## Informed Consent – Verbal Consent Script Template

 **Prospective Social Behavioral Verbal Consent Template**: Below is the template for a prospective verbal social behavioral project informed consent form. Please utilize this template as a guide for all prospective verbal social behavioral consent forms. The italicized/red text should be replaced with relevant study information or deleted if not applicable. Please be sure to upload your completed informed consent as a separate document in the IRBNet submission.

**Script for Obtaining Verbal Informed Consent**

Information to Consider Before Taking Part in this Research Study

**Title:** ***[Title of study, as it appears on the IRB application, grant/contract, or sponsored protocol. Best to bold title so it is more visible.]***

**Study IRBNet # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***[The 2018 Common Rule requires consent documents to begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding why one might or might not want to participate in research. The first page of this template is designed to assist you with drafting that key information. For minimal risk research, the key information (the “Overview” herein) may comprise the majority of the consent document. Information in the Overview does not have to be reiterated in the sections below the Overview.]***

**Overview:** You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate. The sections in this Overview provide the basic information about the study. More detailed information is provided in the remainder of the document.

Study Staff: This study is being led by *[insert name of PI]* who is a *[list PI’s role]* at/in *[list name of PI’s employer].* This person is called the Principal Investigator. *[The following sentence should be included if there is a faculty advisor involved] [He/She]* is being guided in this research by *[insert name of faculty advisor]*. Other approved research staff may act on behalf of the Principal Investigator.

Study Details: This study is being conducted at *[insert location at which research will be conducted; if at LRH please put “Lakeland Regional health Systems, Inc.” here]* and is supported/sponsored by *[insert name of sponsor].* The purpose of the study is to *[insert brief summary of purpose]. Briefly explain in a few sentences, in lay language (understandable at a 7th grade reading level), the purpose of the study and the expected duration of the prospective subject’s participation. Example: The purpose of this study is to find out.... Tell the person, in lay terms, how the research will be carried out and whether the research includes a one-hour interview, a two-hour focus group, a 20-minute questionnaire, a 90-minute lab session in which you will solve complex puzzles, etc.*

Participants: You are being asked to take part because *[explain in lay language the condition(s) or situation that makes the prospective subject eligible for the research. Example: We are asking you to take part in this study because you have anxiety. We want to see how this behavioral intervention helps people with anxiety.]*.

Voluntary Participation: Your participation is voluntary. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. Alternatives to participating in the study include: *[If there are alternatives, describe the procedures/treatments/interventions that the subject could receive such as taking a different course of treatment, etc.]*. *[If extra credit is offered for participation, please state that an alternative assignment will be offered to students as a non-research alternative involving comparable time and effort to that which is involved in the research. If subjects are employees, include as applicable:* Your decision to participate or not to participate will not affect your job status, employment record, employee evaluations, or advancement opportunities*. If subject are students, include as applicable:* Your decision to participate or not to participate will not affect your student status, course grade, recommendations, or access to future courses or training opportunities.*]*

Benefits, Compensation, and Risk: We do not know if you will receive any benefit from your participation. [*If applicable:* There is no cost to participate.] You *[will /will not]* be compensated *[enter amount if compensated]* for your participation. [*If applicable:* This research is considered minimal risk. Minimal risk means that study risks are the same as the risks you face in daily life.]

Confidentiality: Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.

*[If compensation for participation is available, include the dollar amount per visit and payment upon study completion of study activities. Please note raffles/random drawings of chance is not permitted.]*

You will be compensated *[enter amount]* if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion you will be compensated *[enter $ amount here]* for each study visit you complete.

*[If participants are staff of LRH who will be compensated please include the following language]*

If you do not want to complete the tax payer ID form you can still participate in the study. However, if the form is not completed, you will not be compensated.

We will do our best to keep your records private and confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Certain people may need to see your study records. The only people who will be allowed to see these records are: *[include who will have access to the data, list by title, e.g., Principal Investigator, research team, the advising professor. ALSO, if you have a sponsor – please list them as a separate bullet point]*. *All studies must include:* The Lakeland Regional Health Institutional Review Board (LRH IRB). *Studies that are sponsored by federal agencies under the Common Rule must include:* government offices such as, The Department of Health and Human Services (DHHS).

*[Please include one of the following statements if the research involves the collection of identifiable private information or biospecimens.]*

Your identifiers might be removed from your private records or your samples. Your information or samples could be used and/or distributed to another investigator for future research studies without additional consent from you or your Legally Authorized Representative *Or;*

Your information or samples collected as part of the research, even if identifiers are removed, will NOT be used or distributed for future research studies.

*[Use the mandatory statement below if conducting an online survey:]*

It is possible, although unlikely, that unauthorized individuals could gain access to your responses because you are responding online. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the internet. However, your participation in this online survey involves risks similar to a person’s everyday use of the internet. If you complete and submit an anonymous survey and later request your data be withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database.

*[For study sites located in the EU or studies that will enroll EU subjects, include the language in the following five paragraphs through “…with the data supervisory authority in your country.”]*

Data collected for this research will be stored at the *[insert name of LRH study site, e.g. the Hollis Cancer Center]*, located at Lakeland Regional Health in the United States.

***The following information may be used and disclosed to others:***

* Your research records
* All of your past, current or future medical and other health records held by your study site
* Your contact information, including your name, e-mail address and your mailing address
* *[Insert any other personal data that will be collected from EU participants, including, for example, information about subjects’ ethnic or racial background, sexual history or sexual orientation, or political or religious beliefs.]*

Your personal information collected for this research will be kept as long as it is needed to conduct this research. Once your participation in the research is over, your information will be stored in accordance with applicable policies and regulations. Your permission to use your personal data will not expire unless you withdraw it in writing. You may withdraw or take away your permission to use and disclose your information at any time. You do this by sending written notice to the Principal Investigator at the following address: *[Insert appropriate business address.]*

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by LRH policies.

If you have concerns about the use or storage of your personal information, you have a right to lodge a complaint with the data supervisory authority in your country.

 *[If applicable (i.e. for studies involving focus groups, include the following language]*

Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to remind you to respect the privacy of your fellow participants and not repeat what is said in the focus group to others.

*[If your research is NIH funded and you are conducting research involving sensitive, identifiable information, you have automatically received a certificate of confidentiality as a part of the terms and conditions of the award and are required to include this language. If your research is not NIH funded and you have applied for a certificate of confidentiality, insert this language as appropriate.]*

To help us protect your privacy, *[we will obtain/we have obtained]* a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under certain circumstances. The investigative team will voluntarily comply with Florida Statutes and federal regulations, which may mandate or permit certain disclosures of protected information by the investigative team to appropriate individuals.

*[If applicable, insert HIPAA authorization language]*

If you have any questions, concerns or complaints about this study, call *[name of Principal Investigator]* at *[telephone #]*. If you have questions about your rights, complaints, or issues as a person taking part in this study, call the LRH IRB at 863-687-1100 x7214or contact the IRB by email atIRB@myLRH.org.

Would you like to participate in this study? *[PI will record if verbal consent is given]*