Please note that this is a SAMPLE consent form. You must modify this form to ensure that it is applicable to your study.

TITLE OF YOUR STUDY

**Verbal Consent Script Template**

*First Name Last Name, Degree*, Principal Investigator
*Institution/Organization Name*

***NOTE TO INVESTIGATOR****: Please refer to the imbedded comments regarding required Elements of Informed Consent and requirements mandated by HIPAA. As the subject’s consent will be verbal, you must apply for a waiver of DOCUMENTATION of consent for non-exempt studies.*

**The following is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in this study.**

The purpose of this study is *[state study’s purpose/what study is about here].* Study subjects will *[state main study intervention/procedure(s), for example, answer questionnaires, participate in an interview/a focus group, provide one blood sample]*. Your participation in the study is expected to last *[state duration – i.e., number of days, weeks, or months]* and will include *[state number of study visits/encounters]* visits. Participation is completely voluntary. There is no direct benefit to you from taking part in this study. However, information we learn from the study results may help people in the future. *--OR—describe the possible direct benefit to participants, when applicable.* There is the risk of loss of confidentiality of your *[medical and]* personal information collected for this study.

**If you are interested in learning more about this study, please continue to listen, and I will discuss additional information and details related to this study such as the risks, benefits, procedures, alternatives, and contact information.**

This study is being conducted by *[names of investigators]*. The *[name of funding agency or other funding source, if applicable]* has provided funding for this study.

*[INSTITUTION/ORGANIZATION]* is conducting a research study to *[explain purpose of the research]*. We are asking you to consider being a part of this study because you *[state reason participant is being approached here]*. We expect about *[state total accrual goal for your site here]* people to participate in this study. If you agree to be in the study, your participation will take approximately *[state the time of subject participation in hours, days, weeks, months etc. and any follow up calls].*

All participants will be asked to *[list study procedures; clearly specify any that are experimental]*.

The risks in participating in this study are: *[list risks and if possible qualify the severity by stating rare risks, expected risks frequent risks etc.]*.

*--OR--*

There are no physical risks to participating in this study.

There is no direct benefit to you from taking part in this study. However, information we learn from the study results may help people in the future. *--OR— Describe the possible direct benefit to participants, when applicable.*

*--OR--*

*Describe any direct benefit to participants that may reasonably be expected.*

Your alternative is to not take part in the study. *[For interventional studies, when applicable, describe appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.]*

There will be no costs to you.

You will not be paid for participating in this study.

*--OR--*

You will not be paid for participating in this study, but you will be reimbursed for research-related expenses by *cash/debit card/check (specify how)* at *each visit/by mail two weeks* after your visit *(specify when)* for you participation in this study.

Your participation is completely voluntary. You may discuss this study with your doctor, family, and friends before you decide whether you would like to participate. You do not have to take part in the study or finish it. If you don’t take part, it won’t affect the care you receive from your doctor or other benefits to which you are entitled. If those conducting the study think it’s not in your best interest to continue or decide to stop the study, we will end your participation.

*NOTE TO INVESTIGATOR: When HIPAA authorization is needed because the study includes use/disclosure of PHI (Protected Health Information), you can apply for an alteration to HIPAA authorization to allow you to waive the requirement to obtain a written signature and date on a signed HIPAA form, and instead obtain HIPAA authorization verbally. This consent script then needs to include the language below to ensure the required HIPAA authorization statements are conveyed to the subject.*

*[A description of the purpose of each use or disclosure:]* To do this research, we need to collect health information that identifies you. We may collect the results of *[tests, questionnaires and interviews]*. We may also collect information from your medical record. We will only collect information that is needed for the research. For you to be in this research, we will need your permission to collect and share this information.

*[A statement describing the extent to which confidentiality of records identifying the subject will be maintained:]* All study and health information collected by the study team will be kept confidential.

*[Entity(s) authorized to make requested use/disclosure:]* We are asking for your permission to use and/or share protected health information from your medical records *[and/or that we collect during this research]* *[Specify the PHI to be used/disclosed in this sentence]*.

*[State to whom the HIPAA covered entity may make requested use/disclosure of PHI:]* The information will be shared with the study sponsor and people or organizations that oversee research. Some of the people or organizations that oversee research may not be subject to privacy laws, which means the information may no longer be covered by federal privacy laws *[State that redisclosure by entities means PHI may no longer be protected under HIPAA]*.

*[A statement that an individual’s clinical treatment may not be conditioned upon whether or not the individual signed the Authorization; however, participation in research may be conditioned on a signed Authorization:]* If you agree to participate in this study, you are giving us permission to collect, use and share your health information. If you decide not to verbally agree to allow for us to use and disclose your protected health information, you cannot be in the research study. We cannot do the research if we cannot collect, use and share your health information.

*[Expiration date for use/disclosure:]*Once you provide permission, it will not expire. [State that subject has *[Right to revoke in writing:]* But you can withdraw from the study or cancel your permission for us to use your information at any time. If you decide you don’t want your information used, or if you have any questions or complaints, you may contact a person not on the research team at the Biomedical Research Alliance of New York Institutional Review Board at (516) 318-6877 or at [www.branyirb.com/concerns-about-research](http://www.branyirb.com/concerns-about-research).

*[Exceptions to the right to revoke:]*Information that was already collected may still be used and given to others.

Study-related costs associated with your being in this study will be paid by the sponsor, *[Sponsor Name]*. You or your insurance company *will [will not]* be charged or held responsible for the costs of your routine care (the care you would have received if you were not in this study)."

*When the research involves collection of Identifiable Private Information or Identifiable Biospecimens:*

Identifiers might be removed from your identifiable private information or identifiable biospecimens. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent (or consent from your legally authorized representative).

*--OR--*

Your information and biospecimens collected as part of this research study, even if identifiers are removed, will not be used or distributed for future research studies.

*[If biospecimens are part of your study:]* Your biospecimens, with or without identifiers, may be used for commercial profit and you will not share in this profit.

Do you have any questions about the information I have shared with you?

Do you consent to participate in this study at this time?