**TELEPHONE CONSENT TEMPLATE - FOR SCREENING**

**[In seeking informed consent, there are specific elements of consent that are required by regulation to be provided to subjects. This template contains all of the required elements except for the participant’s signature.**

**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 addition, if you choose not to include all of the required elements in your study’s telephone screening consent script, you must request a Waiver of Certain Elements of Consent and list the elements that you want to waive. For more information see WPP XI-1 (**[**http://www.research.vcu.edu/human\_research/irb\_wpp/XI-1.htm**](http://www.research.vcu.edu/human_research/irb_wpp/XI-1.htm)**)]**

[Instructions and comments are in italics and []. Please modify this template as applicable to your study, delete all instructions and comments, and remove all yellow highlighting when finished reading and editing.]

The purpose of this screening interview is to see if *[insert, as applicable:* you / your child / your family member*]* meet(s) the criteria for taking part in our research study of *[state what is being studied]*.

This interview will take approximately *[state the duration]*. I am going to go through a list of questions asking about *[describe the kinds of questions you will ask]*. You may choose not to answer these questions. You may choose to stop participating in this interview at any time. If you would like to stop, or skip any questions, please tell me.

Your participation in this interview is completely voluntary. If you refuse to answer the questions or stop answering them at any time, there will be no penalty, and you will not lose any benefits to which you would otherwise be entitled.

Information about you that you give me during this interview will be kept as confidential as possible, as required by law*. [If the research is FDA-regulated, insert:* It is possible that personal information about you might be shared with or copied by authorized officials of the Federal Food and Drug Administration].

*[RISKS - Modify as appropriate for your study]* The risk to taking part in this interview is very small, but it is possible that some people may feel uncomfortable answering these questions with persons they do not know *[or state other minimal risk(s)].* If you qualify to take part in the study and are interested in taking part, then I will record your name and information; this will be kept confidential, but there is a small risk that people outside of the research team could learn this information. If you are not interested in the study, then I will destroy the personal information you give me *[choose one of the following statements, as appropriate or describe the retention period your study will use:* once we have finished talking / once we have finished recruiting for the study / once we are finished with the study*]*.

*[BENEFITS - Choose one and modify as appropriate]:*

*[Option 1 – Studies with no direct benefit]* There are no benefits to you taking part in this screening interview. However, it is possible that the information from the study that we will be doing may help researchers to learn more about *[state what is being studied]* and may benefit others in the future.

*[Option 2 – Studies with potential for direct benefit]* The benefit to you taking part in this interview is that you will find out whether you can take part in our study of *[state what is being studied]*. This involves *[state what it involves and why this might be beneficial to the person]*.

*[ALTERNATIVES – Choose one and modify as appropriate.]*

*[Option 1 – Studies with no alternatives]* Your alternative is to not take part in this screening interview.

*[Option 2 – Studies that have an alternative]*  If you do not want to answer these questions, you have other choices. You can *[state other alternatives, such as other ways that screening could be completed].*

*[HIPAA AUTHORIZATION - If the screening involves the collection of identifiable health information (PHI) and HIPAA authorization is required, please copy the HIPAA authorization language that is found in the Verbal HIPAA Authorization Template (*[*http://www.research.vcu.edu/forms/index.htm#irb\_forms*](http://www.research.vcu.edu/forms/index.htm#irb_forms)*) and past it into this section of the consent script.]*

If you have any questions, concerns, or complaints about this interview, please contact *[insert name and phone number or email address of PI]*. If you want to talk to someone separate from the research team about a concern or complaint or your rights as a possible research subject, please contact the VCU Office of Research to speak to an informed person who is separate from the research team, at 804-827-2157.

Do you have any questions?

Now that I have explained the procedures, and you have had all your questions answered, do you consent to participate in the screening interview?

\_\_\_\_\_\_\_\_ YES – CONDUCT SCREENING INTERVIEW🡪 **(*document the participant's consent, along with the date, any witnesses, and the name of the person conducting consent*)**

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

*[Studies that plan to keep contact information for future recruitment should include this section:]*

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.*] 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

\_\_\_\_\_\_\_\_\_\_\_ NOT OK FOR INFORMATION TO BE USED OR TO BE CONTACTED ABOUT FUTURE STUDIES 🡪 **(*do not contact subject for future studies*)**

*[Studies that involve adding screening data to a Data Registry should include this section:]*

As part of this research, we are [Choose one: creating / contributing to] a registry, which is a data bank of information about people like you. With your permission, I would like to add the information you provide during this screening interview along with your *[describe the identifiers that will be part of the registry (name, phone, email, etc.)]* to the registry to be stored and used for future research.

Your information would be stored [Insert as appropriate: at [*name of the institution]* / by *[name of investigator who will oversee the registry].* 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 *[or describe the time period that the registry will operate]*.The decision about whether to participate is completely up to you. *[Add an explanation about whether subjects may, in the future, request that their data be destroyed and how that request should be made.]*

*[Additional information about the registry, such as the registry’s purpose, potential secondary uses of data, risks, benefits, ownership of the data, costs, etc. should also be added if/when it is relevant to the subject’s decision about participation.]*

Do you have any questions?

Do you consent to participate in this registry?

\_\_\_\_\_\_\_\_\_\_\_ YES 🡪 Participant’s data may be added to the Registry [GO TO OPTIONAL STIPULATIONS, IF USING] **(*document the participant's consent, along with the date, any witnesses, and the name of the person conducting consent*)**

\_\_\_\_\_\_\_\_\_\_\_ NOT OK FOR INFORMATION TO BE STORED OR USED FOR FUTURE RESEARCH 🡪 **(*do not add subject’s data to the registry*)**

*[Optional stipulations, if obtaining layered consent for data usage; include all that apply:]*

Thank you for agreeing to be part of the Registry! You have a few options about how your data may be used.

1. Do you give permission for your data to be stored and used for research related to [*insert a specific disease or topic*]?

YES \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NO \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Do you give permission for your data to be stored and used for future research about other health problems?

YES \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NO \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Would you prefer to be contacted prior to any future use of your data for research?

YES \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NO \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_