**“On the Street” Interview and Telephone Consent Model Instructions**

Use these model as a guide when writing your oral consent for telephone or “on the street” interviews.

**How to use the assent and parent consent form models…**

* Instructional text is highlighted in yellow.
* Sample text is highlighted in green.
* Recommended/suggested text is in red**.** All other text should be edited according to the needs of your study.
* Fill the gray shaded areas in with text; the box will disappear once text is entered.

**When writing your forms, remember…**

* The parental permission and assent form for ages 13 – 17 should be written for the average person, which means it should be written below an 8th-grade reading level or at a level you believe is easy to comprehend by the target population.
* Avoid the use of medical terms, jargon and acronyms when possible.
* Use the word “you” when writing to your audience.
* If the sole researcher, use “I” in place of “the researcher”.
* Use the term participant, not subject or patient.
* Use the term researcher, not investigator
* The forms should be typed in 11 point font and kept to 2 pages if possible

Before submitting the consent form to the IRB….

1. **Delete** the instructional text highlighted in yellow.
2. **Delete** all example text highlighted in green.
3. **Change** the **red text** to black**.**
4. **Perform** final word smithing and formatting.
5. **Do not** indicate the consent is draft when submitting the consent form with the IRB application.

**“On the Street” Interview Consent Model**

**Study Title:**

|  |
| --- |
| **Introduction** |
| Hello, I’m from Florida Gulf Coast University. My name is      . I am wondering if you are interested in participating in a research study title       conducted through the University. If applicable, specify that the research is being done as part of a class or for a degree from Florida Gulf Coast University. Your participation in this study is voluntary. If you choose to participate in the study, you can leave it at any time with no penalty. Refusal to join the study will not affect any future services you may be eligible to receive from the University add any cooperating agencies in the study. If you join the study you do not have to answer any question you do not want to answer. The University requires that I obtain your consent before you can participate in this study, |
| **Study Summary** |
| The purpose of this study is to      . (1 - 2 sentences)  I am asking you to take part in the study because you      .  (Draw from Section II.C.4. of your IRB application)  Using lay language; explain all technical terms; avoid jargon and acronyms. Include:   * Why the subject is being asked to participate in the study. * If applicable, anticipated circumstance(s) under which the subject's participation may be terminated by the re without the subject's consent. * If applicable, a statement that significant new findings developed during the research, which may relate to the participant’s willingness to continue participation, will be provided.   The information we learn from this study may help us     . (Draw from IRB application Section II.A.1 - II.A.3) using language appropriate for your study population)  Participants in this study will      .  Provide a brief, concise (3 – 4 sentences) description of the research including the expected duration of participation, description of research and/or experimental procedures, the time commitment for the research and/or experimental procedures.  There is a risk of      . (1 - 2 sentences)  Please ask me any questions you have to help you understand the study. |
| **Compensation for Participation** |
| (Draw participant compensation from IRB application Section II.D.2, Will the participants be paid or receive other compensation such as course credit?)  If no payment for participating in study state…  You will not be paid to take part in this study.  **OR**  If participants will be paid, Include the amount, the type of payment (check/gift card/student credit, etc.), when it will be given and provisions for pro-rating the payment if a participant’s participation is terminated prior to completion of the study. State…  You will receive       to thank you for joining this study.  **OR**  There is a potential for you to incur costs for  **AND** if the study is sponsored, modify the following sentence as appropriate.  You will not receive any proceeds, profits, or other benefits from any commercialization that may result from this study. |
| **Confidentiality** |
| If you join the study, I (we) will take the following steps to keep your information confidential and secure      . (Draw from IRB application Section II.H, Confidentiality and Data Security) I (We) will not release information about you unless you authorize us to do so or unless we are required to do so by law. If the results of this study are published or presented, no information will be included that would make it possible to identify you as a study participant.  It is possible that organizations responsible for making sure the research is done safely and properly such as the university, and government offices or the study sponsor, [sponsor name(s), if appropriate] may need to see the information you provide. |
| **Storage and Future Use of Data** |
| Include one of the following statements if private information or identifiable biospecimens are collected in the study.  The identifiers might be removed from the personally identifiable information or biospecimens you provided and the de-identified information or biospecimens may be used for future research.  **OR**  Your information or biospecimens will not be used or distributed for future research studies even if your identifiers are removed from the information or biospecimens you provided for this study. |
| **Contact Information** |
| If you have any questions about this study or your rights as a subject/participant in this research please contact the individuals on this handout. (See handout information template below. |
| Do you have any questions before we begin? |
| Do you agree to participate in this research? |
| Study participants must be age 18 or older and       (study participant criterion). Please verify that you meet this criterion. |
| I appreciate your willingness to help with the study. |
| Let’s begin with the first question. |

Distribute the following information to each participant when the

“On the Street” Interview Consent Model is used

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

FGCU Study Contact Information

**Study Title:**

Sponsor:       (If applicable)

Principal Investigator:       (Must be full-time faculty or staff)

Co-Investigator(s):       (If applicable)

If you have any questions about this study, please contact       (Principal Investigator) at 239-     .

If you have any questions about your rights as a participant in this study, or if you feel you have been placed at risk, you can contact the Human Subjects' Institutional Review Board through [research@fgcu.edu](mailto:research@fgcu.edu) or Sherry Alexander, Office of Research & Sponsored Programs, at [sralexander@fgcu.edu](mailto:sralexander@fgcu.edu).

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

**Telephone Consent Model**

**Instructions:** Make copies of the IRB approved oral script and questions. If the person agrees to participate, document the person’s name or identifier in the attached spreadsheet, and initial by each name it to indicate that you have administered the elements of informed consent and that the person has agreed to participate.

|  |
| --- |
| Study: |
| **Introduction** |
| Hello, I’m calling from Florida Gulf Coast University. My name is      . I am calling to ask if you are interested in participating in a research study title       conducted through the University. If applicable, specify that the research is being done as part of a class or for a degree from Florida Gulf Coast University. Your participation in this study is voluntary. In order for you to participate in this study, the University requires that I obtain your consent.  If you choose to join the study, you can leave it at any time with no penalty. You do not have to answer a question you do not want to answer. |
| **Nature and Purpose of Study** |
| The purpose of this study is to      . (1 - 2 sentences) |
| Participants in this study will      .  Provide a brief, concise (3 – 4 sentences) description of the research including the expected duration of participation, description of research and/or experimental procedures, the time commitment for the research and/or experimental procedures. The information presented in this section will be expanded later in the body of the consent form. |
| There is a risk of      . (1 - 2 sentences)  If you are interested in learning more about this study, I will continue to explain the study. Please ask me any questions you have to help you understand the study. |
| **Invitation to Join Study** |
| I am asking you to take part in the study because you      .  Draw from Section II.C.4. of your IRB application)  Using lay language; explain all technical term; avoid jargon and acronyms. Include why the subject is being asked to participate in the study |
| Study participants must be age 18 or older and       (study participant criterion). Please verify that you meet this criterion. |
| If you join the study, you will be asked to answer       (number of)       (type of questions). I (We) anticipate that this survey/interview will take less than       minutes to complete. |
| Your participation is completely voluntary. You are free to stop the survey at any time. You can skip any questions you do not want to answer. Refusal to join the study will not affect any future services you may be eligible to receive from the University add any cooperating agencies in the study. |
| **Confidentiality of Information** |
| If you join the study, I (we) will take the following steps to keep your information confidential and secure      . (Draw from IRB application Section II.H, Confidentiality and Data Security) I (We) will not release information about you unless you authorize us to do so or unless we are required to do so by law. If the results of this study are published or presented, no information will be included that would make it possible to identify you as a study participant.  It is possible that organizations responsible for making sure the research is done safely and properly such as the university, and government offices or the study sponsor, [sponsor name(s), if appropriate] may need to see the information you provide.  Include one of the following statements if private information is collected for the study.  The identifiers might be removed from the personally identifiable information you provided and the de-identified information may be used for future research.  OR  Your information will not be used or distributed for future research studies even if your identifiers are removed from the information you provided for this study. |

|  |
| --- |
| **Risk(s) of Participating** |
| Describe the potential risks and discomforts if one joins the study. Include any foreseeable hazards, inconveniences and risks the participant may undergo, and an estimate of their likelihood it/they will occur to the best of your knowledge. All risks listed in the protocol must appear in the consent form. (Draw from IRB application Section II.I, Risks)  If more than minimal risk to participant state… There is a chance of harm if you join the study. The activities you will do may      . I (We) will       to prevent them or minimize them.  **OR**  If minimal risk for participant state…  There is minimal risk involved with this study. I (We) will       to prevent them or minimize them.  **OR**  If no risk for participant state…  There are no known or anticipated risks to you if you join the study.  If appropriate to the study, include a statement that the particular treatment or procedure may involve risks which are currently unforeseeable. |
| **Benefit(s) of Participating** |
| (Draw from Section II.J of IRB application)  If no benefit anticipated for participant state  I (We) do not expect this study to benefit you.  **OR**  If there are possible benefits for participant state…Being in this study might benefit you by  **OR**  If there are potential benefits for others state…  I (We) hope the information we get from this study will help others who |
| **Compensation** |
| (Draw participant compensation from IRB application Section II.D.2, Will the participants be paid or receive other compensation such as course credit?)  If no payment for participating in study state…  You will not be paid to take part in this study.  **OR**  If participants will be paid, Include the amount, the type of payment (check/gift card/student credit, etc.), when it will be given and provisions for pro-rating the payment if a participant’s participation is terminated prior to completion of the study. State…  You will receive       to thank you for joining this study.  **OR**  There is a potential for you to incur costs for  **AND** if the study is sponsored, modify the following sentence as appropriate.  You will not receive any proceeds, profits, or other benefits from any commercialization that may result from this study. |
| **Contact Information** |
| I/We do not foresee any medical problems from participating in this study. However, if you believe you experienced a research related injury, please contact       at 239-      . Principal Investigator.  If you have any questions about this study, please contact       Principal Investigator at 239-     . |
| If you have any questions about your rights as a participant in this study, or if you feel you have been placed at risk, you can contact the Human Subjects' Institutional Review Board through [research@fgcu.edu](mailto:research@fgcu.edu) or Sherry Alexander, Office of Research & Sponsored Programs, at [sralexander@fgcu.edu](mailto:sralexander@fgcu.edu). |
| Do you have any questions before we begin? |
| Do you agree to participate in this research? |
| I appreciate your willingness to help with the study. |
| Let’s begin with the first question. |

**List of Individuals Contacted by Phone to give Consent to participate in the Study**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date | Contact/Participant Name/ Identifier | Individual Administering Consent | Agreed to Participate (Y/N) | Notes |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |