**CONSENT SCRIPT FOR TELEPHONE INTERVIEW**

TEMPLATE INSTRUCTIONS: This template is written for an expedited or full board study conducting **telephone interviews as the sole research activity** that a participant will be involved in. If participants will complete multiple research activities or if the study will enroll decisionally impaired adults, use either the Biomedical or Social-Behavioral Consent Templates.

Refer to either the Biomedical or Social-Behavioral Consent Templates for full instructions about what needs to be in consent forms. Use other template language from these templates as appropriate.

**In order to use this template for expedited and full board studies, you must request a “Waiver of Documentation of Consent” (the consent signature) in the IRB submission. In addition, if you choose not to include all of the required elements in your script, you must request a “Waiver of Certain Elements of Consent” in the IRB submission and list the elements that you want to waive**.

* Instructions and comments are indicated in blue boxes, and [yellow highlighting].
* Delete the instructions and comments after reading and following.
* Required information is indicated in the instruction boxes. You may delete the optional sections and language if they are not applicable to your study.
* Example text should be edited to be appropriate for your study.
* Use other template language from the Biomedical Consent Template as appropriate.
* Use lay language at an 8th grade reading level.
* If it is necessary to use technical terms, a lay definition of the term must be provided.
* Define all acronyms at first use.
* Page numbers must be included in the format “Page \_\_ out of \_\_\_\_”.
* If the study enrolls only children, consider replacing “you” with “your child” and “consent” with “parental permission” throughout

*[If obtaining parental permission:] Study team – verify that this individual is the child’s parent or legal guardian.*

**Before we begin, I must review some consent information with you. This information is meant to assist you in carefully thinking about whether being in this study is right for you and your situation.** Please ask me to explain anything that is not clear to you.

*Purpose and Procedures:* You are invited to participate in a research study about [briefly describe the study’s purpose]. If you agree to participate, I will ask you some questions about [describe all the topics of the questions you will ask]. This interview will take approximately [state the estimated duration] and [insert number of participants] people will participate.

*Alternatives:* [If participants have an alternative way of participating (e.g. filling out a paper or online survey instead of a phone interview, going to a study location for an in-person interview, etc.), describe that option. Example:] You have the option to take a paper survey instead of completing this interview over the phone. If you would like to take the paper survey, just let me know. [Example:] You can receive extra credit without being in the study by [explain the alternative way to earn credit].

*Voluntary Participation:* Your participation is voluntary. You may choose not to participate in this interview, stop the interview at any time, or skip any questions with no penalty or loss of benefits to which you are otherwise entitled.

*Risks and Benefits:* The interview questions might make you feel uncomfortable. There is also a small risk that someone outside the study could see and misuse information about you. You will not benefit from this interview, but it may help us learn more about [describe the scientific benefit of the study].

*Confidentiality Protections:* Information that you give me will be kept as confidential as possible by storing it in secure databases accessible only to the following people: study personnel, authorized people at VCU who oversee research, the study sponsor [delete if there is no Sponsor], and authorized officials of the Department of Health and Human Services. [Insert if applicable:] This interview will be audio recorded, and the recording will be destroyed [identify when the recording will be destroyed].

**Additional element of consent 46.116(c)(8):** “A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions”

**\*\* The following text is required for all studies and may be modified as appropriate.**

In general, we will not give you any individual results from the study. [Insert if the study may have clinically relevant findings:] If we find something of medical importance to you, we will inform you, [or explain another method of communicating the information] although we expect that this will be a very rare occurrence. [Insert if participants will receive aggregate study results:] Once the study has been completed, we will send you a summary of all of the results of the study and what they mean.

INSTRUCTIONS: As employees of an institution of higher education in Virginia, VCU faculty and staff are mandated reporters and are obligated to report child and elder abuse. If there is the potential for any participant to disclose that they may cause injury to themselves or others, you should state in this section that you are required by law to report that information to the appropriate authorities.

**\*\*The following information is required if there is the potential for you to discover suspected child or elder abuse during the course of the study.**

[Example:] We will not tell anyone the answers your child gives us. But, if your child tells us that someone is hurting her or him, or that she might hurt herself or someone else, the law says that we must let people in authority know so they can protect your child.

[Example:] If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

INSTRUCTIONS: Insert the language of either Option A or Option B. If there is any chance that information could be used in future studies, insert Option A.

**Basic element of consent 46.116(b)(9):** “One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.”

**\*\*The following text is required for all studies with identifiable or de-identified information (i.e. studies that keep a key linking participant IDs with direct identifiers like names). Modifications are not recommended.**

 [Option A – Studies that will or might use information for future research studies, insert:] In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

[Option B – Studies that will not use information for future research studies, insert:] The information collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

*Certificate of Confidentiality:*

**\*\*This sub-section is required for all studies funded in whole or in part by the NIH, that were commenced or ongoing, on or after December 13, 2016. It is also required for all non NIH-funded studies that will voluntarily seek a Certificate of Confidentiality (note: all human subject research qualifies for a CoC). Modifications are not recommended.**

To help us protect your privacy, we have obtained [or insert: will apply for] a Certificate of Confidentiality from the National Institutes of Health. If this certificate is obtained, it will offer the protections described here. A Certificate of Confidentiality helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited, or if the information is required by the Food and Drug Administration (FDA).

[If you intend to make voluntary disclosure about things such as child abuse, intent to hurt self or others, or other voluntary disclosures, insert:] The researchers may share information about you or your participation in the research project without your consent if: [State here the conditions under which voluntary disclosure would be made, such as child or elder abuse or neglect, or harm to self or others.]

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

**HIPAA AUTHORIZATION**

**\*\*This is an optional section that applies only to studies accessing, using, or maintaining PHI.**

In seeking HIPAA authorization, 8 elements and statements are required by HIPAA regulations to be provided to subjects in order to obtain valid authorization. VCU researchers can ensure all of the HIPAA authorization requirements are being met by utilizing this template language as directed.

**In order to use this template for expedited and full board studies, you must request a Partial Waiver of Authorization in the IRB submission.** Request to waive the following 2 elements:

1) the authorization signature and

2) the requirement to provide the subject with a copy of the signed authorization.

**In addition, if you choose not to include all of the required elements in your script, you must request a Partial Waiver of some elements of authorization and list the elements that you want to waive**.

Researchers also have the option to draft their own authorization language. If drafting your own language, your script should either: include all 8 elements in order for the authorization to be valid, or a Partial Waiver should be requested for the missing elements/statements.

As part of this research study, we will ask you to permit us to access existing information from your healthcare records. [Insert if applicable: New health information will also be added to your healthcare records from study-related tests, procedures, visits, and/or questionnaires.] This type of information is considered “Protected Health Information” that is protected by federal law.

To conduct of this research we may use *[describe the type of health information to be used, including all that apply:* Your complete health record, Diagnosis & treatment codes, Discharge summary, History and physical exam, Consultation reports, Progress notes, Laboratory test results, Medical imaging reports, Imaging films / scans/pictures, Photographs or videotapes, Your complete billing record, Your itemized billing information, Information about drug or alcohol abuse, Information about Hepatitis B or C tests, Information about psychiatric care, Information about sexually transmitted diseases*, or specify others as applicable]*.

By agreeing to this study, you authorize VCU and [VCU Health/VCU Dental Care] to use and/or share your health information for this research. The health information just described may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research: the Principal Investigator and Research Staff, the Study Sponsor [delete if none], Research Collaborators [delete if none], Data Coordinators [delete if none], Data Safety Monitoring Boards [delete if none], Health Care Providers at [VCU Health/VCU Dental Care], Institutional Review Boards, Government/Health Agencies, and Others as Required by Law. Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

**Insert ONE of the following expiration options:**

[Option 1:] This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

[Option 2:] This research study involves the use of a Data Registry and will expire [specify other expiration date].

[Option 3:] This authorization will expire when [specify other expiration date].

You may change your mind and take back the right to use your protected health information at any time. However, even if you take back your Authorization, the researchers may still use or release any health information that they have already collected about you for the study. If you take back this Authorization, you may no longer be allowed to participate in the research study. To take back this Authorization, you must write to [insert the Principal Investigator’s name and mailing address].

*Costs and Compensation:* [Describe any planned compensation and/or additional costs to the participant that may result from the screening interview. Example:] You will be responsible for paying the cost of the minutes used during this telephone call.

[Example:] You will be paid $\_\_\_\_\_ in cash/by check/by gift card if you complete the interview. If you withdraw before the end of the interview, you will be paid $\_\_\_\_\_.

*Questions about the Study:* If you have any questions, concerns, or complaints about your participation in this research, please contact [name of the PI] at [phone number]. If you want to talk to someone separate from the research team, please contact the VCU Office of Research at 804-827-2157.

Do you have any questions about this study?

**CONSENT**

Do you consent to participate in this research interview?

\_\_\_\_\_\_\_\_ YES – CONDUCT INTERVIEW→ **(*Document the participant's consent, along with the date, any witnesses, and the name of the person conducting consent in the study’s records*)**

\_\_\_\_\_\_\_\_ NO – Thank you for your time.

**OPTIONAL MAINTENANCE OF CONTACT INFORMATION FOR FUTURE STUDIES**

**Studies that plan to keep only contact information to aid in recruitment for other future studies should include this section. If you plan to keep research data as well as contact information, use the next section instead of this one.**

We may have other studies like this one that you might be interested in. With your permission, I would like to keep your name and [*describe any other contact information such as address,* *phone number, e-mail address, etc. being kept by the study*] in our research database so that we could contact you when we begin any new studies. This information would not be stored with any of the information you provide in this interview.

Do you give permission for your contact information to be saved and used to contact you about future studies?

\_\_\_\_\_\_\_\_ YES → Great! **(Participant’s contact information may be kept. Document the participant's agreement in the study’s records)**

\_\_\_\_\_\_\_\_ NO → Thank you. → **(Do not contact subject for future studies)**

**OPTIONAL STORAGE OF DATA FOR FUTURE RESEARCH STUDIES**

INSTRUCTIONS: Include in this section a description of what data will be stored for future unspecified research in a registry or repository, either at VCU or at another institution (e.g. sponsor’s, collaborator’s registry, etc.).

The following information is considered to be key information that participants should be told in this section so that they can make an informed decision about participating in the registry:

* The purpose of creating or contributing to a registry
* What data will be stored, where, and by whom
* The potential secondary uses of the data
* Risks of re-identification and potential loss of confidentiality
* Whether/how participants can withdraw their data from the registry.

Additional information about the registry, such as benefits, ownership of the data, costs, etc. should also be added if/when it is relevant to the subject’s decision about participation.

**\*\*This is an optional section that applies only to studies that plan to create or contribute to a research registry and may be modified as appropriate.**

**Data Submission to an NIH-Designated Controlled-Access Database or Repository**

For NIH-funded research, investigators are frequently expected to obtain unrestricted consent for future uses and sharing of data and/or samples, particularly genomic and phenotypic data. Template language may be available at the funding institute or center’s website.

Unrestricted consent:

Participants can be asked to agree to storage of their data and to the use of their data in any future unspecified research on any topic ("general research use"). Unrestricted consent maximizes the utility of collected data.

Specific consent:

Sometimes, it may be appropriate to seek consent for more narrowly defined research uses of participant data. This consent approach may increase participation of people who have concerns about privacy or do not want their data used for research on certain topics.

To advance science, it is helpful for researchers to share information. They do this by putting data into one or more scientific databases (called registries), where it is stored along with information from other studies. Researchers can then study the information in other ways and combine information from many studies to learn even more about health and disease.

[Example – general VCU registry/repository] As part of this study, we would like to keep the information that you provide, along with your [describe the identifiers that will be part of the registry (name, phone, email, etc.)] in a registry to be available for other research studies in the future. Your information would be stored at [VCU] by [full name of investigator who will oversee the registry] and could be used for other research studies about any topic [If future research will be limited to specific types of studies/diseases, indicate here; otherwise leave open-ended]. Your data will be protected, but there is always a possibility that information could be accessed by individuals without authorization. There is no limit on the length of time we will store your information.

[Example - Unrestricted consent for sharing] Your information will be stored indefinitely by \_\_\_\_ in one or more scientific databases at \_\_\_\_, and shared with other researchers. The information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from. This information will not be labeled with your name or other information that could be used to easily identify you. However, it is possible that the information, when combined with information from other public sources could be used to identify you, though we believe it is unlikely that this will happen.

[Insert for all studies with registries:] In the future, if you decide that you don’t want to be part of this registry, you can request that your information be removed and destroyed by contacting [name of investigator who should be contacted (e.g. the PI at VCU)]. However information that has already been shared with other researchers will continue to be used.

**Include the following paragraph if the study registry children. It may be modified to reflect this study’s plan for re-consenting children in the registry who reach the age of majority.**

[Example:] When your child reaches age 18, we will try to contact them to ask whether they want to continue to participate in this research registry. If we cannot find your child, we will remove all identifying information, and continue to use their information in research. [Or describe your plan for recontacting the child to obtain consent]

Do you have any questions about the registry?

Do you agree that your information may be stored and used for future research as described above?

\_\_\_\_\_\_\_\_ YES → Great! **(Participant’s data may be added to the Registry. Document the participant's agreement in the study’s records)**

\_\_\_\_\_\_\_\_ NO → Thank you for your time. → **(Do not add subject’s data to the registry)**