BEFORE YOU BEGIN

Institutional Review Board (IRB) For Human Research Participants Protection

The Institutional Review Board (IRB) for Human Research Participants Protection is a federally mandated committee. Its purpose is to protect the rights and welfare of all persons recruited to participate in research activities associated with UWF. UWF policy requires that all educational, training, or research activities involving human participants must be reviewed by the IRB prior to the recruitment of participants and initiation of data collection. This requirement applies to all research-related activities involving human participants at any UWF campus or conducted by any UWF faculty, staff and/or student.

In reviewing proposals, the UWF IRB is guided by the ethical principles outlined in the Belmont Report - respect for persons, beneficence, and justice. Only research that abides by these principles will be approved by the IRB.

To all investigators: It is a violation of regulations to initiate the research project prior to receiving IRB approval. Therefore, it is important that proposals be submitted to the IRB in a timely manner and with consideration of upcoming IRB meetings whenever the project involves completion deadlines (i.e., for publishing or thesis/dissertation submission). UWF asks that investigators please allow up to 4-6 weeks for IRB review.

For more information concerning the UWF IRB, please contact irb@uwf.edu or at 850-474-2609

The University of West Florida maintains a Federalwide Assurance (FWA) for the Protection of Human Subjects in Research and is a registered IRB with the Office for Human Research Protections (OHRP).

FWA Number: FWA00002657
IORG Number: IORG0001310

IRB Regulations, Policies & Procedures

Researchers engaged in activities involving human participants must be aware of the regulations that outline protections for human research participants.

Federal Regulations

- DHHS Regulations for the Protection of Human Subjects: 45 CFR 46 - Describes the basic mandates regarding protection of human research participants; also called "The Common Rule"
- Additional Protections for Pregnant Women, Human Fetuses & Neonates
- Additional Protections for Prisoners as Research Subjects
- Additional Protections for Children as Research Subjects
- FERPA (Family Educational Rights and Privacy Act): 34 CFR 99 - Protects the privacy of student education records; can apply to research if project utilizes data from a student's "educational record"
- HIPAA (Health Information Portability and Accountability Act): 45 CFR 160, 162, 164 - Protects the privacy of a person's "personal health information" can apply to research if project utilizes health related data obtained from a HIPAA-covered entity.

National and International Policies

- Belmont Report - Originally published in 1978 by a special commission charged with exploring the mistreatment of humans during research; identifies the three fundamental ethical principles for human subjects research (respect for participants, beneficence, and justice)
- Helsinki Declaration - Adopted by the World Medical Association (WMA) in 1964 and most recently updated in 2008; outlines the ethical principles recommended for medical research involving human participants.
- National Institutes of Health (NIH) Policy on the Inclusion of Children in Research
- NIH Policy on the Inclusion of Women and Minorities as Participants in Research Involving Human Subjects

University of West Florida Policies, Procedures, and Guidelines

- UWF IRB Policy and Procedures
- Compliance with Federalwide Assurance (FWA)
- Requests from External Researchers, UWF Policy
- Conflict of Interest, UWF Policy AC-11.02 - 5/13
- Reporting Adverse Events and Unanticipated Problems
- Mandatory Training for Investigators
- UWF Guidelines on Ethnography and IRBs: UWF follows the guidelines expressed in the American Anthropological Association's (AAA) "Statement on Ethnography and IRBs."
- Instructor Guidelines for Classroom Research Projects
- UWF Broadcast Distribution Standards

IRB meetings are reserved for the review of applications in which participants are exposed to "greater than minimal risk." The UWF IRB cannot guarantee that such applications submitted close to meeting dates will be reviewed at the upcoming meeting. Therefore, it is recommended that all applicants submit IRB applications well in advance of the proposed project start date. Applications referencing "minimal risk" studies are reviewed on a continuous basis.

SUBMIT YOUR APPLICATION

IRB Application & Reporting Process

Researchers should follow these 8 steps for submitting a proposal and managing an IRB-approved project.

STEP 1: Confirm that your project requires you to submit an application to the IRB.

The IRB only has jurisdiction over research involving human participants. If both of the definitions below apply to your project, you must seek IRB approval prior to beginning your project.

- "Research" means a **systematic investigation** designed to develop or contribute to **generalizable knowledge**.
  - Systematic investigation: attempt to answer research questions, methodologically driven (collects data in an organized and consistent way), data is analyzed in some way (quantitative or qualitative), conclusions are drawn from results
  - Generalizable knowledge: results are expected to be generalized to a larger population beyond the site of the data collection or population studied (publishing or presenting are common methods), results are intended to be replicated in other settings, knowledge contributes to a body of knowledge
- "Human participant" means a living individual about whom an investigator conducting research obtains: (a) data through intervention or interaction with the individual, or (b) identifiable private information.

Examples of research that do not involve human participants: literature reviews, publicly available data, and online aggregate data. For assistance in determining if your research requires IRB approval, please visit

Types of IRB Applications

- New Projects: For applicants preparing to begin new research. New applicants must complete the entire application process.
- Project Modifications: For applicants wishing to change details of a project that had previously been approved by the IRB. A completed IRB Project Amendment Request Form (Word) must be submitted to the IRB in order for changes to be made to an IRB-approved research project.
- Project Extensions: For applicants wishing to extend the dates of their IRB approval in order to complete their research. Requests for extension must be submitted to the IRB along with a complete Continuing Review Form (PDF).

Special Project Types
External Research Projects: Researchers from institutions outside of UWF wishing to recruit UWF faculty, staff, or students to participate in their research must follow the procedures outlined in the UWF IRB Practice and Procedures Manual.

Commercial/For-Profit IRB Review Fees: The University of West Florida Institutional Review Board (UWF IRB) will assess review fees for commercially/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 $1,000. Continuation requests will be charged $1,000 and project amendments will be charged $500. Please review the Commercial/For-Profit IRB Review Fee guidelines located in the UWF IRB Practice and Procedures Manual.

Projects as part of a research methodology course: Must adhere to the instructor Guidelines for Classroom Research Projects listed in the UWF IRB Practice and Procedure Manual.

STEP 2: Complete mandatory online training.

All investigators and co-investigators must complete a training course on the protection of human research participants.

There are two options for completing the training requirement.

1. **CITI (Collaborative Institutional Training Initiative):** Human Subjects Research Training Modules (Recommended). First-time users must register to complete the training. These instructions will guide you through the registration process.

   The CITI training program contains many educational modules. You will only be required to complete the modules that correspond with your IRB application. **CITI Training must be updated every 3 years**

2. **NIH Office of Extramural Research: Protecting Human Research Participants Training Course**

   First-time users must register to complete the training. Access the course through the NIH Office of Extramural Research.

HIPAA Information Security Training Available through CITI (if applicable)

The Federal privacy regulations of the Health Insurance Portability and Accountability Act (HIPAA) went into effect on April 14, 2003. As a result, certain researchers and research institutions are required to be in compliance with the HIPAA regulations that are known as the “HIPAA Privacy Rule.” Among other provisions, the Privacy Rule sets requirements for the use and disclosure of protected health information (PHI) in research. Updates to this rule, known as the HIPAA/HITECH Omnibus Final Rule, went into effect in March 2013. The UWF HIPAA policy extends directly or indirectly to any researcher who is conducting research using 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 personally identifiable 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). Where deemed necessary, the PI shall obtain a HIPAA certificate of confidentiality form which protects against the compulsory release of individually identifiable research information.

The IRB shall ensure that all studies incorporate HIPAA compliant authorization language into the body of the study’s informed consent form unless the study does not involve the use of PHI. All principal investigators, co-investigators, and other personnel that have access to PHI must complete the CITI UWF HIPAA Training. The HIPAA Training must be completed prior to IRB approval and every three years thereafter.

All investigators and co-investigators are also required to complete the following mandatory readings:

- Belmont Report
- UWF IRB Practice and Procedures Manual
- 45 CFR 46
- UWF Conflict of Interest Policy
STEP 3: Complete the IRB Application.

Please download and complete the UWF IRB Application form in Word or PDF.

When composing your IRB application, make sure that all applicable areas are completed and all questions are thoroughly answered.

STEP 4: Get the necessary signatures.

All IRB applications require the signature of the primary investigator and all co-investigators (if applicable. Students submitting an IRB application are also required to get the signature of their faculty advisor.

STEP 5: Create and attach Informed Consent Forms.

Research involving human participants requires that all participants be provided with certain information regarding the study prior to their participation. Your informed consent form must be submitted with your application.

Things to remember about informed consent documents: There are several sections of information that must be included in your informed consent. These sections are detailed in the UWF IRB Practice and Procedure Manual and a sample is available on the UWF RSP Templates Page. Informed consent forms must be easy to read and easily understood by your participants. The IRB will examine your informed consent to ensure the form is appropriate for your study's participants.

Questions to consider when creating informed consent forms:

1. Are all of your participants adults?

2. Does your research involve young children (less than 7 years old)?

   When research involves young children, the parent assumes responsibility for consenting to the research. See a sample Parental Consent on the UWF RSP Templates Page.

3. Does your research involve children and/or adolescents (7-17 years old)?

   When research involves minors within this age range, the child must agree to participate in the research by signing an assent form. It is important that assent forms be tailored to the age range and abilities of the children involved in the study. Generally, written assent should be obtained from children with an intellectual age above 7 years. NOTE: In this type of research, the parent must sign a parental informed consent as well. A Child Assent Form Template is available on the UWF RSP Templates Page.

4. Could participation in your research potentially cause the participant to experience emotional disturbances?

   Having to deal with negative emotions (e.g. anger, sadness, stress) may be one of the risks to which participants in your study are exposed. In this case, you should inform your participants that counseling is available.

5. Are you using an internet survey in your research (e.g. Qualtrics)?

   For research conducted via the internet, the online survey should include an informed consent form. The participant must agree to participate in the research by clicking an "agree" button on the informed consent page. The participant should also certify that they are at least 18 years of age or older. The University of West Florida General Counsels requires that all electronic surveys use Qualtrics. UWF has a contract with Qualtrics for security and legal provisions.

6. Are you planning to take photographs of the participants and/or make video or audio recordings of the participants?

   If you are planning to photograph or record your participants in any way during the research, the participants must be told that they will be recorded and must be well informed about the potential loss of anonymity. Participants who agree to be recorded must sign a recorded media addendum. If the participant does not wish to be recorded and does not sign a recorded media consent form, no recording may take place.

7. Does your research involve gathering Protected Health Information (PHI)? What is PHI?
PHI refers to private health information that can be traced back to the individual. If your research is collecting information about the health of your participants and is also collecting information (e.g. name, date of birth, address, zip code) that could be used to connect the health information to an individual participant, you must have each participant sign a Health Information Portability and Accountability Act (HIPAA) authorization form.

8. Are you planning to recruit participants who are not proficient in the English language?

If you plan to recruit subjects who do not speak English, you will need to translate your consent documents to obtain true "informed" consent. Please wait until after the IRB has approved the English version of the consent document before you submit a translated version for approval.

9. Are you planning to provide incentives (money, gift cards, etc.) to attract participants?

If you will be providing incentives to your participants, you will need to disclose this information in your consent form. This information should also be noted in your application (in the recruitment section). Due to Florida Statutes, the use of lotteries, drawings and/or raffles as incentives for research participants are NOT allowed; instead, consider incentives that can be given to every participant.

In a few cases, informed consent may not need to be documented. In these cases, you must specify why your project does not require written consent when completing your IRB application and the IRB must approve the use of verbal consent.

For more information on the informed consent process, check out OHRP's Informed Consent Tips and Informed Consent FAQs.

**STEP 6: Include all necessary attachments.**

A) Your application should include any written documents and/or surveys that will be used in your research. This includes, but is not limited to:
   - recruitment flyers
   - recruitment scripts
   - surveys
   - interview questions

B) If you are collecting data from persons at an institution outside of UWF, or an outside institution is helping you with recruitment, the IRB requires a letter of cooperation from the outside site’s authorized institutional official. Preferably, the letter should be on institution letterhead and signed; however, an email is sometimes acceptable if sufficient detail is provided.

C) If you are working in coordination with a Florida public school, the IRB requires documentation of permission from the County Superintendent of Schools.

D) Researchers working in collaboration with agencies and individuals outside of UWF may be required to submit an application to multiple IRBs. If you have received a letter of approval from an IRB at another institution, you must submit the letter as an attachment to your UWF IRB application.

E) All co-investigators or other personnel (with access to the research data and/or human subjects) must complete a UWF Co-investigator/Other Personnel Application and provide a CITI or NIH training certificate.

F) A copy of the informed consent

G) A copy of the recorded media consent form (if applicable)

H) A data use agreement for access to any data not publically accessible (requires UWF General Counsel Approval)

I) Venipuncture/Blood Draw Permission Form (if applicable)

J) Proof of all required UWF Environmental Health and Safety Training (if applicable)

**STEP 7: Submit your IRB application.**

The UWF IRB only accepts emailed signed copies of IRB applications and supporting documents. The IRB no longer accepts any hard copy documents. Your application will be not be reviewed until all signatures and attachments have been received by the IRB office.

**REVISE APPLICATION IN RESPONSE TO IRB REVIEW**
The applicant amends his/her application and supporting materials in response to the IRB Member’s review comments. If the IRB member requested clarification only, then the applicant can respond by email. RSP facilitates the anonymous communication via irb@uwf.edu between the IRB member and the applicant.

**OBTAIN APPROVAL LETTER AND STAMPED DOCUMENTS**

Once approved by the IRB Member, RSP emails an approval letter and stamped final documents. The researcher is required to use the content in the stamped application and attachments. Any modification requires an approval from the IRB.

**MODIFICATIONS REQUIRE AN IRB AMENDMENT**

You are required to have IRB approval before making any changes to your research protocol. If you want to change your project after you have received IRB approval, you must complete an IRB Project Amendment Request Form available on the UWF RSP Forms Page. Examples of protocol changes requiring IRB approval include:

- adding or removing a co-investigator from the project
- adding or removing a research site
- changing the survey, test, or data collection instrument
- changing any part of the informed consent document
- changing any part of your recruitment procedures
- changing your targeted study population
- changing any other of the project methods or procedures

Once completed, you must submit the form to the IRB for approval. No changes may be made in your research protocol until you have received IRB approval.

**STUDY CLOSURE AND EXTENSION REQUESTS**

You are required to stop all data collection on or before your project end date. The approval letter you received from the IRB will provide your approved project end date. Once you have reached the end of the project period, you must stop all data collection. Continuation of data collection past the IRB approved period violates federal regulations.

If you require additional time to collect data, you may request a project extension. Requests for extension must be submitted to the IRB along with a complete Continuing Review Form (available on the UWF RSP Forms Page). The request must be received prior to the project end date.

You are required to report the conclusion of your project to the IRB.

When you have reached the end of the approved project period and have completed data collection, you are required to provide the IRB with your responses to the Final Report Questions (Available on the RSP Forms Page). You must submit your responses to these questions in order to fulfill your duties as a researcher.

**IRB Frequently Asked Questions (FAQs)**

Find the answers to many of your IRB questions.

**General IRB Questions**

1. **How do I know if my project needs to be reviewed?**
   The IRB at UWF reviews all educational, training or research activities involving human subjects, at any UWF campus or by any UWF faculty, staff or student.

   *Research:* a systematic investigation designed to develop or contribute to generalizable knowledge.

   *Human subject involvement* means a living individual about whom an investigator conducting research obtains: (a) data through intervention or interaction with the individual, or (b) identifiable private information.

   For help in determining if your project requires IRB review call RSP at 850-474-2609 or email irb@uwf.edu.
2. **What are some examples of projects that do not require IRB review?**

Projects that do not meet the criteria for research do not require IRB review. For example:

- Survey procedures only for internal purposes (program evaluation) such that results will not be published nor presented in a public setting (e.g. at conferences or professional meetings)
- Gathering of information from a person to assess suitability for and/or supplement a public program, publication, or cultural performance
- Interviews used to provide quotes or illustrative statements (i.e. journalism)
- Gathering of information from a person to clarify the history of a particular item in a museum collection

3. **Do I need IRB approval to conduct ethnographic interviews?**

Yes. UWF guidelines for ethnographic interviews follow the guidelines adopted by the American Anthropological Association (AAA). The AAA Statement on Ethnography and Institutional Review Boards was adopted in 2004 and advises ethnographic researchers to seek help from IRBs so that the welfare of human participants can be protected.

The AAA explains that ethnographic research should require IRB approval as it involves human participants and is research. While this type of research studies human behavior in the participant's natural environment, and not in clinical laboratories, ethnographic researchers should also consider potential harms to participants and take precautions to minimize these risks.

Thus, ethnographic researchers at UWF must submit project proposals to the IRB for approval prior to initiating an ethnography project and must obtain informed consent from all participants prior to beginning the interview process.

4. **Do I need IRB approval to conduct a class-related project?**

Are you the student? Talk to your professor! If you are enrolled in a research design and/or research methods courses, your professor may require you to complete a research project as a part of your regular coursework. By assigning this task, you will experience the use of research methods first hand. In these cases, the UWF IRB allows for the professor teaching the course to act as the party responsible for the protection of human research participants. The professor leading your class, therefore, should conduct a review of your and your classmates' research protocols to ensure that all human research participation protections have been included.

Note: All research projects involving human participants that are completed as a part of a directed study, thesis, or dissertation project require IRB approval. In these cases, the student research proposals should be submitted to the IRB employing the usual application process.

Are you the professor? You may submit one comprehensive IRB application for your classroom-assigned project instead of having each student complete a separate application for IRB review. As a part of the comprehensive application, you must complete the mandatory training for researchers and submit an IRB proposal using the standard form. For instructions on how to complete an IRB application for a classroom-related activity, all professors are encouraged to read the IRB Practice and Procedures Manual.

*Note: Data collected for a class project may not be used for publication or presentation unless the project was reviewed and approved by the IRB prior to recruitment and data collection. Should there be any possibility of or intent to publish, present, or otherwise disseminate research data or findings outside the course in the future an application must be submitted for review and approval by the IRB prior to the start of recruitment and data collection.

5. **Do I need IRB approval to conduct a quality improvement (QI) activity?**

Projects that do not meet the criteria for research do not require IRB review. While the QI activity will most likely be conducted in a systematic manner, the results of the activity are not likely to be used to increase general knowledge. Thus, if your QI activity is designed to discover methods to improve your organization’s department's processes or outcomes and you do not plan on sharing the results outside of your organization/department, IRB approval is not needed.
Note: If you think that you might wish to share the information outside of the organization/department at a later date, you may consider submitting an application to the UWF IRB. IRB approval is required for you to be able to present or the results of your QI activity outside of the group you examined.

Application Process Questions

1. Can students or employees serve as research subjects?
   Students and employees are often recruited to serve as research participants. While UWF does not prohibit the involvement of its students or employees, you should take precautions to avoid the use of coercion and/or undue influence during the recruitment process.

   For example, a professor proposes to include his or her own students in a research project. Students who are contacted and asked to participate may feel that their refusal to participate could affect their course grade. Even if this is not true, any perception of undue influence must be avoided. As such, researchers should avoid using their own students or employees in their research.

   Note: Researchers affiliated with the School of Psychological and Behavioral Sciences (SPBS) proposing to recruit students for participation in their research project should consider the use of the SPBS Psychology Research Pool.

2. Can participants be paid?
   Research subjects may receive incentives or compensation for their participation. If you choose to compensate your research participants, you must clearly describe this compensation in your IRB application. In addition, your informed consent form should explicitly outline any compensation the participant may receive. Note: Compensation should not be described as a benefit of the study. It is important for the IRB to review proposed payments to participants as high levels of compensation could coerce participants into accepting research-related risks that they would normally not accept.

   Important ideas regarding compensation for research participation:
   a. Payments should not encourage participants to participate or continue to participate against their better judgment. When deciding upon the level of compensation you will provide to your research participants, you must remember that the amount paid to participants must correspond to the "burdens of participation". The "burden of participation" assumed by a participant may be estimated by the amount of time that participant has given to the study.

   b. Participants who withdraw from a study prior to the completion of the project should still receive partial compensation. Choosing to withhold compensation to the end of the study constitutes coercion on behalf of the researcher by compelling the participant to continue participation despite any feelings about early withdraw.

   c. UWF policy prohibits cash payments to participants as compensation for research participation. Should you wish to provide compensation to your participants, you may choose to offer gift certificates, gift cards, or store vouchers. You must adhere to the Payments to Research Participants section in the IRB Practice and Procedures Manual.

   d. Florida statutes consider the offering of participation in a drawing or raffle as compensation for participation in research to be a game of chance. As such, the use of drawings/raffles as incentives for research participation is prohibited by state law unless even non-participants are allowed to enter the drawing or raffle.

3. My research and data collection will primarily take place away from the UWF campus. Do I need to have any special approvals to conduct research off-campus?
   As a UWF researcher, you may propose to conduct research at a local public school, a community center, a nursing home and assisted living center, or within a local organization.

   The UWF IRB requires that you obtain approval from the appropriate personnel in order to conduct research at an off-campus site. The appropriate personnel (e.g. director of a nursing home or community center) must provide a letter to the IRB that indicates that you have permission to conduct your proposed research at their site. The IRB will not approve an off-site project without evidence of the sites' approval.
If you are proposing to conduct research in a local public school, you must have written approval from the district's Superintendent of Schools. A copy of this approval letter must be submitted to the IRB.

4. **What is the difference between privacy and confidentiality?**
   Privacy refers to persons and the right of an individual to control who has access to him/herself. In contrast, confidentiality refers to the data collected and the agreement between the researcher and the participant in regards to how the data will be stored and shared.

5. **How can a researcher protect the privacy of participants?**
   When designing the research protocol, a researcher should consider how, when, and where, and what kind of interactions will take place. For example, the researchers should consider:
   - Methods used to identify and contact potential participants (recruitment)
   - The setting in which the participant will interact with the researcher (i.e., participants may not wish to complete an interview in a place where others can overhear their responses.)
   - The methods used to obtain information about participants
   - The nature of the information to be obtained

6. **How can I maintain the confidentiality of my research data?**
   In ensuring that you have adequately planned to protect your participants, the IRB will examine the steps you will take to maintain their confidentiality. The IRB application asks you to describe, in detail, how data will be secured to safeguard confidentiality.
   Some of the common methods used by researchers include:
   - Using codes instead of names to identify different participants
   - Using anonymous surveys
   - Shredding the face sheets of survey instruments should they contain names or addresses
   - Destroying video and/or audio recordings as soon as interview has been transcribed
   - Limiting the access to identifiable data to one or two people
   - Storing all hard copies of records in locked cabinets in locked offices

   Computer security has become an important part of maintaining confidentiality as most data is now stored electronically. Researchers should restrict the storage of research data to secure drives. If the data is of a sensitive nature or when data may be linked to specific individuals, it may be necessary to store the data on an encrypted drive. Finally, identifiable data should not be shared via email or through any other unencrypted electronic means. All researchers must adhere to the UWF information security policy.

   NOTE: Certain types of research projects encompassing interviews with specific individuals may seem to be exempt from confidentiality rules (i.e. ethnography). Researchers leading these projects, however, should ensure that the interviewee is aware that his or her identifiable information will be shared. If the participant does not consent to this sharing of personal information, the researcher must work to maintain the confidentiality of that participant.

7. **Who should be listed on the consent form as the contact to answer questions?**
   The federal regulations outlining human research participant's protection have established 8 minimum topics that must be addressed in an informed consent form. One topic that you must address is whom the participants may contact if they have questions. Specifically, you are required to include contact information for the individual who is capable of answering questions about (a) the research project; (b) the participant's rights as research participants; and (c) research-related injuries.

   In most cases, you will need to include contact information from multiple individuals in order to meet these federal requirements. For example you may include your information so that questions concerning the research and research procedures can be addressed to ensure questions about an individual's rights and the reporting of concerns are adequately handled.

8. **Do HIPAA rules apply to my project?**
The Health Information Portability and Accountability Act (HIPAA) establishes the rights of an individual to maintain the privacy of his or her own personal health information. HIPAA rules apply to health care providers and any other health-related organization. Your research would only be subject to HIPAA regulations if you are collecting identifiable health information from a covered entity.

a. Is UWF a covered entity?
Certain departments within UWF may be considered covered entities under HIPAA because their databases may contain personal health information belonging to UWF faculty, staff, and/or students. These departments include, but may not be limited to:
- Allied Health Sciences;
- Environmental Health and Safety;
- Student Health Services;
- Benefits Section with Human Resources; and
- University Archives.

b. What are examples of other covered entities?
Your research may take place at an external organization that meets the definition of a covered entity. Hospitals, nursing homes, health clinics, physician's offices, and health insurance companies are all examples of covered entities. If you are unsure about whether the organization at which you plan to conduct research is a covered entity, contact RSP (850-474-2609, irb@uwf.edu).

Thus, if you are collecting identifiable health information from one of the above UWF departments or external organizations, your research will be subject HIPAA. As such, participants must agree to your use of their PHI by signing a HIPAA authorization form in addition to the informed consent form.

If you are accessing a dataset that contains PHI from a covered entity, you must first obtain a data use agreement with the covered entity. That data use agreement must be approved by UWF General Counsel.

IRB Review Process Questions

1. What are the categories of review conducted by the IRB?
Based on federal regulations and recommendations, an IRB may conduct several levels of review based on the characteristics of the proposed participant population and on the severity and/or likelihood of risks to participants. For example, the IRB conducts more comprehensive reviews a research application that chooses to study children or a research application that involves places the participant at great risk of physical or social harm.

There are three levels of review conducted by the IRB: 1) exempt review, 2) expedited review, and 3) full board review.

Even if you believe your project qualifies for exempt review or if someone tells you that your project will be exempt, you must still submit an application to the IRB. An exempt project is not exempt from any review; rather, it is only exempt from the complex level of reviews other types of research must undergo. You must still obtain an approval from the IRB in order to begin work on an "exempt" research project.

2. What types of research qualify for an exempt review? What is involved in an exempt review?
If a research project presents no more than minimal risk to participants and belongs to one of the categories of exempt research it may qualify for an exempt review. Applications qualifying for exempt review can be approved after review by a single member of the IRB.

3. What types of research qualify for an expedited review? What is involved in an expedited review?
If a research project presents no more than minimal risk to participants and belongs to one of the categories of expedited research, it may qualify for an expedited review. Qualifying for an expedited review does not mean that the review of your application will be completed quicker than usual. Expedited review refers to a level of IRB review that involves fewer people than the full board review. However, this process may still take up to two weeks.

4. What is minimal risk?
Projects are classified as minimal risk when the probability or magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the course of routine examinations or tests. When trying to consider whether a project classified as a minimum risk project, the researcher must consider physical risks, emotional/psychological risks, financial risks, risks to employability, risk of stigma and more.

5. What types of research require full board review? What is involved in a full board review?
Typically, applications reviewed by the Full Board present more than minimal risk to the participants, deal with sensitive information, or involve the participation of vulnerable populations. During the review, the members of the IRB vote on whether to approve the application. In order for an application to be approved, a majority of the members in attendance (i.e. a quorum of members) must vote for approval.

6. If my project requires full board review, will I be asked to attend an IRB meeting?
If your research proposal requires full board review, you will be invited to attend the IRB meeting. However, you are not required to attend the meeting. Your presence is requested at the IRB meeting so that you will be available to answer any questions brought forth by members of the IRB. Should you choose not to attend the meeting, any questions or concerns of the committee will be forwarded to you upon the meeting’s close. At that time, you will be allowed to respond. Thus, by attending the meeting and working with the IRB on the date of your full board review, you may limit any delay in the approval process that may occur as information is exchanged back and forth post-meeting.

7. When should I submit my proposal for review?
All research proposals should be submitted to the IRB at least four weeks before the researcher intends to begin the project. This provides ample time for the IRB to review the application, for you to make modifications to the application based on reviewer comments, if necessary, and for you to obtain the IRB approval notice. IRB approval cannot be retroactively applied to previous dates. Therefore, be careful when laying out your research timeline. You may not conduct any data collection or interaction with human participants until you have received IRB approval.

Post-Approval Questions - Project Initiation, Continuation, and Conclusion

1. How do I know when my IRB application has been approved? When can I start my research?
You will be notified by the IRB via email when your research project has been approved. Once you have received this notification letter and your approved stamped research documents, you may begin your research. Be sure to keep a copy of the approval letter and your stamped supporting materials for your records.

2. How long will my IRB approval last?
IRB approval of applications approved under expedited or full board review lasts for one year. The notification letter you receive from the IRB stating your approval to conduct research will contain the expiration date for your approval. After this date, you are no longer allowed to add more participants, contact current participants, or gather more data.

You must request an extension for your project should you wish to continue your research past the IRB approval expiration date. This includes continuing the project for additional data collection or to continue with the analysis of identifiable data. (If the only remaining project activities are the analysis of de-identified data, you do not need to submit a request for an extension.)

To request an extension, you must complete a continuing review form to provide an update regarding the status of your project and certify that you are conducting your research by following the protocol approved by the IRB. A continuing review request must be approved by the IRB before the original expiration date in order to continue the project.

Once the IRB-approval end date has been reached, you must stop all data collection. If you still need to collect additional data, you will be required to submit a new application to the IRB and you cannot start collecting that additional data until you receive IRB approval for the new application.
Theref ore, the IRB recommends that requests for extensions be submitted to Research and Sponsored Programs one month before the expiration date. To help you keep track of your project's IRB-approval end date, you will receive an email from the IRB approximately 30-60 days before your project's expiration date reminding you that your expiration date is near.

3. **I've completed my study and data analysis, what should I do?**

As the primary investigator, you are responsible for submitting a final report to the IRB. The final report lets the IRB know that your research is complete, that the research was conducted using the IRB-approved protocol, and that all adverse events were promptly reported. Please compose a document (maximum one page) that answers the final report questions.

On your expiration date, you will receive notification that your project's IRB approval has expired and all data collection must cease. The email notification will also prompt you to complete your final report and submit the report to the IRB.

4. **Can I make changes to my materials or procedures once approved?**

Once the IRB has reviewed a project, the project must be conducted as approved. Any proposed changes in participant population, recruitment plans, research procedures, study instruments, study sites, revisions to the consent/assent forms, or major research personnel must be approved by the IRB.

To request approval for modifications to an IRB-approved protocol, you must complete a project modification form and submit the completed form to the IRB for review. Should the IRB approve your proposed changes, you will be notified via email. Only after that time may the changes you proposed be enacted.

5. **What are the steps for reporting unanticipated problems or adverse events?**

The occurrence of adverse events and/or unanticipated problems during your research project that involves risks to subjects or others MUST be reported to the IRB. Examples of adverse events and unanticipated problems include:

- Unexpected illness or injury to a participant that was related to participation in the activity
- Failure to obtain informed consent/assent for a participant
- Breach of confidentiality

To report an adverse event or unanticipated problem, complete the adverse event reporting form (Word) found on the IRB website. Be sure to detail the facts surrounding the event, what steps were taken to address the problem, whether the problem is likely to happen again, and how you will prevent the problem from recurring.

Upon submission of the complete reporting form, the IRB will review the event and decide upon the best course of action. In the case of severe or frequent adverse events or problems, the IRB has the power to suspend a research project to ensure the safety of all participants.

6. **What should I do with all my research materials after my study is complete?**

Federal regulations require that all documents related to the subject's participation in your research be maintained for three years after your project is complete. This includes the consent forms that each participated signed. All documents should be stored in a secure location until three years after the study is concluded.