Policies and Procedures Manual
for Human Subjects
Institutional Review Board

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I. Function

The primary function of this administrative committee is to review, approve, and monitor research involving human subjects to ensure human subject research is being conducted in accordance with all federal regulations, institutional policies and ethical practices related to human subject treatment. In accordance with this charge the IRB reserves the right: 1) to define categories of research projects involving human subjects that are exempt from committee review, may have expedited committee review, and require full committee review; 2) to establish/monitor the use of The University's Guidelines for Research Involving Human Subjects; 3) to create/process application forms/procedures for review of proposed research projects; 4) to make decisions on the appropriateness of proposed research projects and require revisions from the principal investigators; 5) to establish/carry out periodic review procedures for approved research projects; and 6) to keep records of proposed and approved research projects.

All human subjects research conducted at the University must be reviewed and approved by the Institutional Review Board (IRB) prior to the start of the research.

The National Research Act Public Law 99-156, the Food and Drug Administration regulations published at 21 CFR 50 and 56, Health and Human Subjects regulations published at 45 CFR 46, The Health Research Extension Act of 1985, and the National Commission for the Protection of Human Subject of Biomedical and Behavioral Research provide guidelines for research with human subjects to ensure their protection in the design and conduct of research.

Based on these federal regulations, it is the responsibility of the Principal investigator to refer his or her project to the IRB for review whenever human subjects are being considered for research, even if the investigator does not consider the subjects to be at risk. The IRB chair will have the responsibility for determining what does or does not meet the criteria for exempt, expedited review or full review.

II. Review Process

A. IRB Chair and Membership

The Institutional Review Board at The University Findlay is comprised of the following voting members: two representatives from each college; one external 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; an appointed chair; and an appointed non-voting IRB research officer.

The leadership team may suggest to the VPAA additional temporary members on an as needed basis if it is determined the current board does not have the expertise required to review a particular proposal, ie. expertise in a particular method, topic of study or vulnerable populations. No study involving prisoners will be approved without a temporary prisoner representative as per HHS regulations.

The chair, vice chair and research officer will form the leadership team of the IRB and will serve as the liaison between the IRB and the Vice President for Academic Affairs, principal investigators and the community. They will ensure proper communication and exchange of ideas from the IRB to interested parties. This includes but is not limited to preliminary interpretation of HHS regulation, answering questions, reporting to the faculty, and communicating the slate of chair nominees and other concerns from the IRB to the vice president of academic affairs.

Chair: The Vice President of Academic Affairs, in consultation with the outgoing chair, vice chair, and research officer, reserves the right to appoint a chair who fulfills a minimal of three-years experience serving on an IRB committee, demonstrates an understanding of HHS policy and practices in regards to research involving human subjects, has a strong record of service, and has shown effective leadership through past practices. The chair will be selected from the upcoming year's IRB roster unless there are no members who meet the criteria above. The chair will serve a two-year term to convene on August 1st of the next academic year. At the will of institution, the chair can be reappointed for two subsequent terms.

The chair will call and conduct meetings and full reviews throughout the academic year. The chair will only vote to break a tie. Other duties of the chair include but are not limited to: 1) periodic review of policy changes; 2) oversee policy changes in collaboration with current IRB members; 3) train faculty reviewers; 4) work with IRB research officer in determining risk assessment, and communication with Principal Investigators; 5) act as a sounding board for risk assessment and questions faculty reviewers may have; 6) provide final approval of studies that do not fall under exempt status; 7) conduct mid- and end-year reports to the Committee on Committees; 8) aid in reviewing proposals that the IRB Research Officer flags as problematic; 9) serve on a research misconduct board in the event that research misconduct is presented to the IRB and/or university. 10) Provide a report to the Faculty Senate as requested to update them on the function of the IRB and facilitate communication between the faculty and the IRB. The IRB chair should be contacted to answer any further questions or to provide clarification concerning the policies or their implementation.

Vice-Chair: The position of Vice-Chair will be nominated and elected from the two representatives from each college by current and new members of the IRB at the last meeting of the academic year to commence duties on August 1st of the next academic year. The vice chair will serve a one-year term and can be re-elected for subsequent terms as long as he/she is a college representative of the IRB.

The vice chair will fulfill the chair duties in the absence of the chair. The vice chair will also act as chair in all matters related to an IRB proposal submitted with the current IRB chair as the principal investigator. The Vice Chair will determine final exempt status of proposals to ensure they meet the criteria and include basic protection of human subjects' rights.

IRB Members: Members of the IRB will complete all mandatory training required and related to both HHS regulations involving human subjects research and the policies and procedures of UF's IRB. Members will also: 1) attend all regularly scheduled IRB meetings; 2) provide detailed and thorough reviews of all assigned proposals in a timely manner; 3) provide campus colleagues with guidance related to protecting human subjects rights in research; 4) work with the leadership team to maintain IRB compliance with HHS

regulations by regulating regularly reviewing the IRB policy and procedure manual; and 5) prepare the slate of nominees for the IRB leadership team including electing the vice chair.

External Member: This position must be held by a person 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. The Vice President of Academic Affairs may select membership from the local community-at-large including: ministers, teachers, attorneys, business persons, or homemakers. The external member may serve one-year terms and can be reappointed for subsequent terms as long as he/she continues to have no affiliation with the institution as stated above.

Research Officer. The IRB Research Officer will be a professional staff member appointed and/or hired by The Vice President of Academic Affairs in consultation with the current IRB chair and vice-chair. The research officer will hold the position at the will of The University and will have no voting privileges.

The Research Officer responsibilities include but are not limited to: 1) assisting in the identification of initial level of risk (exempt, expedited, full-review); 2) assigning and managing faculty reviewer assignments; 3) tracking proposals submitted for IRB review from first submission through closer documentation; 4) corresponding with the PI regarding IRB requested revisions and amendments; 5) assisting with documentation and record keeping as required by HHS regulations; 6) assisting and facilitating wider university communications; and 7) preparing and posting meeting minutes.

The University of Findlay IRB Office is located within the Academic Affairs Office. All IRB forms, IRB Policy and Procedures Manual, and training materials are located online within the UF Intranet.

(Established 5 April 1994, Revised 17 Sept. 2007; Revised 1 Aug. 2012; Revised 4 Nov. 2013; Revised Feb. 2017)

B. Basic Principles

The fundamental responsibility of the IRB is to assure that all ethical issues have been fully addressed in the protection of human subjects who volunteer to participate in research studies. The Research Review Board members consider:

1) the risk-benefit relationship to the subjects,
2) the informed consent process and document(s) to be used appropriately, and
3) the importance of the knowledge expected to be gained through the research.

In addition, the IRB reviews the information to determine whether subjects are informed about the nature of the study, the details of their participation, and the voluntary nature of their participation, and whether the risks and benefits of the research are evenly distributed among the possible subject populations.

The risks imposed upon the subject vary with different types of research. There may be physical, psychological, social or ethical risks. There are two classifications of risk used in

determining standards of review. A subject is at minimal risk when the potential for harm is not greater, considering the probability and magnitude, than ordinary encountered in a daily life, or during the performance of routine physical or psychological examinations or tests, as determined by the general population. A subject is at significant risk when the potential for harm is greater, considering the probability and magnitude, than ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations and tests, as determined for the general population.

Each research project is approved by the Review Board for a fixed number of subjects and for a set period (one year). The maximum period between reviews is one year. An application form has been developed to facilitate re-approval of research projects while ensuring a complete review of the project.

C. Submission Deadlines

There are no submission deadlines for IRB review. If the proposal is determined by the IRB to be exempt or expedited, the screening process is ongoing. If the research project is determined to require a full IRB review, then the submission will be reviewed and discussed at a regularly scheduled IRB meeting at least two weeks after proposal submission. It the responsibility of the investigator to submit the IRB forms in a timely manner.

D. Screening Process

All oral and written correspondence to the IRB will be directed to the research officer. Researchers are encouraged not to contact committee members directly, and committee members are not permitted to discuss projects with any persons outside the committee, even the principal investigator. The chair and/ or research officer shall be responsible for all communication between the IRB and principal investigators.

All applications are screened by the IRB Research Officer for the presence of required supporting documents before the level of review is determined. If the application is incomplete or otherwise not fully prepared for IRB review, it is returned to the principal investigator for completion or additional information. The research officer may assist the chair in determining if the project is exempt from review, requires expedited review, or a full review (See section III for clarification). The research officer will then assign faculty reviewers. On occasion, the IRB chair or research officer may contact the principal investigator by phone or email requesting clarification of protocol issues or revisions in consenting documents. The chair may, at his/her discretion, refer the initial review of a research project to the another IRB member if he/she determines a) there is a conflict of interest among the investigator(s), or b) more appropriate expertise lies in the other IRB member(s). The vice chair will perform all duties normally assigned to the IRB chair for all IRB proposals submitted in which the current IRB chair is the principal investigator.

E. Notification

The Principal Investigator will be sent an acknowledgment letter and IRB identification number indicating their proposal has been received. The principal investigator will also receive a letter when the proposal is approved, or when specific modifications or additional

materials are required from the IRB. All communication will be between the research officer or IRB chair and the principal investigator. No recruitment or use of human subjects is permitted before IRB approval.

The IRB will send copies of the approval to the principal investigator who must be a full time faculty/staff member even if a student project. Following approval, the principal investigator is responsible for carrying out the project precisely as presented to the IRB. Any changes in the protocol, additional elements, or problems that arise in the course of the project, must be reported to and reviewed by the IRB before use of human subjects may continue.

F. Consent Requirements

The University of Findlay requires that all investigators secure consent for participation from either subject or the subject's guardian. This consent is to be secured under conditions which give the subject sufficient opportunity to make a considered judgment whether to participate or not, and which minimize the possibility of coercion or undue influence.

The intent of the informed consent is to ensure that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

For subjects under the age of 18, a consent form from the parent will be required. For those subjects ages 7-17, both an assent form and consent form from the parent will be required. (See appendix Pg. 29 for assent form template)

In all instances where a signed consent is utilized, a signed copy of the consent will be given to the subject, and another copy will be maintained as part of the permanent records for the project.

It is recognized that on rare occasions fully informed consent may have an injurious effect on the subject, or may invalidate the research. Such research may only be done after specific approval of the IRB and only if:

- incomplete disclosure is truly necessary for the research or to protect the subject; and;
- there are no undisclosed risks to the subjects which are significant risks (as defined above); and
- where appropriate, there is an adequate plan for debriefing subjects and disseminating research results to them.

The investigator always has the burden of proof when a project incorporates less than fully informed consent.

The voluntariness of participation is indicated in part by the subjects' consent. For some projects, a signed consent form is not appropriate, because that form will be the only identifying link between the subject and the data. Such projects may utilize an 'implied' consent paragraph. All other projects require written consent.

G. Implied Consent

Many research projects utilize retrospective cases, surveys or questionnaires as their data source and pose minimal risk to subjects. Federal regulations at 45 CFR 46.116(d) permit an IRB to approve a consent procedure that eliminates or alters the required elements of informed consent, or to waive the requirement to obtain informed consent altogether. In most cases, it is not necessary to record the data in such a way that respondents may be identified, because data are only reported in composite. The use of a signed consent form will, in the cases, be the only means of identifying a person as participating in a project, and will thus be the only potential basis for the risk of violating confidentiality and privacy. At the same time, persons have the right to be informed, and the right to refuse participation in a research project. In order to maintain these rights, and avoid the risk of violating these rights, an implied consent template has been developed and approved by the IRB. This template should be used in place of the informed consent if the researcher feels that their project meets the above description of minimal risk.

H. Consent Form

The signed, written consent form consists of two sections. The first section constitutes the 'informed' part of the form, that is, a brief statement of the nature of the project, its objectives, its potential benefits in general and possibly to the subject individually. In addition, there must be a complete description of the nature of participation by the subject. This means exactly what the subject will do and what (if anything) will be done to the subject. This section need not be longer than one to several paragraphs but should be complete enough to stand alone as having informed the subject about the nature of the project and what participation means.

In accordance with Federal regulations (45 CFR 46.116 and 46.117 and 21 CFR 50.25 and 50.27) and University of Findlay IRB policies, the following statements must be included in the consent form:

1. A statement to the subjects that the risks are minimized by the use of procedures consistent with sound research design that do not expose subjects to unnecessary risk.

2. A statement that indicates participation in the project is completely voluntary and that he or she may withdraw from the project at any time without explanation or penalty.

3. A statement that indicates informed consent is obtained from each prospective subject, or, where appropriate, from the subject's legally authorized representative.

4. A statement that indicates that the subject has received a complete explanation of the nature of the project and the latter is completely understood.

5. A complete, detailed listing of any and all risks associated with this participation, both immediate and long range. A complete listing of any and all benefits associated with this participation, including payments, gifts, extra credit for a course grade, etc.

6. It should be made clear whether such medical care for side effects will be with or without cost to the subject. A description of the medical measures that is available to the subject both immediately and beyond participation until the undesirable effects are eliminated if any illness or injury, ranging from discomfort to significant side effects should occur.

7. A statement indicating that the project director may discontinue the participation of any subject at any time. The conditions under which this action may be taken by the project director may be detailed or stated simply as, 'At the discretion of the project director.'

8. A listing or description of qualifications or disqualifications for participation by any subject in the project.

9. A statement indicating that all data collected will be kept confidential in that specific data will never be divulged in connection with the nature (or other identification) of a specific participant.

10. A statement to the effect that any questions relevant to the project asked by the subject will be answered, and the name and phone number of the person to contact for information.

11. In projects involving administration of medication, there should be a detailed description of the protocols for the administration of the medication, diagnostic procedures to be used to establish eligibility of a subject for participation, complete enumeration of the side effects from the medication including possible severity and risk to health as well as medical services to be available to the subject until the side effects have disappeared. Conditions that would contraindicate the administration of the medication involved should also be described.

12. A statement to be followed by the subject's signature indicating that the signature means that the subject understands the project, the nature of his or her participation, the possible risks involved and the other information on the sheet. A statement that the subject is 18 years of age or older, or if not that, consent is being given by a parent/guardian for a minor.

In order to maintain these rights, and avoid the risk of violating these rights, an informed consent template has been developed and approved by the IRB. The consent template is available in the Appendix, page 26. This template provides specific guidance on how the forms should be worded and ordered.

I. Deception

Deception is the intentional misleading of a subject or participant by providing incomplete, misleading or false information. It may be used in social or behavioral research to collect an unbiased response from subjects. Deception presents a challenge to the informed consent process. Deception should only be used when there are no alternative to collect the required data.

Deception may only be permitted where there is documentation that an alteration of the usual informed consent requirements is justified under the criteria presented in federal regulations at 45 CFR 46.116(d). Specifically, the IRB must find and document that all four of the following criteria have been satisfied:

1. The research presents no more than minimal risk to participants.
2. The alteration will not adversely affect the rights and welfare of the participants.
3. The research could not practicably be carried out without the alteration.
4. Where appropriate, the participants will be provided with additional pertinent information after participation.

Research involving deception may not be considered exempt from review. It will undergo either an expedited or full review depending on:

1. the nature of the deception
2. the degree of risk to the subject
3. the vulnerability of participants
4. whether the proposal in its entirety meets the requirements for expedited review

Principal investigators must include the following information in the Disclosure section of the IRB proposal.

1. Justification for why deception is necessary for completion of the research.
2. Explain all risks the subjects may face as a participant in the study related to deception. Will the deception upset or inflict any harm to the subject?
3. A full explanation of the debriefing process, including who, when, and how the subjects will be debriefed. Include a debriefing script or handout which will be used. If any aspects of the study will not be revealed to subjects include this information and why it will not be released as well.
4. Provide subjects an option to have their data removed after the debriefing process.

J. Confidentiality of Data

Confidentiality of data is presumed in all research involving human subjects, and must be maintained unless the investigator obtains, via the consent form, specific permission of the subject to release the information.

III. Types of Research

Definition of research according to the Department of Health and Human Services (DHHS) is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Examples include pilot studies, chart reviews of more than 3 patients, comparative studies, survey studies, medical intervention studies, and activity to refine research tool in preparation for study. The Research Determination form is available in the Appendix page 20.

A. Exempt Research

A proposal may be considered exempt from IRB review, if one of the conditions below are met. Exempt from review status can only be determined by the IRB chair or vice chair after submitting a complete IRB proposal. The IRB will still require insurance of basic human subject rights protection.

Criteria for Exempt from review status:

- Research developed for a **specific class project** with no intent to publish and disseminate the results publically. The project must meet the IRB guidelines to be classified as either less than minimal risk or minimal risk. In the absence of an IRB approval the faculty supervising the classroom project is liable.
- A retrospective chart review of less than or equal to **3 patients**.
- Research conducted in established or commonly accepted educational settings, involving **normal educational practices**.
- Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures, interview procedures or observation of public behavior, unless:**
    - human subjects can be **identified**, directly or through identifiers,
    - any disclosure of the human subjects' responses outside the research could reasonably place the **subjects at risk** of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
    - the human subjects are **elected or appointed public officials or candidates for public office**
    - **federal statute(s) require(s)** without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter (HIPAA, FERPA, etc).
- Research involving the **collection or study of existing data, documents, records,** if these sources are publicly available or **subjects cannot be identified**, directly or through identifiers linked to the subjects.
- Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
    - **Public benefit or service programs**;
    - procedures for obtaining benefits or services under those programs;
    - possible changes in or alternatives to those programs or procedures
    - possible changes in methods or levels of payment for benefits or services under those programs.
- **Taste and food quality evaluation and consumer acceptance studies**
    - if wholesome foods without additives are consumed
    - 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.

There is no submission date for less than minimal or minimal risk studies that meet the category of exempt research. One electronic copy with signatures (include a hard copy of

signature page if the proposal if signatures are not available in the electronic copy) of the following should be submitted:

1) Completed *Application for Investigator's Summary Description of Research Involving the Use of Human Subjects* form (IRB Proposal human 2013.doc)
2) Supporting documents

Following the review of materials submitted, the investigator will receive documentation of exempt status from the IRB. No further action or IRB responsibility is required, as long as the study remains the same. However, the investigator must inform the IRB of any changes (i.e., confidentiality, consent, sample population) to determine whether the classification of the study remains the same or changes from expedited into full review. Must inform IRB when study is completed or yearly progress report.

B. Expedited Review

There is no submission deadline for minimal risk studies that meet the criteria of expedited review. If the IRB chair assigns the protocol to expedited review, one electronic copy with signatures of the following should be submitted

1) Completed Application for *Investigator's Summary Description of Research Involving the Use of Human Subjects* form
2) Consent form

The completed form will be reviewed by one or more IRB members. In most cases, approval for minimal risk research will remain in effect for one year. It should be understood that the approval of the research will be presented as information only to the full IRB committee. Any member may request a full committee review. If, in the rare case that the IRB subsequently determines that the study requires full board review, the investigator will be notified and approval will be temporarily suspended if necessary.
Must inform IRB when study is completed or yearly progress report.

C. Full Review

The deadline for submission of research protocols for IRB review is two weeks before the scheduled meeting. If the IRB chair assigns the protocol to full review, one electronic copy with signatures of the following should be submitted:

1) Completed Application for *Investigator's Summary Description of Research Involving the Use of Human Subjects* form
2) Consent form
3) Financial obligations and incentives (i.e., costs to the subject or incentives for participation)
4) References

D. Student Projects

Student research projects will be reviewed using the same criteria as for any other project. All projects must have a faculty advisor who takes responsibility for approval and monitoring of the project and this person must be listed at the Principal Investigator (PI). All projects must be approved by the appropriate faculty committee(s), as determined by programs or college policies, before submission to the committee for review. At the University level, a research project involving human subjects is not considered approved until IRB has given approval.

E. Instructional Projects Using Human Subjects

In a number of program areas across various colleges, it is customary for undergraduate/graduate courses to incorporate small projects that have many characteristics of research, and involve using other persons as project resources. These projects, however, have as their usual purpose the provision of student opportunity for developing familiarity with means of investigation customary to the various disciplines. The process of such projects aims not at the collection of data for its own sake, but instead at the development of student knowledge and skills independent of those data. To the extent that courses involve projects with this intention - which would not later be used as part of a research project and which do not put persons at risk - such projects do **not** need to be submitted to the IRB for approval. Instead, the responsibility will be placed by the IRB on the College and faculty so that such projects are carried out in a manner which protects human subjects. The Research Determination form is available in the Appendix pg. 20.

IV. IRB Decisions

Most funding agencies (private or federal) and many avenues for dissemination (conferences, journal, etc) will not review an application without the appropriate approvals in place. The chair will convey one of the following decisions of the IRB in writing to the principal investigator:

Approval: If a study is approved as submitted, a letter of approval is sent to the principal investigator listing the investigator's responsibilities and stating the date and duration of approval.

Pending: If a study approval is pending approval of minor revisions (i.e, consent form changes that would not affect subject's safety), a letter is sent to the principal investigator requesting these changes. Subjects may not be enrolled in the study until the requested revisions are made. The Chair may approve the study upon receipt of the revisions without further action by the IRB. After the Chair's approval, a letter is sent to the principal investigator listing the investigator's responsibilities and stating the date and duration of approval.

Tabled: More substantive issues regarding the protocol and/or consent form must be addressed. Clarifications or requested revisions may have a significant impact on subject safety or understanding. A letter is sent to the principal investigator requesting that these

issues be addressed. The revisions will be returned to the original reviewers for consideration and then forwarded to the IRB for approval.

Denied: Questions regarding the rights and welfare of the subjects are of such significance that the Board feels approval of the study be unwarranted.

V. HIPAA Authorization Regulations

According to HIPAA requirements outlined in 45 CFR 164.508 (.pdf), researchers should obtain written authorization from subjects before using or collecting protected health information. Authorization should be obtained in writing from prospective subjects.*

Under HIPAA, the following core elements and statements must be included in the authorization document. Attached is a template authorization form for your guidance. The forms are available in the Appendix pages 42-46.

1. A description that identifies the individually identifiable protected health information (PHI) to be used/disclosed in a specific and meaningful fashion (e.g., list the types of data to be collected from the medical records);
2. The name of the person(s) or class of persons to whom the covered entity may make the requested use or disclosure (e.g., research must list all of the entities that might have access to the study's PHI such as research related personnel in the department of ____, UF IRB, BVHC, Food and Drug Administration, DHHS, Biosafety Committees, Data Safety and Monitoring Board or any others given authority by law);
3. A description for each purpose of the requested use or disclosure (e.g., list purpose of research, list reason(s) why the PHI will be collected);
4. An expiration date or an expiration event that relates to the use or disclosure (e.g., length of time researchers plan to maintain the data). The statement "end of research study," "none," or similar language is sufficient;
5. A description of how the individual may revoke the authorization and the exceptions to the revocation; or a copy of the Privacy Notice which explains how to revoke the authorization and the exceptions to the revocation (e.g., HIPAA gives subjects the legal right to revoke authorization. The subjects must be told how they can withdraw. Any request for revocation must be in writing. Also, the subjects should be told that if they do revoke, that they can no longer participate in the research and that researchers may use the PHI already obtained to maintain the integrity of the data.);
6. A statement that a subject's treatment, payment or enrollment in any health plan or their eligibility for benefits will not be effected if they refuse to sign the authorization;
7. A statement that the subject may not participate in a research study if they refuse to sign the authorization;
8. An explanation that information disclosed pursuant to the authorization may no longer be protected when re-disclosed by the recipient (e.g., if the researchers disclose the information collected to a third party then the HIPAA protections may no longer be in place);

9. A signature of the individual and date. If a personal representative signs the authorization, a description of the representative's authority must be provided;
10. Optional item: Under HIPAA, subjects have the right to access their PHI. In research, the right (to research related PHI) can be suspended while the research is in progress. However, subjects must be told in the authorization that this right (to research related PHI) has been suspended and the conditions of the suspension must be listed. The subjects should also be informed that their right to access the research related PHI will be reinstated at the conclusion of the research study;
11. The authorization must be written in plain language not to exceed a 7th grade reading level;
12. The subject must be given a copy of the **signed** authorization.
13. **NOTE:** For VA subjects, it is the responsibility of the PI to place the ORIGINAL Form 10-1086, signed by the subject in the subject's medical record. A COPY is to be placed in the investigator study file under conditions of confidentiality. The same rule applies to the disposition of the authorization document. The original copies of both the Form 10-1086 and the authorization document must be filed on the left-hand side of the VA subject's medical record in the *Progress Notes* section.

VI. Appeals Process

Principal Investigators may appeal The University of Findlay IRB's decisions or determinations by requesting a second review by the full IRB committee. The membership of the IRB committee will be those individuals on the committee at the time of the request. To initiate the appeals process, the PI must notify the IRB chair in writing of their intent to appeal the IRB committee's decision within 7 calendar days of notification of the decision. The IRB will then have 14 calendar days to request additional information/clarification from the PI and schedule a meeting between the PI and the current IRB committee. The meeting will provide an opportunity for the PI to elaborate on the portions of the proposal that were considered unacceptable by the committee. The PI may invite no more than 2 additional specialists/experts/advocates to assist in their appeal. At the conclusion of the meeting, the IRB committee will consider the information presented, deliberate and vote in private. The decision will be determined by a majority. If there is a tie, the current IRB committee chair will make the final decision. The decision of the committee is final and will be communicated in writing to the PI within 7 calendar days of the meeting.

VII. Annual Review of Active Research

Approved research projects must be reviewed at least annually. At the end of each academic year, the IRB will meet to review all research projects. The secretary sends each principal investigator a reminder letter and application form eight weeks before project expiration (see page 49). The application form and required supporting documents should be completed and submitted to the committee for review at least four weeks prior to the expiration date of the last approval. If these timelines are met, the chair or committee should be able to review the application so that approval is renewed before the expiration date of the project. **If you do not receive re-approval before the study's expiration date, your study will be automatically suspended and you must refrain from enrolling any subjects in your study until you receive formal notice of re-approval.**

If the chair determines that the annual review is expeditable, copies of the renewal protocol and cover page, and original protocol approval letter will be circulated to all members of the IRB. Any member may request a full committee review. If full committee review is not requested within ten days, the research project will be approved by the IRB chair or at the next convened meeting of the full committee if the meeting falls within ten days of distribution. An approval letter will be mailed to the principal investigator.

If a full committee is requested, the chair shall assign the review to either a committee member or to the full committee. If the chair assigns the review to a committee member, then copies of the renewal protocol, original protocol and approval letter, and a protocol review form are sent to the reviewer. Copies of these forms are also sent to all other IRB members. If the chair assigns the review to the full committee, approval of the annual review may be granted only after review at a convened IRB meeting and the affirmative vote of a majority of the quorum present.

VIII. Adverse Event

The FDA regulations require reports of serious, unexpected adverse events that are associated with the research project to be made as soon as possible but not later than 15 calendar days after the event. Additionally, FDA requires telephone notification of any unexpected fatal or life-threatening experience associated with use of an intervention, followed by a written report within 7 calendar days.

The University of Findlay accepts these reporting guidelines as appropriate standards for its own policy on reporting adverse events. Therefore, an adverse event that is both serious and unexpected, and related to the study must be reported to the IRB when it occurs. Events that meet these conditions must be reported within 15 calendar days unless they are life-threatening or they result in death, in which case notification of the event must be given immediately. This immediate notification must be followed by a written report filed within 7 calendar days.

For events that do not meet all of the above criteria, investigators should consolidate these into the Adverse Event form and a summary report to be submitted at the time of continuing review to the IRB Office. Any unanticipated problem or other experience that impacts the safe conduct of the study should be reported promptly to the IRB. The Adverse Event form can be obtained on page 40 of the Appendix.

The IRB will review the Adverse Event report to determine whether a revision to the protocol and/or consent form is warranted to protect human subjects. This review does not relieve the investigator from the responsibility for ensuring that studies are always conducted in a safe manner and that occurrence of adverse events are considered as the study proceeds.

IX. Completion of Research Project

When the project is completed, the investigator must submit a Project Completion form and a brief summary report to the IRB Office. The brief summary report includes the number of subjects involved, the duration of subject usage, and a summary of the project results. In

addition, if a code book (or list) was utilized to protect confidentiality, it must either be destroyed or turned into the chair of the IRB for archiving. The Project Completion form can be obtained from the page 33 of the Appendix.

X. IRB Files

The IRB maintains a permanent file of complete records on all projects. Both graduate and undergraduate projects will be housed at the IRB Office within the Academic Affairs Office.

XI. Outside researchers recruiting subjects on The University of Findlay's campus

Researchers not affiliated with The University of Findlay may wish to recruit University community members as subjects in research projects. This includes individual subject recruitment or group recruitment. **This policy is intended to include data collected for research purposes only.** Requests for data for other purposes (ie, program ranking, advertising, government agencies, etc) are not under the jurisdiction of the IRB. If you have questions related to non-research project type of requests please contact, the Office of Academic Affairs or Office of Student Affairs, as appropriate.

In the case of **individual subject recruitment** (you are being asked individually to volunteer as a subject), we ask members of the University community to use their best judgment and consider the components of informed consent, host IRB approval , etc. in deciding to participate in any research study as an individual. The IRB has no jurisdiction over your right to participate or not participate in any research study as an individual.

In the case of **group subject recruitment**, if subjects are being recruited for general population parameters, ie. college students in X major without specific mention of The University of Findlay, we ask members of the University community to use their best judgment and consider the components of risk level, informed consent, host IRB approval , etc. in deciding to assist outside researchers in subject recruitment on UF's campus.

- Review the instruments, data collection procedures, etc and use your best judgment on whether the following conditions are met:
    - Project is approved by the host institution's IRB
    - Project is less than minimal risk or minimal risk
    - If these conditions are met you may forward any recruitment materials to relevant individuals if you choose.

In the case of **program data recruitment** (you are being asked individually to provide program, department, etc. level data), in which The University of Findlay will **not** be identifiable in any published project, we ask members of the University community to use their best judgment and consider the components of informed consent, host IRB approval, etc. in deciding to participate in any research study.

- Review the instruments, data collection procedures, etc and use your best judgment on whether the following conditions are met:
    - Project is approved by the host institutions IRB
    - Project is less than minimal risk or minimal risk

- If these conditions are met you may participate in the project if you choose.

In the case of **identifiable subject recruitment** (if subjects are being recruited as part of the UF community, UF will be identifiable in data collected). The project must be approved by the UF IRB. If you are recruited for this type of study please contact the IRB chair and/ or forward any communication from the researcher.

In case of **studies involving greater than minimal risk, other than individual recruitment,** (group recruitment, program data or identifiable subjects). The project must be approved by the UF IRB. If you are recruited for this type of study please contact the IRB chair and/ or forward any communication from the researcher.

Appendices

University of Findlay

Institutional Review Board
Human Subjects Research Determination Worksheet

- If your activity involves the use of animal subjects please contact, the Chair of the Institutional Animal Care and Use Committee for assistance.
- This worksheet is a guide to help the investigator determine if the activity is human subject research and regulated by the Department of Health and Human Services (DHHS).
- Activities that meet the definition of human subject research will require submission of an IRB application to the UF IRB
- The worksheet does not have to be submitted to the IRB.
- If your activity does not meet these guidelines, but you (or another entity) would like your project reviewed, please submit it using the current IRB procedure.
- If you have any questions about this worksheet or the nature of your project please contact your college IRB representative. We are happy to answer any questions you have. (IRB representatives can be found on the IRB Blackboard site)

Review the following questions to determine whether an activity is human subject research under 45 CFR 46, and requires submission of an ***IRB Application*** to the UF IRB.

A. Does the research meet the DHHS definition of "research?" Check either 1 or 2 below as the appropriate description of the activity:

1. ☐ **A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.**

Ex.: - pilot studies
- chart reviews of more than 3 patients
- comparative studies
- survey studies
- medical intervention studies
- activity to refine research tool in preparation for study

If the activity is a systematic activity as described above, the activity meets the definition of "research" under the DHHS regulations. ***Continue to Question B.***

2. ☐ **NOT a systematic investigation designed to develop or contribute to generalizable knowledge**

Ex.: - Research developed for a **specific class project** with no intent to publish and disseminate the results publically.
- Research conducted in established or commonly accepted educational settings, involving **normal educational practices**.
- Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures, interview procedures or observation of public behavior, unless:**
  - human subjects can be **identified**, directly or through identifiers,
  - any disclosure of the human subjects' responses outside the research could reasonably place the **subjects at risk** of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- the human subjects are **elected or appointed public officials or candidates for public office**
- **federal statute(s) require(s)** without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter (HIPAA, FERPA, etc).

- Research involving the **collection or study of existing data, documents, records,** if these sources are publicly available or **subjects cannot be identified**, directly or through identifiers linked to the subjects.
- Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
  - **Public benefit or service programs**;
  - procedures for obtaining benefits or services under those programs;
  - possible changes in or alternatives to those programs or procedures
  - possible changes in methods or levels of payment for benefits or services under those programs.
- **Taste and food quality evaluation and consumer acceptance studies**
  - if wholesome foods without additives are consumed
  - 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.

If the activity is NOT a systematic investigation designed to develop or contribute to generalizable knowledge, the activity does not meet the definition of research under the DHHS regulations.

B. Under the DHHS regulations "human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(i) data through intervention or interaction with the individual, or

(ii) identifiable private information.

1. Does the activity involve a living "human subject" under the DHHS definition? If yes, indicate whether the subjects are living by checking below.

☐ At least one, if not all, of the subjects are alive.
If at least one of the subjects is living, the activity involves a "human subject" under the DHHS regulations. ***Continue to Question C.***

☐ None of the subjects are living.
If none of the subjects are living, the activity ***does not*** *involve a human subject under the DHHS regulations. The activity may require compliance with HIPAA.*

C. Indicate the type of information the activity will collect about the subjects by checking items 1, 2, and or 3 below:

1. ☐ Activity involves obtaining data through interaction or intervention with the subjects. This activity includes interviews (in person or not), surveys, physical procedures, manipulations of the subject's environment, and any other direct contact or communication with a subject.

2. ☐ Activity involves obtaining private identifiable information about the subject. This activity includes chart reviews, lab studies on tissue/specimens, using information from data or tissue repositories. *The activity may require compliance with HIPAA.*

If you have checked off 1 or 2 above, the activity is collecting human subject research information under the DHHS regulations. An IRB application should be submitted to the UF IRB.

3. ☐ Activity involves use of de-indentified data, information, tissue or specimens obtained from a data repository and for which the investigator has **no access to a code or link to re-identify the source** of the data, information, tissue or specimens.

If you have checked off only ***3****, above, then the research* ***does not*** *involve obtaining human subject research information under the DHHS regulations.*

University of Findlay

Office Use Only
Project # _____
_____ Exempt Review
_____ Expedited Review
_____ Full Review

Institutional Review Board

Investigator's Summary Description of Research
Involving the Use of Human Subjects

PROJECT TITLE:	
SUBMISSION DATE:	**PROPOSED START-UP DATE:**
COLLEGE/DEPARTMENT:	
FUNDING AGENCY:	
PRINCIPAL INVESTIGATOR (PI):	
PI CONTACT (PHONE, E-MAIL, ADDRESS):	
STUDENT/SECONDARY INVESTIGATOR(S) (SI):	
STUDENT/SI CONTACT (PHONE, E-MAIL, ADDRESS):	
TYPES OF DATA (*Choose All That Apply*)	**REASON FOR RESEARCH CONDUCTED**
____ Primary Data ____ Secondary Data _____ Hospital/Clinic chart review _____ Purchased Data Base _____ Other	____ Faculty Research ____ Undergraduate Course Number: _____ ____ Graduate Course Number: _____ ____ Master Project/Thesis/Dissertation: _____ ____ Other:_____
TYPE OF RESEARCH *(Choose One)*	
____ Quantitative ____ Qualitative ____ Mixed-Methods	
RESEARCH DESIGN *(Choose One)*	**RESEARCH INVOLVES EXTERNAL ORGANIZATION**
____ Experimental ____ Quasi Experimental ____ Non-Experimental	____ No ____ Yes: _____ (Approval Documentation Must be Provided)

I hereby certify that upon approval of this proposal by the IRB, no changes will be made without approval of the IRB, and that any problems, adverse reaction, or unforeseen conditions encountered in the use of human subjects will be immediately reported to the Chair of the IRB. I further agree to supply the IRB with all requested reports and a Certificate of Compliance upon completion of the project.

_____ _____
Principal Investigator's Signature Date

_____ _____
Student Researcher's Signature Date

_____ _____
Program Director's Signature Date

_____ _____
IRB Chair's Signature Date

The IRB approval of the research project is for a period of one year.

University of Findlay IRB Proposal

Consent/assent forms, instruments, recruitment material and other requested documentation to be attached as appendixes to this proposal

1. Project Introduction/Overview

Please provide your statement of purpose, significance of study, and relevant supporting literature

2. Research Question and/or Research Hypothesis

Please provide concise answers

3. Setting ☑*Is the study conducted in, or recruited from the following categories?*

____ Schools (private/public P-12) ____Hospital/Clinic ____ College ____ General Public ____Other

Please describe setting used:

4. Subjects

a. Characteristics of Subject Group ☑*Are any of the subjects in the following categories?*

____ Pregnant ____ Fetus ____ Children ____ Mentally Impaired ____ Legally Restricted ____Other

Please describe subjects used:

b. Health of Subject Group ☑*Check the physical and mental health of the subjects for inclusion in this study.*

Physical Health: ____ Poor ____ Good ____ Excellent ____ Unknown

Mental Health: ____ Poor ____ Good ____ Excellent ____ Unknown

Please state the necessity of using these particular groups:

c. Subject Inclusion Criteria:

Please provide concise and complete inclusion criteria:

d. Subject Exclusion Criteria:

Please provide concise and complete exclusion criteria:

e. Recruitment of Subjects: ☑*Check which one applies to the recruitment of your subjects.*

____ Recruitment of UF class, students, or personnel ____ Outside agencies, schools, organizations, or data base ____ Open call for particpants (general public)

Please describe how you will recruit participants and attach copies or script (if recruiting orally) of the recruitment material (e.g. flyers, advertisements, letters, etc.):

f. Sampling Plan: ☑*Check which one applies.*

____ Random Sampling ____ Stratified Sampling ____ Convenience Sampling ____ Other

Please provide a rationale for your sampling plan:

g. Sample Size

Please provide the total number of expected participants and rationale.

5. Instruments (Attach all instruments to be used)

Please describe all means used to collect data and attach the instruments to be used (e.g. interview questions, surveys, assessments, etc.):

6. Procedures

Please describe the procedures used to collect data based on identified instruments and total time investment of the participant:

7. Analysis

Please describe how you will analyze the data collected:

8. Risk to the subjects

☑Identify the following risk categories and your perception of the level of risk involved

Please note that Health & Human Services (HHS) states that there is always risk to the subject and have defined the categories of risk as follows.

____ Physical ____ Psychological ____ Social ____ Legal ____ Economic

Please describe the risk in detail:

Perceived level of risk _____ Less than minimal ____ Minimal _____ Greater than Minimal

9. Mitigation of Risk to the Subject

a. Researcher Mitigation

Please describe how the researcher will try to mitigate the risk (a mitigation has to be supplied for every identified risk):

b. Research Gain

Please describe the importance of the information gained in relationship to the risk:

c. Equity and Equality

Please describe how the researcher will ensure equity and equality for the participants:

10. Compensations and Benefits

a. Are you offering any compensations to individuals for participating in your study? ____ Yes* ____ No

If yes, please describe:

b. Benefits to individual

Outside of any compensation offered what are the benefits for the individual for participating?

c. Benefits to society

How will participating in this study benefit society?

11. Consent Procedures

Federal regulations require precautionary measures to be taken to insure the protection of human subjects on physical, psychological, social, economical and other issues. This includes the use of "informed consent" procedures.

a. Type of Consent	*☑Which one(s) applies to your study?*
____ Oral Consent	*Script must be provied with short consent form*
____ Written Consent	*Long Consent forms must be provided; please use our long consent template.*
____ Assent _____ Oral _____ Written ____ Parent Consent/Permission	*In conjunction with parental consent for children 7-17.* *Assent form should be a Flesh-Kicaide reading grade level 5-7.*
____ Implied Consent Waiver*	*Consent description must be provided; please use our implied consent template.*
____ Secondary Data Waiver*	*Consent was given: 1) to hospital/clinic upon initial collection under HIPPA guidelines and study does not necessitate additional consent or further contact with human subject; 2) data purchased has been scrubbed of all human subject identifying features and contact information; or 3) data is part of public domain. No further documentation needed.*

** If requesting a waiver please give rationale for waver request.*

b. Are your subject(s) minors or mentally impaired? ____ Yes* ____ No

*If yes, Please describe how and by whom permission will be granted. *Subject Assent form must accompany Parent/legal guardian's Permission/consent form.*

c. Do subject(s) have a cognitive limitation/impairment and/or a language/literacy barrier? ____ Yes ____ No

Please describe the limitation/impairments and/or barrier and how you plan to ensure participants understanding for informed consent.

d. Will subject(s) be provided copies of all consent documentation including implied consent description? ____ Yes ____ No

If consent/assent documentation is not provided to participants please justify why.

12. Disclosure *☑Check which one applies.*

Federal regulations require precautionary measures to be taken to insure the protection of human subjects on physical, psychological, social, economical and other issues. This includes the use of "informed consent" procedures.

____ Full-disclosure ____ Less than Full Disclosure ____ Necessary Deception

Please describe how you will disclose the study to the participants. If less than full disclosure or necessary deception is chosen, please justify the need for such action. All studies using less than full disclosure or necessary deception must provide a debriefing script or handout explaining to the participants the true purpose of the study and need for deception.

13. Data Confidentiality

a. Does this data fall within: _____ Public Domain *(Ex: public record document, public access documents, court transcripts, etc.)* ____ Confidential Domain *(Ex: data only accessible by through permission of the institution and/or subject being studied)*

b. Data Access

*Please describe **all parties** who will have access to the data.*
Please provide (in an attachment) evidence of human subject training/confidentiality agreement for those who have access.

c. Subjects' anonymity/confidentiality

How do you plan to protect the individual subjects' anonymity/confidentiality?

d. Data Storage

How, where and for how long will the data be stored? (Please not that for IRB purposes all data must be stored for a minimal of three years.)

e. Data Deletion

How will the data be destroyed? (Please address all data sources, e.g. video, audio-visual, interview, questionnaires, consent forms, electronic data, etc.)

14. HIPAA (Health Insurance Portability & Accountability Act)

If you answer "Yes" to any of the following questions, your project is subject to HIPAA and you must complete the HIPAA Supplement (available Research and Grants Office and IRB CD) and attach it to the application.

____ Yes	____ No	Will health information be obtained from a covered entity (a health plan, health care clearing house, or a health care provider who bills health insurers (e.g. hospitals, doctor's offices, dentists, the UF Student Health Center, UF Counseling Services, etc.)?
____Yes	____ No	Will the study involve the provision of health care in a covered entity?
____ Yes	____ No	If the study involves the provision of health care, will a health insurer or billing agency be contacted for billing or eligibility?

Institutional Review Board

Adult Research Consent Form

Instructions to PI: ***Please replace red placeholder text within bracket areas as indicated and remove the directions following each section before submission. **Please write the consent to address the subject.***

DATE: [Insert *planned* date of study commencement here.]

PROJECT TITLE: [Insert title here (must match title on approved IRB proposal).]

PRIMARY INVESTIGATOR(S) AND CO-INVESTIGATORS: [Insert PI and Co-investigator names, email addresses, and office phone numbers.]

PURPOSE OF THE STUDY: [Insert explanation of why the study is being conducted here.]

DESCRIPTION OF STUDY PROCEDURES: [Insert description of procedures here, using special care to ensure it is understandable to all readers.]

DURATION/TIME ASSOCIATED WITH YOUR INVOLVEMENT: [Insert description here.]

POTENTIAL RISKS OR DISCOMFORTS: [Insert description of physical, legal, economic, psychological, and other risks or discomforts possible with respect to participation in this study.]

POTENTIAL BENEFITS: [Insert description of non-financial benefits to participation here.]

PROJECT ALTERNATIVES TO PARTICIPATION IN THE STUDY: [Insert description here.]

CONFIDENTIALITY OF DATA: [Insert description here.]

COSTS AND/OR COMPENSATION FOR PARTICIPATION: [Insert description here.]

CIRCUMSTANCES FOR DISMISSAL FROM THE STUDY: [Insert description here.]

COMPENSATION FOR INJURY: [Insert description here.]

CONTACT PERSONS: For more information concerning this research, please contact [PRINCIPAL INVESTIGATOR at OFFICE TELEPHONE NUMBER]. If you believe that you may have suffered a research related injury, contact [PRINCIPAL INVESTIGATOR at OFFICE TELEPHONE NUMBER]. If you have further questions about your rights as a research subject, you may contact:

IRB Chairperson
The University of Findlay
Findlay, OH 45840
419 434-4640
irb@findlay.edu

VOLUNTARY PARTICIPATION: Participation in this study is voluntary. You are free to participate or to withdraw at any time, for whatever reason. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner. If you choose to withdraw, you may request that your data which has been collected be destroyed when possible.

[Note to investigators, please include if applicable:
For medical studies, state that the subject does not risk loss of present or future care they would otherwise receive.

For studies with students, state that the subject does not jeopardize grades nor risk loss of present or future faculty/school/university relationships.]

NEW FINDINGS: You will be notified of any new information that may change your decision to be included in this study, should any new information become available when possible.

CONSENT: Federal regulations require precautionary measures to be taken to insure the protection of human subjects on physical, psychological, social, and other issues. This includes the use of "informed consent" procedures. Please read carefully.

I, _____ (PRINTED NAME OF SUBJECT) have been adequately informed regarding the risks and benefits of participating in this study. My signature also indicates that I can change my mind and withdraw my consent to participate at any time without penalty by contacting the study contact person designated above. Any and all questions I had about my participation in this study have been fully answered.

SUBJECT SIGNATURE:_____

DATE

I have witnessed the consent process and believe the subject has been fully informed, understands the research study, and has agreed to participate in the study.

WITNESS PRINTED NAME:_____

WITNESS SIGNATURE:_____

DATE

YOU WILL BE GIVEN A SIGNED COPY OF THIS FORM TO KEEP.

Institutional Review Board

Implied Consent Form

[Date]

Dear [Participant],

You are invited to participate in a study of [*state what is being studied]*. We hope to learn more about [*state what the study is designed to discover or establish]*. You were selected as a possible participant in this study because [*state why and how the subject was selected]*. If you decide to participate, please complete the enclosed survey. Your return of this survey constitutes implied consent. The survey is designed to [*explain purpose of survey]*. It will take you about *[length of time expected to complete survey]* to complete. No compensation will be provided to you for answering the survey, but your responses will be used to [*explain research benefit]*. Any discomfort or inconvenience to you will not exceed the time taken to complete the survey.
Information that is obtained via this study and that can be identified with you will remain confidential and will not be disclosed. Your decision to participate (or not) will not prejudice any future relationships with The University of Findlay. If you decide to participate, you are free to discontinue participation at any time without prejudice. You will be made aware of any information that varies from what has been provided to you and/or might affect your willingness to continue to participate in the study.

This survey and consent waiver have been approved by Institutional Review Board at The University of Findlay which works to ensure that all research involving human subjects follows applicable federal regulations. If you have any questions about your rights as a human subject please contact the IRB chair, at irb@findlay.edu.

We may submit the results of this study for publication. Participant data will be destroyed 3 years after publication. If you are interested in the study results, please email the primary investigator (PI) to request this information. Please keep a copy of this email for your records. If you have any questions regarding this study feel free to contact [*insert PI name]* at [xxxxx]@findlay.edu or 419-[XXX-XXXX].

[Student researchers may want to include a paragraph such as "This project is being completed as part of graduation requirements for our [insert degree]. If you have any questions about our project you may contact us insert SI names and email addresses or our research adviser, [insert PI name and email address.]"

Thank you for your time.

[PI and SI names]

RESEARCH ASSENT FORM

Required for children 7-17 years old

Project Title:

IRB #:

Sponsor: *[delete if not applicable]*

Principal Investigator:

Date:

We want to tell you about a research study we are doing. A research study is a way to learn information about something. We would like to find out more about *[insert purpose of study in simple language]*. You are being asked to join the study because [*insert name of medical condition or other reasons for inclusion]*.

If you agree to join this study, you will be asked to
[Describe procedures, (e.g., blood work, questionnaires, medication) in words a child would know and understand. Also, include number of visits and time frame in words easily understood by a child].

[Describe possible risks, e.g., discomforts and/or side effects in simple language].

We do not know if being in the study will help you. We may learn something that will help other children with *[insert name of medical condition or subject matter of study]* some day.

You do not have to join this study. It is up to you. You can say okay now, and you can change your mind later. All you have to do is tell us. No one will be mad at you if you change your mind.

Before you say yes to being in this study, we will answer any questions you have.

If you want to be in this study, please sign your name. You will get a copy of this form to keep for yourself.

_____ _____

(Sign your name here) (Date)

University of Findlay

CONSENT FOR A MINOR TO ACT AS A HUMAN PARTICIPANT
Parent/Legal Guardian permission form

Directions:

This is a template for the long form for obtaining informed consent/permission from a parent or guardian for a child's participation in research. Insert your information in the bracket areas as indicated and remove the directions from the template in each section.

Project Title:

Principal Investigator:

Participant's Name:

What is the study about?
[This section should include a statement that the study involves research, the purpose of the study, and how their child will be involved.]

Why are you asking my child?
[The reason for selecting their child; inclusion/exclusion criteria]

What will you ask my child to do if I agree to let him or her be in the study?
[The procedures to be used and identification of any procedures which are experimental, the expected duration (time) of the child's participation, and any anticipated follow-up should be discussed. Any procedure which is likely to cause stress, pain (physical, psychological, or emotional), or any other unpleasant reaction should be described so that the parent/guardian understands fully to what they are consenting.]

Is there any audio/video recording of my child?
[This section should describe any plans to use audio/video recording if it is applicable to the project proposed (section should be omitted if there will be no audio/video recording). It should include the statement "Because your child's voice will be potentially identifiable by anyone who hears the tape, confidentiality for things said on the tape cannot be guaranteed although the researcher will try to limit access to the tape as described below."]

What are the dangers to my child?
[If there are no risks to the child in this study, include the following statement: "The Institutional Review Board at The University of Findlay has determined that participation in this study poses less than minimal risk to participants." Describe the risks and how the risk will be minimized. Research involving more than minimal risk must also include an explanation as to whether compensation, medical, psychological or other types of treatments are available if injury or a stressful situation occurs and at whose expense.]

If you have any concerns about your child's rights, how they are being treated or if you have [*questions about this project or benefits or risks associated with being in this study can be answered by [name of principal investigator] who may be contacted at (333) 333-3333 (you can also include your email address if you like).]*

Are there any benefits to my child as a result of participation in this research study?
[Parents should be informed about direct or indirect potential benefits to their children or the absence of benefits. Be sure that your language does not guarantee any benefits (use the word "may"). Payment and incentives are not considered "benefits" to a participant and should not be discussed within this section. If there are no direct benefits, state "There are no direct benefits to participants in this study."]

Are there any benefits to society as a result of my child taking part in this research?
[Describe any benefits to society that may result from this study. Be sure that your language does not guarantee any benefits (use the word "may").]

Will my child get paid for being in the study? Will it cost me anything for my child to be in this study?
[Costs and payments/incentives should be described explicitly, including conditions under which payments will not be given if that is the case. Describe how payments will be made if the participant elects to discontinue participation part way through the study. If there are no costs or payments involved, you may state, "There are no costs to you or payments to you or your child as a result of participation in this study."]

How will my child's information be kept confidential?
*[Describe how information will be kept confidential. For example: stored in a locked file cabinet, password protection, encryption, not identifying participants by name when data are disseminated, anonymous data collection procedures. Include a statement that reads, "all information obtained in this study is strictly confidential unless disclosure is required by law." If applicable, the researcher must add a description of any legal duty to report abuse that might supersede these confidentiality promises. For Internet Research, include this wording: "**Absolute confidentiality of data provided through the Internet cannot be guaranteed due to the limited protections of Internet access. Please be sure to close your browser when finished so no one will be able to see what you have been doing."***
Alternatively, add security statement from commercial survey tool used for the study.]

What if my child wants to leave the study or I want him/her to leave the study?

"You have the right to refuse to allow your child to participate or to withdraw him or her at any time, without penalty. If your child does withdraw, it will not affect you or your child in any way. If you or your child chooses to withdraw, you may request that his/her data which has been collected be destroyed when possible.

What about new information/changes in the study?
"If significant new information relating to the study becomes available which may relate to your willingness allow your child to continue to participate, this information will be provided to you when possible."

Voluntary Consent by Participant:

[By signing this consent form, you are agreeing that you have read it or it has been read to you, you fully understand the contents of this document and consent to your child taking part in this study. All of your questions concerning this study have been answered. By signing this form, you are agreeing that you are the legal parent or guardian of the child who wishes to participate in this study described to you by _____.]

_____ Date: _____

Participant's Parent/Legal Guardian's Signature

_____ Date: _____

Participant's Parent/Legal Guardian's Signature

University of Findlay

Institutional Review Board **Project Completion Form**	
Date:	**IRB Project Number:**
Project Title:	
Principal Investigator (PI):	
College/Department:	
Funding Agency (if applicable):	
PI Phone Number:	**PI Email Address: @findlay.edu**
PI Address:	
Enrollment Information	
Total Number of Human Subjects in this Research:	
Last Date of Data Collection:	
Date of Project Completion (Publication, Cessation, etc.):	

Signature of the Principal Investigator **Date**

Signature of the IRB Chairperson **Date**

Project # _____
Office Use Only

University of Findlay

Institutional Review Board **Amendment/Modification Request**	
DATE:	**IRB PROJECT NUMBER:**
PROJECT TITLE:	
PRINCIPAL INVESTIGATOR (PI):	
COLLEGE/DEPARTMENT:	
FUNDING AGENCY:	
PI CONTACT (PHONE, E-MAIL, ADDRESS):	
Understand that the proposed changes may not be implemented before IRB approval	
☐ Personnel ☐ Setting ☐ Human subjects ☐ Health of subjects ☐ Inclusion/Exclusion Criteria ☐ Recruitment procedures ☐ Sampling Plan ☐ Sample Size ☐ Instruments ☐ Procedure ☐ Consent ☐ Risk and Risk Mitigation ☐ Compensations and Benefits ☐ Disclosure ☐ Data Confidentiality ☐ HIPAA ☐ Other changes	
DESCRIPTION OF PROPOSED CHANGES (USE ATTACHMENTS/ADDITIONAL PAGES AS NECESSARY):	
REASON FOR AMENDMENT/MODIFICATION:	
CONSENT FORM. ARE CHANGES IN THE CONSENT FORM REQUIRED? NO_____ YES_____ (ATTACH NEW FORM)	

_____ _____
Principal Investigator Signature Date

Please return completed form: University of Findlay, IRB Office

If you have any questions, please contact the IRB Office.

Cc: IRB,
Program Director

Project # _____
Office Use Only

Institutional Review Board
Progress Report

Date:

Investigator's Name:

Project Title:

U.F. College/Program Area:

Funding Agency:

Expiration Date:

Instructions: In order to comply with UF policy and federal regulations, human subject research must be reviewed by the IRB on at least a yearly basis. The IRB may require review at a period shorter than one year, or for a fixed number of subjects. It is the investigator's responsibility to ensure that the progress report is completed in a timely fashion to allow IRB to process the re-approval before the expiration date, which is printed above.

- Please type or neatly print the information.
- If an item is not applicable to your study, please state as such. Do not leave items blank.
- Additional pages can be appended as necessary.
- If you have any questions about completing this form, please contact
    - IRB office
- Return completed form to:
    - IRB Office
- Your signature certifies that the above titled research has been and will be conducted in full compliance with the University of Findlay IRB policies governing human subject research. IRB continuing review is required to maintain approval. Any changes in the research proposal or activity and consent forms must be approved by the IRB prior to implementation. Adverse events must be reported to the IRB immediately.

_____ _____
Principal Investigator Signature Date

_____ _____
Instructor/Advisor's Signature Date

Section I

A. Status of Study Check the status of the study and note any additional information requested.

ACTIVE STUDY

☐ **1. Training Grant**

☐ **2. Multi-Site Coordination Center**

☐ **3. No local recruitment/enrollment to date, enrollment is possible (keep study open)**

_____ Check here if enrollment has occurred at other sites

_____ Explain why there has been no enrollment to date (e.g. no funding)

_____

_____

☐ **4. Recruitment/Enrollment continues**

☐ **5. Open to recruitment/enrollment, but no enrollment since last annual review**

☐ **6. Recruitment complete, but research intervention continues**

_____ Describe what types of intervention are continuing: actively collecting surveys, employing interventions, or other

_____

_____

☐ **7. Follow-Up Data Collection Only**- Non-experimental data collection only

☐ **8. Data Analysis Only**-No further involvement with subjects

_____ Check here if there are identifiers linking data to the study subject

☐ **9. Waiting for presentation/publication**

Completed/Withdrawn Projects:

☐ **1. Completed study** Complete Sections I and II as a final report
☐ **2. Study closed before completion** Complete Sections I and II as a final report

☐ **3. Study has not been/will not be conducted**
State reason_____

B. Modifications to Study

Provide a brief summary of any changes that have been made to the project since the last IRB approval (e.g., changes in consent process, protocol additions/deletions)

C. Attachments: Please include the following, if applicable:

- ✓ Last signed consent form (If you have enrolled subjects since the last annual review, attach a copy of the consent form which the last subject signed, with the subject's name and signature blocked out).
- ✓ New consent form original (If enrollment is continuing)
- ✓ Subject recruitment materials (letters, posters, advertisements to recruit subjects)
- ✓ Publications (any publication or abstracts derived from the study in the past year)
- ✓ National Summary Reports (results from multi-center study group for this study)
- ✓ Audit Reports (any reports from audit/monitoring visits conducted by external organization (FDA, APTA) since last IRB review)

Section II. Complete if subjects have been enrolled (local or national)

A. Enrollment and Demographic Information. Please specify below the numbers and demographics of subjects in your study. (For multi-site studies, please list local statistics only).

1. Subject Enrollment:

Number of subjects requested in proposal: _____

Date first subject was enrolled: _____

Number enrolled since last progress report: _____

Total number of subjects enrolled to date: _____

2. Please report the number of subjects in the following categories: (Greater than minimal risks studies only)

_____ Currently undergoing research intervention

_____ Follow-up data collection only

_____ Completed intervention and any follow up

_____ Lost to follow-up

_____ Withdrawn from study

_____ Death related to study

_____ Death unrelated to study

3. Please list all sites where you are responsible for subject enrollment and/or research interventions.

B. Adverse Events, Complications, Subject Withdrawal (since your last IRB review)

1. Adverse event(s). Did any subject suffer an unanticipated or serious adverse event or death? **Circle YES or NO** If the answer is yes, specify the number of reported events and describe briefly their nature and relationship to the study. If a report on adverse events has not been made previously to the IRB, please include the adverse event report(s) with the progress report form.

    a. Local occurrences:

    b. Occurrences at other sites (multi-site trials only):

2. Adverse events/overall risk. Based on your knowledge of adverse events for this study, do you feel there is a significant increase in risks to subjects? **Circle YES or NO** If yes, please explain.

3. Investigator-initiated withdrawal. Did you withdraw any subject(s) from your study because of a problem or complication? **Circle YES or NO** If yes, please explain.

4. Subject self-withdrawal. Did any subjects withdraw themselves from your study? **Circle YES or NO** If yes, please explain.

5. Obtaining and documenting informed consent. Did any problems occur in the process of obtaining and documenting informed consent (i.e. problems with subject understanding, high subject refusal rates)? **Circle YES or NO** If yes, please explain.

6. Subject Referral. Were any subjects referred to the study without their knowledge that a research procedure(s) was to be conducted? (For example, did any patients believe that referral was for medical care, not research?) **Circle YES or NO** If yes, please explain.

7. Other problems or complications. Were there any other problems or complications in the study that affect subjects or others? **Circle YES or NO** If yes, please explain.

C. Study Findings and Risk/Benefit Assessment

1. Findings. Provide a brief summary of findings (preliminary or final) obtained in the study. If there are no findings at this time, this should be stated and explained. (Attach any publication, if available).

2. Risk/Benefit assessment. Has anything occurred since the last IRB review which may have altered the risk/benefit relationship? **Circle YES or NO** If yes, please explain.

3. Informed consent assessment. Is the consent document(s) still accurate and complete? **Circle YES or NO** Any significant new findings or risks which may relate to subjects' willingness to continue participation must be provided to subjects.

University of Findlay

Institutional Review Board

Adverse Event/ Unanticipated Problem Report

Serious adverse events must be reported to IRB within 7 calendar days. Any other adverse event or other experience that impacts the safe conduct of the study should be reported to the IRB within 14 calendar days.

The IRB will review the report to determine whether a revision to the protocol and/or consent form is warranted to protect human subjects. This review does not relieve the investigator from the responsibility for ensuring that studies are always conducted in a safe manner and that occurrence of adverse events are considered as the study proceeds.

PROJECT TITLE:		**Project #**
COLLEGE/DEPARTMENT:		
PRINCIPAL INVESTIGATORS (PI):		
PI CONTACT (PHONE, E-MAIL, ADDRESS):		
STUDENT/SECONDARY INVESTIGATOR(S) (SI):		
STUDENT/SI CONTACT (PHONE, E-MAIL, ADDRESS):		
Date of Event/ Problem:		
Subject I.D.(number/ code):		
Adverse Event:	Yes ___ No ___	• Unfavorable medical occurrence • Physical or psychological harm
Unanticipated Problem:	Yes ___ No ___	• Unexpected • Related or possibly related to participation • Suggests that there may be greater risk to subjects than previously known
Serious:	Yes ___ No ___	• Death • Hospitalization • Persistent/ significant disability • Jeopardize subject heath/ require medical treatment to prevent the above.
Related:	Yes ___ No ___ Unable to judge ____	• Directly related to procedures/ intervention
Brief description of adverse event/ unanticipated problem:		

Is this kind of adverse event described in the currently approved consent form?	Yes No
Explain:	
Will the event require changes in the consent/assent form or to the protocol?:	Yes No
Explain:	
Will individuals currently enrolled be notified of this event?:	Yes No
Explain:	
Study Procedure or intervention suspected of causing event(s):	

PI Signature: _____ Date:

For IRB/ use only:

Reviewed by: ☐ **IRB Chair** ☐ **Convened IRB** **Determinations:** ☐ No further action required ☐ Additional Actions required (See letter dated_____) ☐ IRB requirements met on: _____	Initials: Date Reviewed:
Institutional Official Determination (if applicable, check all that apply): ☐ Reportable (to Institutional Officials, and OHRP/FDA/other federal agency (if federally funded) ☐ Unanticipated Problem ☐ Not Reportable	Initials: Date Determination Made:
IRB Chair Determination (if applicable): ☐ Suspend: ☐ enrollment ☐ limited study activities (specify) _____ ☐ all study activities ☐ Terminate	Initials: Date Determination Made:

HIPAA Identification Authorization Form

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

The privacy law, Health Insurance Portability & Accountability Act (HIPAA), protects my individually identifiable health information (protected health information). The privacy law requires me to sign an authorization (or agreement) in order for researchers to be able to use or disclose my protected health information for research purposes in the study entitled *[insert title of study/protocol/project]*.

I authorize *[name of investigator]* and his/her research staff to use and disclose my protected health information for the purposes described below. I also permit my doctors and other health care providers to disclose my protected health information for the purposes described below.

My protected health information that may be used and disclosed includes:

- *[List all of the protected health information* to be collected for this protocol/study such as demographic information, results of physical exams, blood test, X-rays, and other diagnostic and medical procedures as well as medical history.]*

The Investigator, (name of researcher) may use and share my health information with:

- The University of Findlay Institutional Review Board (IRB) when the researcher or the research site is undergoing Higher Learning Commission or accreditation reviews.
- Government representatives, when required by law
- *[List any collaborators, outside laboratories or research sites, etc.]*
- *[If applicable -- list the sponsor's name]*
- *[List any other groups with whom the information may reasonably be shared]*

The Investigator, (name of researcher) intends to use or disclose my health information for the purposes of: *[As required by 45 CFR 164.508(c)(1)(iv), describe each purpose of the requested use or disclosure of the protected health information]*

Once my health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

The investigator(s) (researcher) and *[list sponsor's name if applicable]* agree to protect my health information by using and disclosing it only as permitted by me in this Authorization and as directed by state and federal law.

I do not have to sign this Authorization. If I decide not to sign the Authorization:

- It will not affect my treatment, payment or enrollment in any health plans nor affect my eligibility for benefits.

- I may not be allowed to participate in this research study.

After signing the Authorization, I can change my mind and:

- Not let the researcher disclose or use my protected health information (revoke the Authorization).
- If I revoke the Authorization, I will send a written letter to: *[name and contact information of research advisor]* to inform him/her of my decision.
- If I revoke this Authorization, researchers may only use and disclose the protected health information **already collected** for this research study.
- If I revoke this Authorization my protected health information may still be used and disclosed should I have an adverse event (a bad effect, or experience something unanticipated).
- If I change my mind and withdraw the authorization, I may not be allowed to continue to participate in the study.

Optional item: It has been explained to me that I will not be allowed to review the information collected for the research until after the study is completed. When the study is over, I will have the right to access the information again.

This Authorization does not have an expiration date.

If I have not already received a copy of the Privacy Notice, I may request one by contacting the IRB Chairperson. If I have any questions or concerns about my privacy rights, I should contact the University of Findlay, IRB Chairperson.

I am the subject or am authorized to act on behalf of the subject. I have read this information, and I will receive a copy of this form after it is signed.

_____	_____
Signature of subject or *research subject's legal representative	Date
_____	_____
Printed name of subject or *research subject's legal representative	Representative's relationship to research subject

*Please explain Representative's relationship to patient/subject and include a description of Representative's Authority to act on behalf of Patient:_____
_____
_____

*Name, Address, Dates Directly Related to an Individual, Telephone/Fax Number, E-mail/Internet Protocol or Web URL Address, Social Security Number, Medical Record or Health Plan Number, Account Number, Certificate of License Number, Photographic Images, Vehicle Identifiers, Device Identifiers, Biometric Identifiers, any other unique code.

HIPAA IRB WAIVER OF AUTHORIZATION***

IRB# _____

Project Title:
_____

1. The use or disclosure of Protected Health Information (PHI)* involves no more than a minimal risk to the privacy of individuals. Explain why. Include a detailed list of the PHI to be collected and a list of the sources(s) used/accessed for the PHI.

_____
_____

2. Describe the plan to protect identifiers and indicate where PHI will be stored and who will have access (researchers must list all of the entities that might have access to the study's PHI such as student advisors, hospitals, private clinics, FDA, and any others given authority by law);

_____
_____

3. All identifiers collected during the study will be destroyed at the earliest opportunity consistent with the conduct of research, which is (explain below):

_____
_____

4. The research could not practicably be conducted without the waiver because (explain below):

_____
_____

5. The research could not practicably be conducted without access to and use of the PHI because (explain below):

_____
_____

6. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Please note that researchers are also accountable for any PHI released under a waiver. Explain why PHI obtained for this study is/are the minimum information needed to meet the research objectives.

_____
_____

The information listed in the waiver application is accurate and all research staff** will comply with the HIPAA regulations and the waiver criteria. I assure that the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law.

If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entities, I will seek approval from the University of Findlay IRB.

Principal Investigator Signature _____ Date _____

Name typed/printed_____

---

*PHI: individually identifiable health information transmitted or maintained in any form (electronic means, on paper, or through oral communication) that relates to the past, present or future physical or mental health or conditions of an individual.
**Note: *Research staff* is defined as ALL study personnel (including PI) that is involved in the research.
***HIPAA Regulations allow IRBs to waive use of authorization form if all of the criteria listed above are met.

HIPAA DE-IDENTIFICATION CERTIFICATION FORM

DO NOT COMPLETE IF AUTHORIZATION WILL BE OBTAINED
OR WAIVER OF AUTHORIZATION IS REQUESTED

IRB# _____ PI Name:_____

Title:
_____

Research which involves the use of "de-identified" protected health information (PHI)* is exempt from HIPAA requirements. To be exempt from HIPAA, none of the following subject identifiers can be reviewed (accessed) or recorded by the research team.

- Names (individual, employer, relatives, etc.)
- Address (street, city, county, zip code - initial 3 digits if geographic unit contains less than 20K people, or any other geographical codes)
- Telephone/Fax Numbers
- Social Security Numbers
- Dates (except for years)
  - Birth Date
  - Admission Date
  - Discharge Date
  - Date of Death
  - Ages > 89 and all elements of dates indicative of such age (except that such age and elements may be aggregated into a category "Age>90
- E-mail Addresses/URLs
- Medical Record Numbers
- Health Plan Beneficiary Numbers
- Account Numbers
- Certificate/License Numbers
- Vehicle Identifiers and Serial Numbers (e.g., VINs, License Plate Numbers)
- Device Identifiers and Serial Numbers
- Biometric Identifiers (e.g., finger or voice prints or full face photographic images)
- Any other unique identifying number, characteristic, or code

I certify the protected health information (PHI)* received or reviewed by research personnel for the research project referenced above does not include any of the 18 identifiers listed above.

Principal Investigator Signature: _____ Date: _____