.117 and Part IX-XII of this policy.

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, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these research participants.

B. Human Subjects Research Definition

1. A **human subject** 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

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

c. 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.

d. Interaction includes communication or interpersonal contact between investigator and subject.

e. 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 "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.

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

3. Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (e.g., publications or presentations). However, research results do not have to be published or presented to qualify the experiment 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 never is published is still research. Participants in research studies deserve protection whether or not the research is published.

4. Thesis or dissertation projects involving human subjects conducted to meet the requirement are usually considered generalizable, and require IRB review and approval.

5. Examples of activities that typically are not generalizable (not research) include:

    a. Biographies

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

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

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

    e. Quality assurance activities 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.

C. **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 categories are exempt from this policy:

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 subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

   b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

   c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

3.

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

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

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

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 subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

c. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that 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 of 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 subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

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 subjects.

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.

D. 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 increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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

    a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

    b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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 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 subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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

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

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

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 authorities 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 reviewed under the expedited review process.

10. **Full Board Review**

Any proposal which does not qualify for exemption 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.

VII. AMENDMENTS

An amendment package must be created for your previously approved project in IRBNet and submitted for approval PRIOR to the modification of a previously approved project. Such modifications could include changes in personnel, recruitment, consent, questionnaires, or procedures. Amendments are required for any proposed change to the:

- Study team members
- Study protocol or procedures
- Study documentation (e.g., informed consent, recruitment materials, survey instruments)

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 previously reviewed by the full board most likely will require full board approval also and are subject to the IRB submission deadlines and committee meeting dates. Minor amendments may be reviewed via an expedited or administrative (i.e., IRB staff) process. Examples of minor amendments include but are not limited to:

- Addition or deletion of study team members
- Addition of procedures that do not increase risk
- Removal of procedures which would result in reduced risk to subjects
- Addition of non-sensitive survey or interview questions
- Document changes that do not modify the intent of the content (e.g., typographical error corrections, improvements for clarity)
- Addition of, or changes to, recruitment materials or recruitment strategies that do not increase risk

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

VIII. CONTINUING REVIEW

Approval of a human subject research proposal is in effect for one year. (However, if research involves extreme risk to subjects, 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. To request an extension the principal investigator is responsible for submitting a continuing review report of the project to date including:

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 subjects 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 will complete 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.

IX. GENERAL REQUIREMENTS FOR INFORMED CONSENT

Except as provided elsewhere in this policy, no investigator may involve a human being as a research participant in research covered by this policy 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. 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 risk 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 research subject, documented in writing in language that is understandable and

3. Providing the participant with a written informed consent document that outlines the purpose, risk 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). If the researcher plans to conduct research in a language other than English, they must also submit copies of the Informed Consent document in that target language and should, as a courtesy to the IRB, make a suggestion for individual(s) with appropriate language competency who can determine whether the target language version of the Informed Consent document meets all of the standards and expectations of the English-language version.

C. Except as provided in Section XII, 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 subject or the legally authorized representative, if this might be a possibility; or

ii. A statement that the subject'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.

D. 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 subject 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 subject'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 subject;

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 subject;

6. The approximate number of subjects 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 subject 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).

X. SUBJECT COMPREHENSION ASSESSMENT

The responsibility of ensuring that a potential subject understands the research and the risks and benefits involved falls upon the Investigator and not upon the potential subject. 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 subject, prompt the potential subject 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."

<u>Examples of open-ended questions are:</u>

- "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 subject comprehension. In contrast, closed-ended questions do not further discussion and tend to bring it to a stop, so they should be avoided.

<u>Examples of closed-ended questions are:</u>

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

XI. DOCUMENTATION OF INFORMED CONSENT

A. Except as provided in Section XII, 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 subject 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 hyper links to information on the internet, the hyperlinks should be maintained and 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 subject 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 obtain a signed Recorded Media Addendum from potential participants in addition to a signed consent form. If recording is required to participate in the study, you should specify such on both the addendum and on the consent form used to enroll participants in the study. If recording is not required to participate in the study, please be sure to indicate so on this addendum.

E. The Investigator who has oriented and consented the subject also must sign and date the consent form. NOTE: The subject is not technically enrolled until both the subject and the Investigator have signed. It may be appropriate for the Investigator to sign after the subject 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 subject and that the subject:

   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, subject and impartial witness (when required—see below) sign at the same time.

G. The Investigator's signature cannot pre-date the subject's signature.

H. The subject should always be provided with a copy of the consent form to use as 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 subject. 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 subject, guardian, or surrogate, without any element of force, fraud, deceit, duress, coercion, or undue influence.

L. Except as provided in Section XII, 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 IX-XII of this policy. 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 IX-XII 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 of 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.

XII. INFORMED CONSENT WAIVER OR ALTERATION

Policy: It is the preference of the University Institutional Review Board (IRB) that written informed consents are received from all research participants; however, the

University recognizes that under certain circumstances, written consent is either impossible or impracticable to obtain. In order 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. The IRB may approve a consent procedure which 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.

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

C. 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.

Verbal Consent

D. 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 is 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:

   1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; (i.e., study that involves illegal activity or substance abuse). Each subject must be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern (i.e., the subject is

from a culture that may punish the individual for participating) (THIS EXCEPTION IS NOT AVAILABLE FOR FDA FUNDED RESEARCH); or

2. The research presents no more than a minimal risk of harm to subjects 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 not a "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 consents. Verbal consent should be documented in either the written study record or included in any audio or video recordings. Participants should be provided 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. Completion of the survey indicates participant consent.

E. **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.

F. **Educational Evaluation Practices**

The UWF IRB will review requests for waivers of informed consents 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 such 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?

G. **Research in emergency settings**

An 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.

H. **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 of 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, the researcher must provide statements as to how each of the above is applicable to his or her research with his

or her IRB application. If a debriefing statement is going to be utilized, it should be included with the IRB application.

XIII. EMAILS SENT TO RESEARCH PARTICIPANTS

A. As with any other recruitment materials, a description of how email will be used to communicate with potential subjects for recruitment purposes should be included in the IRB application along with any 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 subject through email.

B. 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.

C. 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."

D. Emails sent to research participants must adhere to the UWF Electronic Communications Policy stated in Policy University Policy IT-01.03-07/19.

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

F. Use of non-public email list-serves and distribution lists may be used with permission of the list owner. This procedure must be detailed in the IRB application. Investigators are required to submit a copy of the list 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.

XIV. SOCIAL & ELECTRONIC MEDIA

Research conducted using social media creates new challenges for both investigators and those charged with maintaining protections for research participants. Examples of electronic and social media used for recruitment include advertising on a website or 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.

A. Recruitment

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.

B. 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.

C. 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 that research opportunity. Oftentimes this is allowable so long as it is done so the instructor is merely passing on the information while making it clear to students the research is not related to the course and interested students contact the investigator directly. UNIVERSITY-SPONSORED WEBSITES AND SOCIAL MEDIA SITES MAY NOT BE USED FOR RECRUITMENT OF RESEARCH SUBJECTS.

D. 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.

E. 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.

F. 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 subjects. 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 identification of a potential subject.

G. Amazon Mechanical Turk

The use of Amazon Mechanical Turk, or analogous commercial recruitment method companies, as a recruitment method for human participant studies continues to grow. Mechanical Turk is 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 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 is 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

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 therefore collect data using a third party survey software, such as Qualtrics, with known policies for data security and anonymity.

H. Informed Consent Considerations

Consent for enrollment into the 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 consent the individual only as part of the recruitment message.

1. 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 OK for no more than minimal risk studies.

2. 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.

3. 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:

    a. Under Facebook's privacy policy, consent must be obtained for the use of any data from a Facebook user's page.
    b. 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.
    c. Under MTurk's policy you cannot ask workers for identifiable data such as their name or email address

XV. 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. Working with students in another class or having a research assistant handle recruitment, informed consent and data collection are both preferable to using your own students. When course credit or extra credit is given to students who participate in research as part of a course requirements, 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.

Policy: Instructors of research design and methods courses are responsible for 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 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: this is 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 statement of Policy and Procedures.

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

3. **<u>This policy does not apply to the following:</u>**
    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 the results of which are to be used outside of class
    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 involving 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 the mentally or physically disabled, children under the age of 18, older adults (>65 years of age), pregnant women, and criminal offenders (e.g., inmates, parolees, or probationers); or
    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

Purpose: Primary School based research projects require special considerations beyond the federal regulations and University policy. The purpose of this guideline is to outline the requirements for studies in elementary, middle, and high schools.

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 by 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 process, 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).

2. **Engagement**
   If teachers are engaged in research activities taking place in their school or classroom, they must complete human subjects 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, answering questions about the project, etc. PLEASE NOTE THAT THE IRB DISCOURAGES USE OF TEACHERS IN RESEARCH ACTIVITIES DUE TO THE POTENTIAL FOR INFLUENCE TO PARTICIPATE. 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 subjects. 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 subjects. 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 subject 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 is included as part of your description of the scope of research to potential sites. Further, the researcher must provide a separate consent for video or audio recording.

7. **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.

   See Student Information in Research Guideline for further information.

XVI. PAYMENTS TO RESEARCH PARTICIPANTS

The following are the procedures to follow when making payments to research participants. Adherence to these procedures apply for 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 such 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. A copy of the UWF Gift Card Log is available from the Office of Research Administration & Engagement.

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 subjects 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 subjects to be paid for their participation in research, especially in the early phases of investigational drug, biologic or device development. Payment to research subjects 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 are coercive or present undue influence [21 CFR 50.20].

   Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. Unless it creates undue inconvenience or a coercive practice, payment to subjects 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 subjects 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 FDA, providing that such 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 subjects 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: 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.

XVII. UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS AND ADVERSE EVENTS

Investigators must report to the IRB as soon as possible, but in all cases within 24 hours after the event had been made known to the investigator, any of the following:

1. Adverse events which, in the opinion of the investigator, are serious, unexpected and related:
   - An adverse event is “unexpected” when its specificity and severity are not accurately reflected in the informed consent document or study protocol.
   - An adverse event is “related to the research procedures” if, in the opinion of the investigator, it was more likely than not to be caused by the research procedures or if it is more likely than not that the event affects the rights and welfare of current subjects.

2. Serious adverse event
   - Event that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect

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 subjects, research staff, or others, or
   - An adverse event or problem in the research is also considered serious when 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 subjects 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. Complaint from a subject when the complaint indicates unexpected risk or cannot be resolved by the research team

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

8. Change to the protocol taken without prior IRB review to eliminate an apparent

immediate hazard to a research subject

9. Event that requires prompt reporting to the sponsor

10. Sponsor-imposed suspension for risk

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

12. Incarceration of a subject in a protocol not approved to enroll prisoners

13. 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 subjects)

The investigator must complete the adverse event 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 in which the investigator is responsible for the conduct of the research.

Review of the event or problem
The Research Compliance Officer will review the event or problem within 5 days of receiving the event or problem. If appropriate to the event or problem, the 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 subjects or others (because the event is either anticipated or does not indicate that the subjects 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 subjects or others because the problem (1) is unanticipated and (2) indicated that the subjects 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 subjects' 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.

Actions that may be taken during or after the investigation of an adverse event or unanticipated problem

1. Modification of the research protocol
2. Modification of the information disclosed during the consent process
3. Additional information provided to past subjects
4. Notification of current subjects (required when such information may relate to subjects' willingness to continue to take part in the research)
5. Requirement that current subjects 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 subjects
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 content
16. The determination will be reported in the minutes and the investigator will be notified.

Notification

The investigator will be notified within five (5) business days of the Research Compliance Officer, 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 subjects or others, no action will be required. If the event is determined to be an unanticipated problem involving risks to subjects 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

Researchers must promptly (within 2 working business days) report the following to the Office of Research Integrity:

- Any significant adverse events, unanticipated risk, 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
- The timeframe for "promptly" is defined as within 48 hours
- Any compromise of personally identifiable information must be reported immediately (within one working business day).

XVIII. EXTERNAL RESEARCHERS

1. Requests from external researchers will be submitted to the IRB on the form provided at the following website: https://uwf.edu/academic-affairs/departments/research-administration-engagement/research-integrity-compliance/institutional-review-board-irb/

2. External researchers must provide a copy of the approval letter from the researcher's host institution in the UWF IRB application package.

3. External researchers must designate a UWF liaison for the research project. The UWF liaison must complete a UWF Co-Investigator/Other Personnel IRB Application.

4. 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 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 Policy and Procedures, 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 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. If the recruitment mechanism involves participants from UWF departments, the external researcher must gain approval from the selected UWF department(s) and provide a letter of commitment from the Department Chair(s) in the IRB application.

5. At no time can an external IRB application apply for an informed consent waiver.

6. At any time, UWF Department Chairs and the Director of Research Administration & Engagement have the right to refuse access to UWF students for the purposes of outside research.

XIX. IRB REVIEW FEE SCHEDULE

The University of West Florida Institutional Review Board (UWF IRB) will assess review fees for commercial/for-profit funded projects involving human subjects. 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 $1000.

Continuation 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.

<u>Frequently Asked Questions</u>

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.

XX. CLINICAL TRIALS BILLING

This policy establishes uniform requirements for billing clinical services for subjects 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 policy and the roles, responsibilities, and procedures described herein. Corrective and disciplinary action may be taken for violations of this policy 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 to the research subject;
2. Informing the research subject of the charges and how they will be allocated as a part of the informed consent process;
3. Completing required documentation to support charges for each research subject.

XXI. VENIPUNCTURE/PHLEBOTOMY/BLOOD DRAW POLICY

This policy provides standards for safely conducting blood draws and requirements for obtaining human blood and human blood products for research purposes. This policy 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 will be provided to a qualified faculty member for determination of competency. Completion of this form by all persons who will perform blood draws in connection with a sponsored research project is required prior to IRB consideration of the project.

XXII. 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.

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.

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"). There are 18 identifiers that are defined in HIPAA as Protected Health Information. These are as follows:

- Names;
- 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;
- 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;
- Phone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social Security numbers;

- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

A UWF Researcher should review the "Evaluating a Research Study for HIPAA Compliance" Procedure in order to determine whether PHI is required to perform his or her research (Attached, Appendix I). 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 is contained in Appendix II. Procedures for the use and disclosure of Limited Data Sets is contained in Appendix III.

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 CITI Health Information Privacy and Security (HIPS) 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 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 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 and Sponsored Programs 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 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 subjects (living or deceased) or health information that can be linked in any manner to the identity of the subject? (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 which 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 subjects' 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/

    a. If yes, refer to the Standard Operating Procedure for Use and Disclosure of De-Identified Data for Research Purposes.

    b. If not, can the research be conducted with the only identifying information linking the subject'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 the UWF Standard Operating Procedure for 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)?

    a. If yes, refer to the Standard Operating Procedure for Use and Disclosure of PHI for Reviews Preparatory to Research.

3. Is the review or use of the PHI primarily to recruit research subjects from a population that does not consist of the UWF Researcher's own patients?

    a. If yes, refer to the Standard Operating Procedure for Use and Disclosure of PHI for Recruitment of Research Subjects.

4. Does the research involve PHI related only to deceased subjects where the focus of research does not involve any living relative of the decedent?

    a. If yes, refer to the Standard Operating Procedure for Use and Disclosure of Decedents' PHI for Research Purposes.

5. Is use of the PHI necessary to the research study, yet will it be difficult or impossible

to obtain the subjects' Authorizations?

a. If yes, will the use or disclosure of the subject'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 the UWF Standard Operating Procedure for 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 Standard Operating Procedure (SOP). Prior to 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 approval all requests for the use and disclosure of PHI for purposes "Preparatory to Research"

PROCEDURE

The UWF Researcher who has the need to access PHI for purposes of reviews preparatory research must complete and submit a Preparatory to Research report request via the Office of Research and Sponsored Programs. For more information on determining whether a proposed use of PHI qualifies as a "review preparatory to research," refer to the HIPAA Research Compliance Program Standard Operating Procedure for 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 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 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 Standard Operating Procedure. 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.

Special Note on Reviewing PHI for Recruitment Purposes
UWF Researchers are not permitted to use PHI obtained pursuant to this procedure for the recruitment of study subjects. UWF Researchers must obtain a partial Waiver of Authorization from the UWF IRB pursuant to the procedures set forth in the HIPAA Research Compliance Program Standard Operating Procedure for 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 subject 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 the HIPAA Research Compliance Program Standard Operating Procedure for Evaluating a Research Study for HIPAA Compliance.

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

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 must include:

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 subject 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 subject Authorization.

RESPONSIBILITIES

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

PROCEDURES

The UWF Researcher must obtain written Authorizations from human subjects enrolled in research studies that comply with HIPAA Privacy Rule Regulations. For additional information regarding HIPAA authorizations, please see https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/

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 persons(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 is 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, and 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 Authorizations already obtained, the UWF Researcher must submit the amended Authorization to the UWF IRB.

An individual may revoke his/her Authorization at any time, provided that the revocation is in writing, unless the Covered Entity/UWF Researcher has taken action in reliance upon the Authorization and the use/disclosure as necessary to preserve the integrity of the research study ("Reliance Exception"). Under the Reliance Exception, the UWF Researcher is not permitted to use and disclose PHI that was not already gathered at the time the individual revoked his/her Authorization.

Instances where the Covered Entity/UWF Researcher will be permitted to continue to use/disclose the PHI notwithstanding revocation by an individual are as follows:

1. To account for the individual's withdrawal from the research study;
2. As necessary to incorporate the PHI as part of a marketing application submitted to the FDA;
3. To conduct investigations of scientific misconduct or to report adverse events.

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. 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 abided by. 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

Providers 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 Standard Operating Procedure.

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 determination.

The Provider 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 of 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 are required to be reviewed and approved by the UWF Office of the General Counsel prior to 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 Standard Operating Procedure.

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.

Limited Data Sets created in accordance with this Standard Operating Procedure may be disclosed to UWF Researchers without the need for approval by the IRB.

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, video tapes, 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 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.

Data is considered to be coded if:

- 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 not 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.