**WAIVER CONCENT FORM SAMPLES**

**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.

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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