FINDLAY

THE UNIVERSITY OF FINDLAY

Policies and Procedures Guidelines for Human and Animal Subjects Institutional Review Board

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University of Findlay
IRB Policies and Procedures Guidelines

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I. Introduction

The University of Findlay has established a Research Review Committee to review and approve all research involving human and animal subjects. All human and animal subjects research conducted at the University must be reviewed and approved by an 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 investigator to refer his or her project to the IRB for review whenever human and animal subjects are being considered for research, even if the investigator does not consider the subjects to be at risk. The Review Board 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 Structure

The chair of the Institutional Review Board will call and conduct meetings throughout the academic year. All oral and written correspondence to the IRB will be directed to the IRB recording secretary. 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 project director. The chair shall be responsible for all communication between the committee and project investigators. The IRB chair should be contacted to answer any further questions or to provide clarification concerning the policies or their implementation.

The University of Findlay IRB Office and the following forms are located within the Academic Affairs Office. (Investigator's Summary Description of Research (see pg 8), Certificate of Compliance, Amendment/Modification, Progress report, Adverse Event report, Consent templates, and HIPAA forms)(see pgs 36-52).

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. (see IRB Principal Investigator Protocol Brochure)

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

If the research is categorized as either exempt or expedited, there is no submission date for these types of research (refer to Section III "Types of Research"). If the research project is neither exempt nor expedited, then the submission deadline for IRB forms is two weeks before the scheduled IRB meeting dates. It the responsibility of the investigator to submit the IRB forms in a timely manner. The IRB chair will conduct an initial screening of all research proposals submitted to ensure that the applications are complete and to determine the category of research.

D. Screening Process

All applications are screened by the chair of the IRB for complete documentation before determination if the project is exempt from review, requires expedited review, or a full review by the board members. If the application is incomplete or otherwise not fully prepared for IRB review, it is returned to the investigator for completion or additional information. On occasion, an IRB chair may contact the investigator by phone or letter requesting clarification of protocol issues or revisions in consenting documents. The chair may, at his/her discretion, refer the 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).

E. Notification

Investigators will be sent an acknowledgment letter and IRB identification number indicating that their proposal is complete, or that specific modifications or additional materials are required from the IRB. No use of human subjects is permitted before such approval. The IRB will send copies of the approval to the principal investigator who must be a 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 8-18, both an assent form and consent form from the parent will be required. (See appendix Pg. 39 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. The implied consent template is found in the Appendix, page 38.

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 36. This template provides specific guidance on how the forms should be worded and ordered.

I. 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 16.

A. Exempt Research

There is no submission date for minimal risk studies that meet the category of exempt research. If the IRB chair assigns the protocol to exempt 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

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

Most funding agencies (private or federal) 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 investigator promptly after the meeting:

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. The original consent document is stamped with the date of approval expiration and returned. Must inform IRB when study is completed or submit yearly progress report.

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. The original consent document is stamped with the date of approval expiration and returned.

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 investigator requesting that these issues be addressed. Full board review of the investigator's response is required prior to approval.

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

Principal investigators may appeal a disapproval decision made by the IRB. Such appeals will be heard (either in person or in writing) by the IRB. Upon consideration of the appeal materials and/or presentation, the decision may stand (disapproval) or, if appropriate, the decision may be to approve as resubmitted, or to approve after required modifications. As disapproval of studies may only be an action of the convened IRB, approval of a previously disapproved study may only be given at a convened meeting of the IRB.

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 page 16.

IV. 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 48-52.

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.

V. 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.

VI. 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 <u>automatically suspended</u> 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.

VII. 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 (see page 55) 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 Blackboard within IRB community section.

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.

VIII. Completion of Research Project

When the project is completed, the investigator must submit a Certificate of Compliance 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 Certificate of Compliance form can be obtained from the UF Blackboard site within IRB community section.(see page 47).

IX. 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.

X. 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

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Institutional Review Board
Human Subjects Research Determination Worksheet

- If your activity involves the use of animal subjects please contact, the Chair of the Animal Subjects Subcommittee 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.*

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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	____ Faculty Research ____ Undergraduate Course Number: _____ ____ Graduate Course Number: _____ ____ Master Project/Thesis/Dissertation*: _____ ____ Other:_____ **Note: Before applying for human subjects review, masters project, thesis or dissertation proposal must be formally approved by the project advisor or thesis committee, and a copy of the informed consent must accompany this form to the Institutional Review Board (IRB).*
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?*

____Private/Public P-12 ____Hospital ____ 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/Exclusion Criteria:

Please describe the population and provide concise and complete answers for inclusion and/or exclusion criteria:

d. 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.):

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

____ Random Sampling ____ Stratified Sampling ____ Convenience Sampling ____ Other

Please provide a rationale for your sampling plan:

f. Sample Size

Please provide the total number of expected participants and rationale.

5. Instruments (Attach all instruments to be used)

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

6. Procedures

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

7. Analysis

Please briefly 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:

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)*

____ Waiver
*Implied Consent *(Consent description must be provided)*

____ Assent *(In conjunction with parental consent for children 8-17)*
_____ Oral
_____ Written

** 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 legal guardian's 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 ____ Confidential Domain

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?

Upon completion of this form (including all documentation requested),
please submit one proposal copy electronically to irb@findlay.edu and one hard copy to Heather Riffle, Academic Affairs.

Project # _____
Office Use Only

FINDLAY
THE UNIVERSITY OF FINDLAY

Institutional Review Board
Investigator's Summary Description of Research
Involving the Use of Animals

Please print or type all information.

Submission date:

Proposed start-up date:

Investigator's Name:

Project Title:

U.F. College/Program Area:

Funding Agency:

This research is being conducted for:

_____ Undergraduate Course Number: _____

_____ Graduate Course Number: _____

_____ Masters Project or Thesis

Check One:

☐ Experimental

☐ Descriptive

Primary Investigator Phone #/email:

_____

Instructor/Research Advisor's Name:

_____

Research Advisor's Department and Phone #/email:

_____

Note: Before applying for animal review, the Masters Project or Thesis proposal must be formally approved by the project or thesis committee before submission to the Institutional Review Board (IRB).

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 animals 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
Instructor/Advisor's Signature	Date
Program Director's Signature	Date
IRB Chair's Signature	Date

☐ Expedited ☐ Exempt

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

Please provide concise and complete answers for the following areas. If necessary, you may attach extra pages.

1. **Project Description/Overview:**

2. Provide a comprehensive summary of the design and methods of the proposed teaching/research activity.

3. **Does the proposed activity duplicate any previous experiments using animals?**
YES_____ NO _____

If YES, provide the rationale for duplication.

4. **Are there any potentially painful procedures being proposed?**
YES_____NO_____

If YES, identify procedures that may cause discomfort, distress and pain to the animals at any point in this protocol.

5. **Does the proposed project require a departure from established guidelines for the care and use of animals as established by the Animal Welfare Act or Public Health Service.**

Policy? YES_____NO_____

If YES, describe the rationale for the proposed departure.

6. Please describe the current status of the PI's training in the following:

A. The biomethodology (handling, surgical procedures, nutrition, etc.) of the animals species being used.

B. Alternatives to the use of animals.

C. The humane care and use of animals.

7. Description of animal

A. Provide Information Required Below:

SPECIES *	Total # to be used		AGE/WEIGHT RANGE	HUMANE USE CATAGORIES			
	M	F					
				A	B	C	D
				A	B	C	D
				A	B	C	D
				A	B	C	D

* Provide Full Scientific Name Including Strain- Example: Rattus norvegicus (Long-Evans)

Category A: Experiments involving either no living materials or use of plants, bacteria, protozoa, or invertebrate animal species.

Category B: Experiments on vertebrate animal species that are expected to produce little or no discomfort.

Category C:	Experiments that involve some minor stress or pain (short-duration pain) to vertebrate animal species.
Category D:	Experiments that involve significant but unavoidable stress or pain to vertebrate animal species.
Category E:	Procedures that involve inflicting severe pain near, at, or above the pain tolerance threshold of unanesthetized, conscious animals.

The USDA requires documentation from the Attending Veterinarian regarding the AV's involvement in the planning of studies in the Humane Use Categories C, D and E. Please attach documentation to the proposal.

B. Provide the rationale for:

1. Use of animals -

2. Number of animals requested -

3. Appropriateness of species/strain -

C. Identify the source(s) of animals (name, address, and phone # of vendor)

D. Specify the proposed length of time that the animals will be housed in the facility.

E. Specify any special requirements for animal housing, diet, environment, etc.

F. Are biological, chemical, or physical agents to be administered to the animals?

YES____NO____

If YES, identify agents to be used:

AGENTS	AMOUNT*	ROUTE**

* If liquids are to be ingested or injected, indicate the dosage, volume of Chemical, and total volume of the liquid per day.

** Identify the location and number of injection sites.

1. List the number of animals receiving test agent(s) or placebo treatment(s).

2. Describe the expected result(s) of agent(s).

8. Are invasive procedures to be employed for collection of tissue and body fluids from live animals during experimentation?

YES_____NO_____

If YES, continue:

TISSUE OR BODY FLUID TO BE COLLECTED	AMOUNT TO BE COLLECTED	METHOD OF COLLECTION

9. List anesthetic, sedative or tranquilizing agents to be administered prior to specimen collection:

10. Are surgical procedures on live animals to be performed <u>as part of the</u> experimental protocol?
YES____NO____

If YES, continue:

A. Identify the number and species of animals on which surgery will be performed.

B. Explain pre-operative procedures (deprivation of food and/or water, administration of antibiotics, sedatives or other medication prior to the induction of anesthesia).

C. List all anesthetic, sedative or tranquilizing agents to be employed to prevent pain and distress during surgery.

D. List dosage and route of administration of anesthetic, sedative or tranquilizing agents.

E. List monitoring and supportive care to be provided during surgery.

F. Are major operative procedures being conducted on non-rodents?

YES_____NO_____

If YES, are the facilities in which major operative procedures are to be conducted intended for that purpose and operated and maintained under aseptic conditions?

YES_____NO_____

If No, please explain.

G. Does the study include multiple major operative procedures from which animals will recover? YES_____NO_____

If YES, please justify.

H. Describe surgical procedure(s). _____

I. Describe the plan for postoperative care including the use of analgesic or tranquilizing agents to reduce pain, if warranted.

J. Describe the relevant training and/or experience of the individual(s) performing surgery.

11. Will animals be deprived of food or water in preparation for or as part of experimental treatment?

YES_____NO_____

If YES, describe the deprivation, its degree, and how the animal's health will be monitored during the period of deprivation.

12. Will the animals be subject to other forms of stress, such as sleep deprivation, aggression, maternal deprivation, prolonged restraint, social isolation, etc.?

YES_____NO_____

If YES, describe the kind and degree of stress, and how the animals will be monitored.

13. Will any anatomical, physiological, or behavioral abnormality be caused by the experimental procedure or surgery on animals? YES_____NO_____

If YES, please describe.

14. Will the animals be exposed to noxious, stressful, or painful stimuli? YES_____NO_____

If YES, describe and also indicate whether the stimuli are warned or unwarned, escapable, or avoidable.

A. Would drug intervention for pain and/or distress interfere with the purpose of the study?

YES_____NO_____

If YES, provide justification(s) for withholding anesthetics, analgesics and tranquilizers.

B. Explain how the animal(s) will be monitored to determine when the experimental procedures should be terminated because of unnecessary distress and/or pain (see instructions in Protocol Review Form).

15. Are field observations involved? YES_____NO_____

If YES, describe whether or not the animal(s) will be disturbed or affected in any way and any specialized care, which will be provided.

16. Are animals to be euthanized at the end of this study? YES_____NO_____
Euthanasia must comply with 1993 AVMA recommendations. After euthanasia, death must be assured by a second means (e.g., cervical dislocation, transection of the aorta or decapitation).

1. If YES, describe method(s) of euthanasia.

2. If NO, then describe the disposition of the animals at the conclusion of the study.

17. Does the Animal Protocol involve the use of hazardous materials? YES_____NO_____

If YES, list hazardous materials in proposed study and explain why used:

Radioactive Materials - License #:_____

Biohazardous Materials

Hazardous Chemicals

Hazardous Waste

18. Identify the risk to personnel and the safety precautions to be taken regarding the hazardous material noted above.

Cc: IRB Office
Program Director

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Institutional Review Board
Consent Form Template

DATE:

PROJECT TITLE:

PRIMARY INVESTIGATOR(S) AND CO-INVESTIGATORS:

INTRODUCTION:

PURPOSE OF THE STUDY:

DESCRIPTION OF STUDY PROCEDURES:

TIME ASSOCIATED WITH STUDY:

POTENTIAL RISKS:

POTENTIAL BENEFITS:

PROJECT ALTERNATIVES TO PARTICIPATION IN THE STUDY:

CONFIDENTIALITY OF DATA:

COSTS AND/OR COMPENSATION FOR PARTICIPATION:

CIRCUMSTANCES FOR DISMISSAL FROM THE STUDY:

COMPENSATION FOR INJURY:

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

IRB Chairperson
University of Findlay
Findlay, OH 45840

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.

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.

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.

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. I will receive a copy of this consent form.

SUBJECT PRINTED NAME:_____

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

FINDLAY

THE UNIVERSITY OF FINDLAY

Institutional Review Board
Implied Consent Form Template

Date

Dear ...

You are invited to participate in a study of ... *state what is being studied*. I hope to learn without prejudice ... *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 is implied consent. The survey is designed to ... *explain purpose of survey*. It will take about ... *length of time expected to complete survey*. No benefits accrue to you for answering the survey, but your responses will be used to ... *explain research benefit*. Any discomfort or inconvenience to you derives only from the amount of time taken to complete the survey.

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will not be disclosed. Your decision whether or not to participate 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.

If you have any questions, please ask. If you have any additional questions later, contact ... *list advisor's contact name and phone number or email address*.

Thank you for your time.
Sincerely,
researcher's name, etc.

RESEARCH ASSENT FORM

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 you will be helped by being in this study. 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)

Project #:_____
Office Use Only

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THE UNIVERSITY OF FINDLAY

Institutional Review Board

Certificate of Compliance

Please print or type all information where applicable:

Investigator's Name:

Project Title:

U.F. College/Program Area:

This is to certify that the above named research project involving human subjects was performed according to the procedures approved by The University of Findlay Institutional Review Board, and is now complete.

In the course of this project, which began on (date) _____, and ended on (date) _____, a total of _____ human subjects were utilized. All records for this project will be maintained and available to the Institutional Review Board for a period of three years from this date.

_____ _____
Principal Investigator's Signature Date

_____ _____
Advisor/Instructor's Signature Date

_____ _____
IRB Chair's Signature Date

Cc: IRB Office

Project # _____
Office Use Only

FINDLAY
THE UNIVERSITY OF FINDLAY

Institutional Review Board
Amendment/Modification Report

Date:

Investigator's Name:

Project Title:

U.F. College/Program Area:

Funding Agency:

Understand that any of the proposed changes may not be implemented before IRB approval

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

_____ _____
Instructor/Advisor's 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

FINDLAY
THE UNIVERSITY OF FINDLAY

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.

Project # _____
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THE UNIVERSITY OF FINDLAY

Institutional Review Board
Adverse Event Report

Adverse events that are serious and unexpected and are related to the study must be reported to IRB within 15 calendar days. Any unanticipated problem or other experience that impacts the safe conduct of the study should be reported promptly to the IRB.

The IRB will review the Adverse Event form and summary 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. Please attach the summary report to the adverse event form.

Date:

Investigator's Name:

Advisor/Instructor Name:

Project Title:

U.F. College/Program Area:

Date of Event:

Subject I.D.:

Brief description of adverse event:

Study site: Local _____ Non-local _____

Serious: Yes _____ No _____

Related: Yes _____ No _____

If related to the study, what intervention is the event most likely related to?_____

_____

Cc: IRB
Program Director

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]*

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_____

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*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: _____