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| Academic Logo (Print)_Primary_Black |  | *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

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| **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** (*Check All That Apply*) | | | **Reason for Research Conducted** *(Check One)* |
| \_\_\_\_ Primary Data  \_\_\_\_ Secondary Data | | | \_\_\_\_ Faculty Research  \_\_\_\_ Student Research  Course Number(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_ Dissertation  \_\_\_\_\_ Capstone  \_\_\_\_\_ Thesis  \_\_\_\_ Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  | Hospital/Clinic Chart Review |
|  | Purchased Data Base |
|  | Other |
|  |  |  |
| **Type of Research** *(Check One)* | | |
| \_\_\_\_ Quantitative  \_\_\_\_ Qualitative  \_\_\_\_ Mixed-Methods | | |
| **Research Design** *(Check One)* | | | **Research involves External Organization** *(Check One)* |
| \_\_\_\_ Experimental  \_\_\_\_ Quasi Experimental  \_\_\_\_ Non-Experimental | | | \_\_\_\_ No  \_\_\_\_ Yes: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (Documentation of Formal Approval From  Organization Must be Attached to Proposal) |
|  | | |

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.

(Please insert additional Investigator signature lines as needed.)

Principal Investigator’s Signature Date

Student/Secondary Investigator’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

Recruitment material/script, data collection instruments, consent/assent forms, and other requested documentation

to be attached as appendixes to this proposal

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| **1. Study Introduction/Overview** |
| *Provide your statement of purpose, significance of study, and relevant supporting literature.* |
| **2. Research Question and/or Research Hypothesis** |
| *Provide concise research question(s) and/or study hypothesis.* |

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| **3. Setting**** |
| * Check the setting type the study will be conducted in or recruitment will occur from.* |

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| \_\_\_\_ Schools (private/public P-12) | | | | \_\_\_\_Hospital/Clinic | | | \_\_\_\_ University  /College | | \_\_\_\_ General Public | \_\_\_\_Other | |
| *Describe setting to be used.* | | | | | | | | | | | |
| **4. Participants** | | | | | | | | | | | |
| a. Characteristics of Participant Population: * Check if the participants are included in the following categories.* | | | | | | | | | | | |
| \_\_\_\_ Pregnant | \_\_\_\_ Fetus | | \_\_\_\_ Children | | | \_\_\_\_ Cognitively Impaired | | | \_\_\_\_ Legally Restricted | | \_\_\_\_Other |
| *Describe population to be used.* | | | | | | | | | | | |
| b. Health of Participant Group: * Check the physical and mental health of the participants for inclusion in this study.* | | | | | | | | | | | |
| Physical Health: | | \_\_\_\_ Poor | | | \_\_\_\_ Good | | | \_\_\_\_ Excellent | | \_\_\_\_ Unknown | |
| Mental Health: | | \_\_\_\_ Poor | | | \_\_\_\_ Good | | | \_\_\_\_ Excellent | | \_\_\_\_ Unknown | |
| *State the necessity of using this particular group.* | | | | | | | | | | | |

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| c. Participant Inclusion Criteria: | | | | | |
| *Provide concise and complete inclusion criteria.* | | | | | |
| d. Participant Exclusion Criteria: | | | | | |
| *Provide concise and complete exclusion criteria.* | | | | | |
| e. Recruitment of Participants: * Check the recruitment location type from which the participants will be gathered.* | | | | | |
| \_\_\_\_ Recruitment of UF class,  students, or personnel | | \_\_\_\_ Outside agencies, schools,  organizations, or data base | | \_\_\_\_ Open call for particpants  (general public) | |
| *Describe in detail the recruitment process for participants and attach recruitment material (e.g. flyers, advertisements, letters, emails, social media posts etc.) or script (if recruiting orally).* | | | | | |
| f. Sampling Plan: * Check the type of sampling method that will be used for this study.* | | | | | |
| \_\_\_\_ Random Sampling | \_\_\_\_ Stratified Sampling | | \_\_\_\_ Convenience Sampling | | \_\_\_\_ Other |
| *Provide a rationale for your sampling plan.* | | | | | |
| g. Sample Size:  *Provide the total number of expected participants with rationale.* | | | | | |
| **5. Instruments (Attach all instruments to be used)** | | | | | |
| *Describe all data collection instruments to be used including their psychometric properties if applicable and/or piloting process.* | | | | | |
| **6. Procedures for Data Collection** | | | | | |
| *Describe in detail the procedures that will be used to collect data including the total time investment of the participant.* | | | | | |
| **7. Procedures for Data Analysis** | | | | | |
| *Describe how you will analyze the data collected.* | | | | | |

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| **8. Risk to the Participant**  Health & Human Services (HHS) states that risk exists for the participant in any study and have defined the categories of risk as follows. | | | | |
| *Check all potential risk categories and your perception of the level of risk involved.* | | | | |
| Type of risk: | \_\_\_\_ Physical | \_\_\_\_ Psychological | \_\_\_\_ Social | \_\_\_\_ Legal \_\_\_\_ Economic |
| Perceived level of risk: \_\_\_\_\_ Less than minimal \_\_\_\_ Minimal \_\_\_\_\_ Greater than Minimal  *Describe each identified risk in detail.* | | | | |
| **9. Mitigation of Risk to the Participant** | | | | |
| a. Researcher Mitigation: | | | | |
| *Describe how the researcher will try to mitigate each identified risk.* | | | | |
| b. Research Gain: | | | | |
| *Describe the importance of the information gained from this study in relation to the risk to the participant.* | | | | |
| c. Equity and Equality: | | | | |
| *Describe how the researcher will ensure equity and equality for all potential participant.* | | | | |

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| **10. Compensations and Benefits** | | | | | | | | | |
| a. Are you offering any compensations to individuals for participating in your study? | | | | | | | | | |
| *If yes, please describe.* | | | | | | | | \_\_\_\_ Yes\* | \_\_\_\_ No |
| b. Benefits to Individual:  *Outside of any compensation offered, what are the benefits to the individual for participating in this study?* | | | | | | | | | |
| c. Benefits to Society:  *How will conducting 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: | | | | *Check the type of consent to be gained prior to participation in the study.* | | | | | |
| \_\_\_\_ Oral Consent | | | | *Script must be provided with short consent form using language that is understandable to the population.* | | | | | |
| \_\_\_\_ Written Consent | | | | *Long Consent form must be provided; using the University of Findlay long consent template using a Flesh-Kincaide reading grade level appropriate for the population.* | | | | | |
| \_\_\_\_ Assent  \_\_\_\_\_ Oral  \_\_\_\_\_ Written  \_\_\_\_ Parent Consent/Permission | | | | *Assent form/script must be provided using a Flesh-Kincaide reading grade level appropriate. Should be used in conjunction with Parental Consent/Permission form for children 7-17.* | | | | | |
| \_\_\_\_ Implied Consent Waiver\* | | | | *Consent description must be provided; please use the University of Findlay implied consent template using a Flesh-Kincaide reading grade level appropriate for the population.* | | | | | |
| *\_\_\_\_\_* 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, provide rationale for request.* | | | | | | | | | |
| b. Are the participant(s) minors or have a legal guardian? | | | | | | | | \_\_\_\_ Yes\* | \_\_\_\_ No |
| *If yes, describe how and by whom consent will be granted for participation*. *\*Subject Assent form must accompany parent/legal guardian’s consent/permission form.* | | | | | | | | | |
| c. Does the participant(s) have a cognitive limitation/impairment? | | | | | | | | \_\_\_\_ Yes | \_\_\_\_ No |
| *Describe the limitation/impairment and how participant’s understanding will be ensured when gaining informed consent.* | | | | | | | | | |
| d. Does the participant(s) have a language/literacy barrier? \_\_\_\_ Yes \_\_\_\_ No  *Describe the limitation/barrier and how participant’s understanding will be ensured when gaining informed consent.* | | | | | | | | | |
| e. Will participant(s) be provided copies of all consent documentation including implied consent description? \_\_\_\_ Yes \_\_\_\_ No | | | | | | | | | |
| *If consent/assent documentation is not provided to participants, justify the rationale.* | | | | | | | | | |
| **12. Disclosure**  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. | | | | | | | | | |
| *Check the type of disclosure of the study that will be used* | | | | | | | | | |
| \_\_\_\_ Full Disclosure | | | \_\_\_\_ Less than Full Disclosure | | | \_\_\_\_ Necessary Deception | | | |
| *Describe how disclosure of the study to the participants will occur. If less than full disclosure or necessary deception is chosen, 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** | | | | | | | | | |
| 1. Data Falls Within: | | | | | \_\_\_\_\_ Public Domain  *(Ex: public record document, public access documents, court transcripts, etc.)* | | \_\_\_\_ Confidential Domain  *(Ex: data only accessible through permission of the institution and/or subject being studied)* | | |
| 1. Data Access: | | | | | | | | | |
| *Describe all parties who will have access to the data and provide evidence of human subject training certificate/confidentiality agreement for each.* | | | | | | | | | |
| c. Participants’ Anonymity/Confidentiality: | | | | | | | | | |
| *How will the individual participants’ anonymity/confidentiality be protected?* | | | | | | | | | |
| d. Data Storage: | | | | | | | | | |
| *How, where and for how long will the data be stored according to professional best practices? (Please note that federal law requires all data must be stored for a minimum 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 “Yes” is checked for any of the following questions, this study is subject to HIPAA and the HIPAA Supplement must be completed and attached to this proposal.* | | | | | | | | | |
| \_\_\_\_ 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? | | | | | | | |

**Electronically submit one proposal copy including all requested documentation to** [**irb@findlay.edu**](mailto:irb@findlay.edu)