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**Institutional Review Board**

**FSU HRRC (Human Rights in Research Committee)**

Application for the Use of Human Subjects in Research

1. **Instructions: All instructions in this section must be followed for the application to be reviewed:**

* All materials must be typed
* Only the current application will be accepted (check the header for revision date)
* **A signed original is required**
* Do not staple any part of the application
* All submitted material must be **single sided**
* All questions/statements listed in blue on the application must be answered
* Once each section in blue is fully answered, be sure to delete all of the blue instructions prior to submission for review
* If a survey or other instrument is being used, a copy of the actual survey or instrument must be supplied with the application
* All researchers, faculty, staff, administration and students who conduct research for or at FSU must complete trainings in 1) Social and Behavioral Research; and 2) Ethics for Researchers
* If references are used, complete citations are required at the end of each section in which the reference appears
* Sample forms are included at the end of this application, only include in your submission those that will be used in the study
* Omission of any required document(s) will yield an incomplete application and prolong your review process
* Responses are generally rendered within 14 business days to the Principal Investigator
* Questions can be directed to the HRRC Chair, Dr. Theodore Kaniuka (910-672-1636 or tkaniuka@uncfsu.edu) prior to the submission of your application

**Checklist for application submission:**

* IRB Application with applicable signatures
* Certificates of All Required CITI Trainings (from Principal Investigator, all Co-Investigators and Key Study Personnel)
* Applicable consent form
* Child assent form (if applicable)
* Recruiting materials (phone script, fliers, ads, etc.)
* Survey/questionnaire(s), focus group or interview questions (if applicable)
* [Conflict of interest/financial interest disclosure](http://minerva.stkate.edu/irb.nsf/pages/conflictinterest) (if applicable)
* Letter(s) of support or agreement (if conducting research at another agency, school, etc.)
* When appropriate, include IRB approved protocol from other involved institution or organizations

**Applications should be delivered to:**

The Office of Sponsored Research and Programs

Attn: Dr. Leslie Evelyn

College of Business and Economics, Room 310

**This study will be reviewed in accordance with federal regulations governing human subjects research including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), where applicable.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigator (PI) and FSU E-Mail address:** | | | |
| **PI Status: (check one)**:  FSU Faculty  FSUStaff  FSUUndergraduate Student FSU GraduateStudent  Visiting Scholar  Non-FSU Affiliation (Specify Institution): | | | |
| **Office Location or Mailing Address:** | | | |
| **Department:** | | | |
| **Project Title:** | | | |
| **Phone Number: University E-mail:** | | | |
| **Co-Investigator #1: Department: E-Mail:** | | | |
| **Co-Investigator #2: Department: E-Mail:** | | | |
| **Key Study Personnel:** Key personnel are defined as individuals who participate in the design, conduct, or reporting of human subjects’ involvement in the research. At a minimum, these individuals may be involved in conducting procedures and obtainment of legally effective informed consent/assent. All key personnel must have sufficient knowledge about the protocol to facilitate effective interaction with the subject as well as complete the Human Subjects Training. | | | |
| **Names (or TBD\*)** | **Position** | **Department** | **E-Mail** |
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| **Is internal or external funding being sought for this research?**  **Yes**  **No**  **Funding Source(s):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. If yes, you must (1) submit a complete copy of that proposal as soon as it is available and (2) provide one copy of the funding announcement and all relevant forms, instructions, etc., with your original copy of this application. Does the funding agency require notification of Institutional Review Board approval?  Yes  No  Project period dates to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *This is required information, must be future dates - after you have received final IRB approval to conduct your research.*  **Other Institutional Review Boards:** Does the research involve another institution or site?  Yes  No  If yes, please list all institutions and sites: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Has any other IRB approved this project?  Yes  No  If **Yes**, please provide a copy of the approval letter with this application.  If **No**, will any other IRB be asked for approval?  Yes (please specify which IRB)  No    **Certificates of Training:** All Principal Investigators, Faculty Advisors, Co-Investigators, Research Assistants, Graduate Assistants, personnel and volunteers associated with the study must complete the training. NOTE: Only valid certificates from the Collaborative Institutional Training Initiative (CITI) will be accepted. | | | |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator’s Signature Date

The activity described herein is in conformity with the standards set by our department and I assure that the Principal Investigator has met all departmental requirements for review and approval of this research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department Chair’s or Dean’s Signature Date

**II. COMPLETE THIS SECTION IF THE PRINCIPAL INVESTIGATOR IS A GRADUATE STUDENT (NOTE: Graduate Faculty Status is required for all Thesis/Dissertation Chair or Advisors.)**

Check one:  Thesis  Dissertation  Other

Has the Thesis/Dissertation Committee approved the proposal?  Yes, Date Approved: / /  No

Name of Thesis/Dissertation Advisor:

Advisor’s Department: Advisor’s Phone No.: \_\_\_\_\_\_\_\_\_

**III. COMPLETE THIS SECTION IF THE PRINCIPAL INVESTIGATOR IS AN UNDERGRADUATE STUDENT**

Check one:  Class Project/Paper  Honors Project  Independent Study  Other

Name of Research Supervisor/Class Instructor:

Department: Phone No.:

Course Name (if applicable):

**IV. INVESTIGATOR ASSURANCES AND AFFIRMATION OF COMPLIANCE**

I agree to follow the procedures outlined in the summary description and any attachments to ensure that the rights and welfare of human participants in my project are properly protected. I understand that the study will not commence until I have received approval of these procedures from the IRB: HRRC; I have complied with any required modifications in connection with that approval. I understand that additions to or changes in the procedures involving human participants, or any problems with the rights or welfare of the human participants must be promptly reported to the IRB. I further understand that if the project continues for more than one year from the approval date, it must be re-submitted as a renewal application.

\***NOTE**: You (the investigator/researcher) are required to notify the IRB: HRRC if any substantive changes are made in your research prospectus/protocol, if any unanticipated adverse events are experienced by subjects during your research, and when your project has ended. **Important:** If your project lasts longer than one year, you (the investigator/researcher) are required to notify the Office of Sponsored Research and Programs in writing of *Notice of Project Ending* or *Request for Continuation* at the end of each year. See the OSRP website for the proper form at <http://uncfsu.edu/research> Failure to notify the IRB of the above may result in disciplinary action under the FSU campus student and faculty misconduct policy. You are required to keep copies of the informed consent forms and data for at least three years.

\*(**Required for all Investigators**):I affirm the accuracy of this application, and I accept responsibility for the conduct of this research, the supervision of human participants, and maintenance of informed consent documentation as required by the IRB: HRRC.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator’s Signature Date Co-Investigator’s Signature Date

**V. APPROVAL OF FACULTY ADVISOR/SPONSOR**

\*(**Required for all faculty advisors**) By signing, you as Faculty Advisor affirm the accuracy of your students application and accept responsibility for the conduct of this research, the supervision of the researcher (student) in ethical conduct of research, and maintenance of informed consent documentation as required by the IRB.

Supervisor or Committee Chair Signature Date

(for student investigator)

**VI. DESCRIPTION OF PARTICIPANTS:**

Anticipated number to enroll (if applicable): Gender:  Males  Females

**Please check all that apply**

Fayetteville State University employees/students

Prisoners – include authorization from appropriate correctional department(s)

Minors (17 years of age or younger) - include child’s assent and parent’s consent forms

Pregnant Women

Vulnerable populations, which include, but are not limited to persons with physical or mental disabilities, cognitive impairments (including persons in institutions)

Use of Protected Health Information

Members of the United States Military or their immediate family members (spouse or dependent children)

Non-English-speaking subjects

Persons otherwise dependent on the researcher (such as students of the researchers, etc.)

Students in a school system. Name of School/System

Other populations (explain) \_\_\_\_\_\_-

Existing Data (specify source)

Data already collected for another research study

Data already collected for administrative purposes (e.g., Medicare data, hospital discharge data)

Medical records (custodian may also require form, e.g., HD-974 if UNC-Health Care System)

Electronic information from clinical database (custodian may also require form)

Patient specimens (tissues, blood, serum, surgical discards, etc.)

Other (specify):

**Which of the following best describes your proposed activity?**

Program evaluation  Class projects for educational purposes only

QI/QA for internal purposes  Center or core grants (to establish infrastructure)

Training grants  Demonstration projects

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Explain:

**Will the research be conducted on the FSU campus? \_ Yes No.** If no, please indicate the location(s) of the study and attach an institutional consent letter that details their participation in the researcher’s study.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**VII. IDENTIFIERS: (check all of the identifiers that will be collected and associated with your study).**

1. \_\_ Names
2. \_\_ Telephone numbers
3. \_\_ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
4. \_\_ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code
5. \_\_ Fax numbers
6. \_\_ Electronic mail addresses
7. \_\_ Social security numbers or other ID numbers (including BANNER)
8. \_\_ Medical record numbers
9. \_\_ Health plan beneficiary numbers
10. \_\_ Account numbers
11. \_\_ Certificate/license numbers
12. \_\_ Vehicle identifiers and serial numbers (VIN), including license plate numbers
13. \_\_ Device identifiers and serial numbers (e.g., implanted medical device)
14. \_\_ Web universal resource locators (URLs)
15. \_\_ Internet protocol (IP) address numbers
16. \_\_ Biometric identifiers, including finger and voice prints
17. \_\_ Full face photographic images and any comparable images
18. \_\_ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher
19. \_\_ **NONE** of the above

**VIII. Please answer questions fully and succinctly.** Do NOT copy chapters associated with your thesis or dissertation to the application. All information must be incorporated into the application itself. Use as many separate sheets of paper as needed to respond to minimize delays in your review.Replace all blue statement/questions with your responses below.

1. **PURPOSE AND RATIONALE:**

Provide in the first sentence(s) the purpose of the research

Provide a summary of the background information, state the research question(s), and tell why the study is needed. If there is no external funding proposal, provide a rationale and literature review, including references. If a complete rationale and literature review are in an accompanying grant application or other type of proposal, only provide a brief summary here.

1. **RESEARCH SUBJECTS:**

Information is required even if existing data is being used. Describe the sources of potential participants, recruitment strategies, and how and where you will contact them. If participants are chosen from records, please describe of the type of records as well as documentation of approval for use of the records. Describe all relevant characteristics of the participants with regard to age, ethnic background, sex, institutional status (i.e., patients or prisoners), and their general state of mental and physical health. Attach a copy of any and all recruitment materials to be used e.g. advertisements, bulletin board notices, email scripts, letters, phone scripts, or URLs. Explain who will approach subjects to take part in the research and what will be done to protect the subjects’ privacy in this process. Clarify if participants will receive any inducements before or rewards after the research study (stipends, gift cards, reimbursement for travel or parking, value of monetary token, etc.,) and the source of sponsorship. Be aware that payment over a certain amount may require the collection of the subjects’ Social Security Numbers. Describe the subjects about whom personal information will be collected. Where active recruitment is required, please describe inclusion and exclusion criteria. Where the research involves extraction or collection of personal information, please describe from whom the information will be obtained and what it will include.

1. **STUDY DESIGN, METHODOLOGY AND PROCEDURES**:

Describe the research study and if applicable all personnel to be associated with the study. Explain expertise of Investigator, any co-investigators or other key personnel listed in the application, and how it relates to their specific roles on the study team. Discuss the study design (including hypotheses and/or research questions); study procedures; sequential description of what subjects will be asked to do; assignment of subjects to various arms of the study if applicable; how will participants be recruited; how data are to be collected (questionnaire, interview, focus group or specific procedure such as physical examination, venipuncture, etc.); who will administer the questionnaires. Include information on who will collect data, who will conduct procedures or measurements. Indicate the number and duration of contacts with each subject and location; outcome measurements; and follow-up procedures. Attach a copy of all questionnaires, interview guides, instruments and flyers. If applicable, please provide documentation of use authorization from instrument create or proof of purchase.

1. **DATA ANALYSIS:**

Describe the data to be used for the research study to include, if applicable, an explanation of the type of identifiers that will be collected. Tell how the qualitative and/or quantitative data will be analyzed. Explain how the sample size is sufficient to achieve the study aims. This might include a formal power calculation or explanation of why a small sample is sufficient (e.g., qualitative research, pilot studies). Letters of authorization from agency officials must be included.

1. **CONFIDENTIALITY OF DATA:**

Describe procedures for maintaining confidentiality of the data you will collect or will receive. What procedures will be used to safeguard identifiable records of individuals and protect the confidentiality and privacy of participants? If this is not possible, state why. Describe how you will protect the data from access by those not authorized. How will data be transmitted among research personnel? Where relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs). Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. Describe your plan to destroy identifiers.

1. **RISKS AND BENEFITS:**

Describe in detail the immediate or long-range risks to participants, if any, that may arise from the procedures used in this study. Risks may be embarrassment, physical, psychological, social, legal, or economic. They would include side effects, risks of placebo, risks of normal treatment delay, etc. Indicate any precautions that will be taken to minimize these risks. Describe what will be done to minimize these risks. Describe procedures for follow-up, when necessary, such as when subjects are found to be in need of medical or psychological referral. If there is no direct interaction with subjects, and risk is limited to breach of confidentiality (e.g., for existing data), state this. Also describe the anticipated benefits to participants and to society from the knowledge that may be reasonably expected to result from this study. If there is no direct benefit to the individual subject, say so here and in the consent form (if there is a consent form).

1. **INFORMED CONSENT:**

Informed consent can be in either written or oral format. If you request a waiver of informed written informed consent, please state your justifications (Please note that waiver of informed consent is only granted in limited circumstances and therefore an informed consent should always be prepared and submitted with your application on University letterhead). If an oral consent is planned, attach a copy of the text of the statement. The consent should include identification of 1) the researcher(s), 2) explanation of the nature and purpose of the study and the research method, 2) duration of research participation, 3) a description of how confidentiality/anonymity will be maintained, 4) mention of participants' right to withdraw their participation and their data from the study at any time without penalty, 5) information about the reasonably foreseeable risks and benefits (If there are no foreseeable risks and benefits please state so), 6) the voluntary nature of his or her participation, 7) who to contact regarding questions about participants' rights or injuries, 8) and a statement that the research has been approved by the Institutional Review Board at Fayetteville State University. Attach a copy of the written informed consent, web script or oral informed consent, with this application. For Non-English-speaking subjects please include a translation of the informed consent in their language. (See OSRP Informed Consent checklist and other sample forms at [www.uncfsu.edu/research](http://www.uncfsu.edu/research)). Non-English tools must be accompanied by a letter from an authorized translator of its accuracy.

1. **PROTECTED HEALTH INFORMATION (PHI):**

If the researcher needs to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a *limited waiver of HIPAA authorization*. If this applies to your study, please provide the following information: (a) Under this limited waiver, you are allowed to access and use only the minimum amount of PHI necessary to review eligibility criteria and contact potential subjects; (b)What information are you planning to collect for this purpose? (c) How will confidentiality/privacy be protected prior to ascertaining desire to participate? (d) When and how will you destroy the contact information if an individual declines participation? If you are not requesting a *limited waiver of HIPAA authorization* and are gathering PHI, then a specific statement that HIPAA information is being requested of the participant must be included in the consent form.

1. **DEBRIEFING STATEMENT**:

The participants also should be debriefed about their behavioral response(s) to the study. In the debriefing statement describe the reason(s) for conducting the research, the way to obtain the general results of the study, and the person(s). Also include in the debriefing statement: 1) The researchers name and their affiliation with Fayetteville State University; 2) the word “research” must be used; 3) the reason for the research must be re-iterated or in the case of a deception study disclosed; and 4) professional resources to contact if the participant has any questions or concerns as a result of his/her participation

1. **GENERALIZABLE KNOWLEDGE:** Will the proposed activity result in the development of or contribution to generalizable knowledge? Yes No If No, please explain.

Generalizable knowledge might include information presented to a broader audience or published with the intent of drawing scientific conclusions or increasing the body of scientific knowledge. This would not typically describe projects that are intended solely for internal assessment purposes, such as quality improvement, quality assurance, and program evaluations.]

1. **SUMMARY OF THE RESEARCH/ABSTRACT:**

Summarize the proposed research using ***non-technical*** language that can be readily understood by someone outside the discipline. Explain briefly the research design, procedures to be used, risks and anticipated benefits, and the importance of the knowledge that may reasonably be expected to result. ***Use complete sentences (limit of 300 words)****.*

1. **USE OF THE RESULTS:**

Describe with specificity to whom will the results be presented (class, conference, published article, other, etc.).

**SAMPLE CONSENT FORM**

**[Title of your study - IRB Study #:]**

You are invited to participate in a study of **[a brief description of your study]**.

My name is **[Your NAME]**, and I am a **[Your affiliation with]** at Fayetteville State University, in the Office of Sponsored Research and Programs. I hope to gain a better understanding about **[a brief description of what you hope to learn from this study]**. You will be one of **[number]** participants chosen to participate in this study.

If you decide to participate, you may be asked to participate in the following phases of data collection: **[list the phases that the subject will be involved with; give a brief description of each task the subject will have to perform]**. You may decide not to participate in any task or you may decide to not answer any questions on the questionnaire, inventories, or during the interviews that make you feel uncomfortable or embarrassed **[list any other risks that the subject maybe exposed to]**; you may stop your participation at any time during the study. There is **[no monetary compensation or monetary compensation (chose one). If there is monetary compensation or credit given specify the amount]** for participation in this study. I will make all reasonable efforts to accommodate your schedule and time constraints.

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. **Audio tapes and transcription, completed questionnaires, journals, and scores on inventories will be kept under lock and key. All audio tapes and video tapes will be erased following data collection, analysis, and manuscript development**. At no time will your name or institution be identified in reports, papers, or publications.

Your decision whether or not to participate will not affect your future relations with Fayetteville State University. If you decide to participate, you are free to discontinue participation at any time.

You are making a decision whether or not to participate. Your signature indicates that you have read the information provided above and that you have decided to participate. You may withdraw at any time after signing this form, should you choose to discontinue your participation in this study.

If you have questions, please ask me. If you have additional questions later, I will be happy to answer them. You can reach me at **[your phone number and email]** or write me at **[your name and address]**. **[If the research is a student project, please include identical information for the researcher and the Faculty Sponsor. The student researcher should identify him/herself as a student of FSU.]** If you have questions or concerns, at any time during this study, about your rights as a research subject you may contact:

**Dr. Theodore Kaniuka**, Chair of the Human Rights in Research Committee

Fayetteville State University

Fayetteville, NC 28301-4298

(910) 672-1636

You may keep a blank copy of this form for your records.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date Signature of Investigator Date

*This project has been approved by the Fayetteville State University Institutional Review Board Human Rights in Research Committee (Phone: 910-672-1569)***WAIVER OF INFORMED CONSENT DOCUMENTATION**

* **Use this form** to request a waiver of the requirement
  + to obtain a signed consent document (cannot be used for FDA-regulated research) or
  + to give participants a signed copy of the document.
* **Do not use this form** to request a waiver of part or all of the informed consent process. Instead, use the Waiver of Consent or Waiver of Authorization and Informed Consent. Instead, contact the Office of the Sponsored Research and Programs’ IRB Administrator at (910-672-1569).
* **General information about informed consent can be found at:** <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>

1. IRB Protocol Title:

2. Principal Investigator:

3. Choose one of the checkboxes below, indicating why the waiver of documentation is being requested for this research, and provide protocol-specific details as requested.

Confidentiality Risk—Respond to Items a-c, below:

1. Would the only record linking the subject and the research be the consent document? Yes No
2. Would the principal risk be the potential harm resulting from a breach in confidentiality? Yes No
3. Describe your plans to ask each subject whether he/she wants documentation linking his/her name with the research, and how each subject's wishes will govern (e.g., a document could be used for the informed consent process, subjects would be asked if they wanted a signed copy to document their consent, and those who did not would receive an unsigned copy).

The research involves no greater than minimal risk and no procedures for which written consent is normally required outside the research context. Respond to Item a, below.

1. Describe plans, if any, that you have for providing subjects with a written statement regarding the research. (*Note: The IRB may require that a written statement be given to the subject.*)

By signing this request for waiver of informed consent documentation, I certify the information included in it is accurate.

Principal Investigator's Signature Date

**WAIVER OF CONSENT**

* **Use this form** to request a waiver of informed consent when HIPAA does not apply to the information being collected.
* **Do not use this form** if you are also requesting waiver of patient authorization (HIPAA) to use protected health information in research. Use the Waiver of Authorization and Informed Consent instead.
* **Do not use this form** if the research or a demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service programs. Instead, contact the Office of the Sponsored Research and Programs’ IRB Administrator at (910-672-1569).
* **General information about informed consent can be found at:** <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>

1. IRB Protocol Title:

2. Principal Investigator:

3. Provide protocol-specific responses to Items a-d that describe why the waiver is being requested for this research.

a. Describe why the research involves no more than minimal risk to the subjects:

b. Describe why the waiver or alteration will not adversely affect the rights and welfare of the subjects:

c. Describe why the research could not practicably be carried out without the waiver or alteration of informed consent:

d. Do you expect that additional pertinent information will become available during or after the research?  Yes  No If yes, describe how the information will be provided to participants:

By signing this request for waiver of informed consent, I certify the information included in it is accurate.

By signing this request for waiver of informed consent documentation, I certify the information included in it is accurate.

Principal Investigator's Signature Date

**Waiver of HIPAA Authorization and Informed Consent**

* **Use this form** to request a waiver of patient authorization to use protected health information (PHI) in research. Complete Items 1-4. To also request a waiver of informed consent, complete Item 5.
* **Do not use this form** to request a waiver of informed consent when Health Insurance Portability and Accountability Act (HIPAA) does not apply. Instead, use the Waiver of Informed Consent form.
* **Do not use this form** if the research or a demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service programs.
* **General information about informed consent can be found at:** <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116>

Protected health information (PHI) is defined under the HIPAA regulations as

information that is a subset of health information, including demographic information collected from an individual, and: (1) is created by a health care provider, health plan, employer, or health care clearinghouse: and (2) relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

1. IRB Protocol Title:

2. Principal Investigator:

3. Request to Waive HIPAA Authorization for Research. Provide protocol-specific responses to the following items that describe why the waiver is being requested for this use of PHI in this research.

a. The use/disclosure of protected health information (PHI) involves no more than minimal risk to the privacy of individuals.

i. Describe the plan to protect the identifiers from improper use and disclosure:

ii. Describe the plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law:

b. Describe why the research cannot practicably be conducted without the waiver or alteration of patient authorization to use PHI in research:

c. Describe why the research cannot practicably be conducted without access to and use of the PHI:

4. Non-FSU Disclosure or Use of PHI

Do you plan to use the waiver from the FSU IRB to justify disclosure or use of PHI from a non-FSU covered entity? Yes  No If yes, complete a and b.

a. What covered entity or entities will disclose or use the PHI?

b. What PHI will the entity or entity disclose or use and how?

*If the IRB approves this request for waiver, the PI can forward the IRB-issued waiver to the non-FSU covered entity as documentation of the waiver of authorization for the disclosure of PHI to FSU. Please note the entity may or may not accept the IRB's waiver and may request an additional review.*

5. Request to Waive or Alter Informed Consent Along with HIPAA Authorization

Complete this item only if you are requesting a waiver or alteration of informed consent along with the waiver of HIPAA authorization. Provide protocol-specific responses to the following four items that describe why the waiver of consent is being requested along with this use of PHI in this research.

a. Describe why the research involves no more than minimal risk to the subjects:

b. Describe why the waiver or alteration will not adversely affect the privacy, rights and welfare of the subjects:

c. Describe why the research could not practicably be carried out without the waiver or alteration of informed consent:

d. Describe how, whenever appropriate, the subjects will be provided with additional pertinent information after participation:

**By signing this request for waiver of patient authorization, I certify that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.**  Check here if also requesting waiver of informed consent.

Principal Investigator's Signature Date

**ORAL CONSENT SCRIPT**

Protocol Title:

Principal Investigator:

<<Remove all blue instructions before submitting to the IRB>

You are being asked to participate in a research study about <<describe project in non-technical language; explain purpose of the research.>> <<Explain why the subject is being invited to participate.>>

If you agree to participate you will be asked to <<insert brief description of research procedure(s) and how long it will take.>> <<Insert statement to explain what information will be recorded about subjects, how confidentiality will be maintained, etc.>> <<Describe alternative procedures, if any.>> You will receive <<describe payment; where there is none, state as such>> as payment for your participation.

The risks associated with the research study are <<describe foreseeable risks or discomfort to subjects; time, burden and discomfort during interviews using sensitive questions are common risks and discomforts of studies that use an oral consent process.>> << For questionnaires, be sure to state that subjects may refuse to answer any question(s) that they do not wish to answer.>> <<Example: “The risks of this research study are minimal, which means that we do not believe that they will be any different than what you would experience at a routine clinical visit or during your daily life.” or “There are no known risks to you from taking part in this research study.”>>

The benefits which may reasonably be expected to result from this research study are <<describe any benefits; if there is no direct benefit to subject, describe potential benefit to people in the future as a result of information gathered in the research study.>> <<Example: “This study will not make your health better. It is for the benefit of research.”>>

Please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty. Neither your current nor future involvement with Fayetteville State University will be jeopardized if you choose not to participate.

If you have any questions about this research study you can contact me at <<provide your phone number.>> If you have any concerns, complaints, or general questions about research or your rights as a participant, please contact FSU’s Institutional Review Board (IRB) Human Rights in Research Committee (HRRC) Co-Chairperson, Dr. Theodore Kaniuka 910-672-1636 or tkaniuka@uncfsu.edu. <<If possible, hand out a separate business card or contact sheet to subjects which includes the contact information above.>>

**INFORMED CONSENT PROCESS FOR INTERNET-BASED RESEARCH**

Internet data collection via email, list serves, electronic bulletin boards and web surveys falls under the purview of the Institutional Review Board.

The Internet is an insecure medium as data in transit is vulnerable. So, internet data collection is rarely private, anonymous, or even confidential**.** The potential source of risk is harm resulting from a breach of confidentiality. This risk is accentuated if the research involves data that places subjects at risk of criminal or civil liability or could damage their financial standing, employability, insurability, reputation or could be stigmatizing.

For Internet-based surveys, it is usually appropriate to use implied informed consent. Participants would still need to be presented with the consent information but would be informed that their consent is implied by submitting the completed survey. Please see the following sites for implied informed consent templates:

1. Internet-based surveys can include at the end of the informed consent text, "I agree," or "I do not agree" buttons on the website for participants to click their choice of whether or not they consent to participate.
2. If the IRB determines that some sort of documented consent is required, the consent form can be mailed or emailed to the participant who can then sign the form and return it via fax or postal mail.
3. Researchers conducting web-based research should be careful not to make guarantees of confidentiality or anonymity, as the security of online transmissions is in question. A statement in the informed consent form indicating the limits to confidentiality is typically required. The following statement may be used: "Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties."
4. The instrument should be formatted in a way that will allow participants to skip questions if they wish to or provide a response like "I choose not to answer."
5. Researchers working with children online are subjects to [Children's Online Privacy Protection Act (COPPA)](http://www.ftc.gov/ogc/coppa1.htm) in addition to the human subjects regulations. Researchers are prohibited from collecting personal information from a child without posting notices about how the information will be used and without getting verifiable parental consent.
6. For assistance developing your online tool, contacting the Office of University Testing Services (x1217) is recommended.
7. All researchers conducting Internet-based Research or using the Internet to Conduct any part of their research must complete the CITI training on Internet Research. A copy of that training must be submitted to the Committee as part of the research approval review.

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Signature of Researcher Date