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

**For Subjects Ages 13-17 years old and Parents / Legal Guardians**

**OR**

**For Subjects 13 Years or Older and Parents / Legal Guardians**

**Informed Consent/Assent Form**

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

* In this form, consent also refers to assent (of minors) and permission (of parent/guardian).
* To Parent/Guardian: In this form, the words ‘you’ and ‘your’ refer to the child who is the study subject, not to you.

*Key Information*

**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 research.**

* You are being asked to be in a research study because you *[state reason participant is being approached here]*.
* Your decision to be in this study is voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which they are otherwise entitled. *[For most non-interventional studies: ]*
* 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]*
* The purpose of the study is *[state study’s purpose/what study is about here]*.
* 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.
* The main study procedures include *[state main study intervention/procedure(s)]*.
* The risks of the study include *[state main risks of the study here, such as physical risks, discomfort from answering survey questions, risks from taking an experimental drug, or risks of breach of confidential information).*
* There is no direct benefit 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.*

**This overview does not include all the information you need to know before deciding whether to take part. Additional detail is given in the rest of this consent form found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.**

*Who is the Study Team and How is the Study Funded?*

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.

*How Many People Will Take Part in the Study?*

About *[state total accrual goal here]* people are expected to participate in this study*.*

*What is Involved in this Research Study?*

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

*Will Participating in this Study Benefit Me?*

Participating in this study will not benefit you directly, but it will help us learn *[explain what you hope to learn from the study]*. *[--OR—describe the possible direct benefit to participants, when applicable.]*

*What Are the Risks Associated with This Research?*

*[List and explain the detailed physical, psychological, and social risks]* Answering some of the questions maybe upsetting to you, but we expect that this would not be different from the kinds of things you discuss with family or friends. Youmay skip any questions they don’t want to answer, and they may end the interview at any time.

*What Are the Costs of Taking Part in This Study?*

*[Use one of the following paragraphs as appropriate:]*

There are no costs to you for taking part in this study. All the study costs, including any study tests, supplies and procedures related directly to the study, will be paid for by the study.

*--OR--*

There will be some cost to you for taking part in this study. You will have to pay about *$[amount]* for these study tests, supplies and procedures.

*Will You Be Paid for Participating?*

If you participate in the study, you will receive \_\_\_ for your time *[if applicable]*.

*What About Confidentiality?*

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study may be looked at by the research team, the institution, the sponsor/funding agency supporting the study, and those responsible for overseeing the conduct of research. This may include representatives from the federal Office for Human Research Protections (OHRP) or other regulatory agencies, the Institutional Review Board (IRB), and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this study may be presented at meetings or in publications; however, youwill not be identified in these presentations and/ or publications.

If you decide to take part in this study, they will be assigned a unique subject code to help protect his/her privacy. Your study records and study samples will be labeled with this code that does not directly identify them. The study site staff securely stores the linking code between your name and study information.

*NOTE TO INVESTIGATOR: For online surveys special attention must be paid to how participants’ data will be secured. This entails having a familiarity with: the survey software being used, the types of information being collected (IP address, email address), the options the survey software provides regarding what information to collect, the ways in which information will be stored, and how any identifying information will be de-linked from survey data, etc.*

*In this section, please include what information will be collected, such as email or IP address. For example:* Your information will be assigned a code number that is unique to this study. The list connecting your name to this number will be kept in a locked file *[specify where]* and only the Study Director and other researchers will be able to see the survey your participated in *[if collecting names]*. No one at *[e.g., NAME OF AGENCY]* will be able to see your survey or even know whether you participated in this study. When the study is completed and the data has been analyzed, the list linking participant’s names to study numbers will be destroyed *[if collecting names]*. Study findings will be presented only in summary form and your name would not be used in any report *[if collecting names]*. While the investigator(s) will keep your information confidential, there are some risks of data breeches when sending information over the internet that are beyond the control of the investigator(s).

*NOTE TO INVESTIGATOR: When HIPAA applies and the study includes PHI (Protected Health Information), this version with embedded HIPAA authorization language can be used instead of the “Confidentiality” section above.*

*What about Confidentiality and Authorization to Use and Disclose Protected Health Information?*

To the extent allowed by law, every effort will be made to keep your personal and medical information confidential. However, total confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law.

The study institution and study doctor will use your medical information collected or created as part of the study, such as medical records, test results, research records, and billing information. Some of this information may identify you by name or in another way. The study institution and study investigator may obtain your medical information that they request for study purposes from your physicians and other health care providers and may also inspect and copy this information.

The study investigator and study staff may use and share information about your health with other professionals involved in the study, such as the study sponsor and its authorized agents, the FDA, Biomedical Research Alliance of New York Institutional Review Board, government agencies in the U.S. and other countries, accrediting agencies, safety boards and health insurers/payers. These groups may then also share your personal health information, in which case it may no longer be covered by federal privacy laws.

The purposes for using and sharing your medical information include: to carry out the research study and evaluate its results, to seek marketing approval for new products resulting from this research, and to meet government reporting requirements. Results of this research may be presented at meetings or in publications. Your name will not be used in any study reports or presentations. You have the right to review and copy your health information, but you may not be allowed to do so until after the research is completed.

This authorization does not have an expiration date. You have the right to take away your permission to use and disclose your health information at any time by giving written notice to the study investigator. If you withdraw your permission, youwill not be able to continue in this study, but you will not lose access to treatment or other benefits to which they are entitled. When you withdraw your permission, no new health information about you will be gathered after that date. Information that has already been collected may still be used and given to others.

*What About Identifiable Private Information or Identifiable Biospecimens?*

*[Omit this section if not applicable] [If this section is applicable then edit it to apply to either private information or 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--*

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.

*Whom Do You Call If You Have Questions Or Problems?*

If you have any questions about this study, please contact *[names of PIs, phone numbers and email* *addresses]*. 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).

*[When a signed consent form will not be obtained by the researcher, you can use language such as the below example for a survey study.]*

**By completing this survey, you are consenting to participate in this study.**

**\*Please print or save a copy of this form for your records.\***

*[When a signed consent form will be obtained by the researcher, use the following after updating to reflect the circumstances of your study.]*

*STATEMENT OF CONSENT - SIGNATURES*

By signing this form, I confirm the following:

* I have read all of this consent form.
* All of my questions have been answered to my satisfaction.
* I can remove myselffrom the study at any time without giving a reason and without penalty.
* I agree to the collection, use, sharing and analysis of my personal health information *[when HIPAA applies and the study includes PHI: Protected Health Information]* and study information collected as part of this study by research team, the sponsor/funding entity *[when applicable]*, and other authorized persons and regulatory agencies as described in this form.
* I will be given a copy of this signed and dated consent form to keep.
* I do not give up any legal rights that we would otherwise have if I were not in this study.

**I voluntarily agree to participate in this study.**

**Subject:** Name (Print)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Subject** (13-17 years old): Signature Date

OR

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**Subject**: Name (Print) Signature Date

Witness required only if subject is 13-17 years old and assenting on this form.

Witness must be a third party unrelated to the study subject.

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**Witness**: Name (Print) Signature Date

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**Parent/Legal Guardian**: Name (Print) Signature Date

Relation to Subject:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Person Obtaining Consent/Assent**: Name (Print) Signature Date

**FOR SUBJECTS WHO TURN 18 YEARS OLD DURING THE STUDY**

I have read (re-read) this consent form. I voluntarily agree to continue to participate in this research study.

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**Subject**: Name (Print) Signature Date

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**Person Obtaining Consent**: Name (Print) Signature Date

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**Witness**: Name (Print) Signature Date