Columbia University Medical Center

Consent Form to Participate in a Research Study and HIPAA Authorization

*Instructions for Consent form Preparer:*

*Fill in the information requested in italics or delete as applicable. Include a version date in the footer. If your study has more than one consent form, clearly identify the individual forms in the footer.*

### Title of research study and general information

**Study title:**

**Study number:** IRB-[*Insert IRB protocol number*]

Participation duration:

Anticipated number of research participants at this site:

Sponsor/Supporter: *[insert names of funding agencies if any]*

### 2. Researchers’ contact information

## Principal Investigator: *[name and degree(s) of the Researcher conducting the study]*

**Phone Number:**

**Co-Investigator/Study Coordinator:** *[name(s) and degree(s), as applicable*]

**Phone Number:**

### 3. What information is on this form?

We are asking you to take part in a research study.

This form explains why we are doing this study and what you will be asked to do if you choose to be in this study. It also describes the way we (Researchers) would like to use and share information about you.

Please take the time to read this form. We will talk to you about taking part in this research study. You should ask us any questions you have about this form and about this research study.

You do not have to participate if you don’t want to.

*Add the following paragraph only if the study will enroll children, the children are at least 12 years old and are capable of providing assent, and parental permission is required. This consent form will also be used as both the assent form and parental permission form.*

This consent form is written to address a research subject. If consent will be obtained from the parent (or legal guardian) of a minor, the words “you” and “your” should be read as (“your child” or “the research subject”).

### 4. Why is this study being done?

*Choose one of the following:*

We are doing this research study to find out if *[insert specifics*] can help people who have [*insert condition*]*.*

*or*

We are doing this research study to better understand how people think about [*insert specifics*].

*or*

We are doing this research study to learn more about *[insert specifics].*

*or*

We are asking you to take part in this study because *[choose one of the following options as appropriate]*

-you have [*insert condition*].

-you are scheduled to have [*a routine medical care procedure*].

-you are part of [*some organization/event*] and we would like information about people in this group.

*Add if applicable:*

We also want to find out if [*insert specifics*].

### 5. What will I be asked to do if I choose to be in this study?

*Choose as appropriate:*

We will ask you to come to [*insert location*].

*or*

We will come to [*insert location*] to see you.

*Choose as appropriate:*

We will ask you to complete [*number*] survey(*s*) / answer questions.

*or*

We will ask you to give a blood sample [*insert volume in teaspoon, tablespoon*.]. The blood will be drawn (taken) by [*insert specifics*] and sent to [*insert specifics if applicable*] to be tested for [*insert specifics].*

*or*

We will contact you in [*insert specific*] month[*s*]/week[*s*] by telephone to [*insert specifics*].

*or*

We will get information from your medical records such as [*insert specifics*].

*or*

The following tests and procedures will be done on scheduled visits:

[*Describe simply what the research participant will do or experience in chronological order. If some procedures are optional, it should be clearly noted and statements should be added to the consent form so that permission from the research participant can be obtained for the optional procedures (i.e. “i agree…” and “ . “i do not agree…-“). If many procedures will be performed, a table can be used instead of or in addition to a paragraph.]*

1. *If the research will involve mandatory audio/video recording or photography of research participants, please add the following:*

Audio/video recording or photography

We are asking for you to allow us to [include all recording procedures such as audiotape (voice recording), videotape (movie), photograph (picture)] you as part of the research study.

The recording(s) will be used for [*include purpose of recording; e.g., analysis by the research team, possible use as a teaching tool to those who are not members of the research staff (i.e., for educational purposes), commercial purposes. if the tapes will be used for commercial purposes, the consent form must specifically state whether or not the subject would be compensated for this use*.]

The recording(s) will include [*indicate whether the subject's name or any other identifier will be recorded. if videotaping will be utilized, indicate the extent to which the subject's identity would be masked, e.g., facial features partially blocked out, recording will not include facial pictures, recording will include full facial pictures*.]

The recording(s) will be stored [*include measures taken to protect subject's privacy, e.g., in a password protected database; in a locked file cabinet with no link to subject's identity, in a locked file cabinet and linked with a code to subject's identity, in a locked file cabinet and labeled with subject's name or other identifiable information] and will be [indicate the length of time the recording(s) will be retained, e.g., destroyed upon completion of the study procedures, destroyed upon publication of study results, retained indefinitely*.]

*1.a. If recording is an optional procedure, add the following*:

Please write your initials next to the choice you make below:

\_\_\_\_\_\_ (initial) yes, I agree to recording as described above

\_\_\_\_\_\_ (initial) no, I do not want to be recorded

1. *The statement below is applicable for any other optional procedures and should be added immediately after the full description in lay language of the optional procedure.*

Please write your initials next to the choice you make below:

\_\_\_\_ (initial) yes, I agree to [*insert optional procedure*]

\_\_\_\_ (initial) no, I do not agree to [*insert optional procedure*]

*Additional language for describing procedures is available at:* [*Consent Form Builder Sample Language*](http://www.cumc.columbia.edu/dept/irb/policies/documents/RASCALConsentformbuilderSampleText4412.doc)

This study will last [*insert total length of study period*].

### 6. Are there any risks?

*Risks* [*physical, social, financial, psychological, privacy, or other*] *and possible discomforts need to be described. Depending on the study, there can be risks related to confidentiality of information, risks from procedures, risks from incidental findings, and discomforts from the procedures.*

*Choose one or more of the following, as applicable:*

We do not think that there are any risks to taking part in this study.

*or*

There are no physical risks related to participating in this research study.

*or*

You may feel uncomfortable when [*insert specific*].

*or*

You can choose to skip questions if they make you uncomfortable.

*or*

There may be risks or discomforts if you take part in this study.

These include: [*describe any reasonably foreseeable risks, discomforts or side effects and the likelihood of the occurrence*].

*Below are suggested texts for describing risks frequently listed/applicable in minimal risk studies. Additional language is available at:* [*Consent Form Builder Sample Language*](http://www.cumc.columbia.edu/dept/irb/policies/documents/RASCALConsentformbuilderSampleText4412.doc)

*If the study involves collection or use of private information:*

Loss of confidentiality

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. Their plans for keeping your information private are described in section 8 of this consent form.

*If study involves blood draw:*

Blood Draw

Risks of having blood drawn are soreness and/or a black and blue mark at the site from where the blood is drawn. Sometimes, people feel uncomfortable at the time of the blood draw. Occasionally people feel lightheaded or weak. There is also a small risk of infection whenever blood is drawn.

### 7. Are there any benefits?

You will not benefit from taking part in this study, but your participation may help people who have [*insert condition*] in the future.

*or*

You may or may not receive personal [direct] benefit from taking part in this study. The possible benefits of taking part in this study include: [*insert specifics*].

**8. What about my privacy?**

Every effort will be made to keep your personal information confidential. However, we cannot guarantee total privacy.

*Describe the steps that will be taken to maintain confidentiality of subject data:*

*Suggested procedures/text:*

The data collected [*and/or specimens*] will be given a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in a *[Choose as appropriate]* password protected database *or* locked file cabinet*]*. Only the Principal Investigator and the study staff will be able to see this file.

If information from this study is published or presented at scientific meetings, your name and other personal information about you will not be used.

Access to your health information is required to be part of this study. If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. The health information that we may collect and use for this research may include medical history that may be considered sensitive. [*If you are collecting HIV test results, history of drug or alcohol abuse, or mental health information it must be stated here. If you are not collecting HIV test results, history of drug or alcohol abuse, or mental health information, include a statement that the project does not involve collecting health information that may be considered sensitive*.]

Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care that is needed for this research purpose, including [*Insert list if necessary***].**

[*Revise as necessary if identifiers will be shared outside of CUMC/NYP***]**

The research information that is shared with people outside of Columbia University Medical Center and NewYork-Presbyterian Hospital will not include your name, address, telephone number or any other direct identifier unless disclosure of the information is required by law or you have authorized the disclosure.

The following people and/or agencies will be able to look at, copy, use and share your research information:

- The investigator, Columbia University Medical Center and [***add NYPH if applicable:***] *NewYork-Presbyterian Hospital* study staff and other professionals who may be evaluating the study;

- Authorities from Columbia University *and NewYork-Presbyterian Hospital*, including the Institutional Review Board ('IRB'). An IRB is a committee organized to protect the rights and welfare of people involved in research.

- The Federal Office of Human Research Protections ('OHRP') *and/or [add FDA if applicable] United States Food and Drug Administration ('FDA');*

- [*If this study is sponsored [money or supplies are being provided]* The sponsor of this study, [*name sponsor*], including persons or organizations working with or owned by the sponsor may review your data for accuracy but may not copy information with your name on it.

- [*List other entities that may receive and process PHI, i.e. Data Coordinating Center, Data Safety and Monitoring Board/Committee ...]*

*[Choose one of the following statements:]*

Your authorization to use and share your health information does not have an expiration (ending) date.

[or]

Your authorization to use and share your health information will expire when the research is completed.

Once your health information has been disclosed to a third party (for example, a pharmaceutical company participating in a study), federal privacy laws may no longer protect it from further disclosure.

You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator**,** [*Insert contact information*].

However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers and the Sponsor (if applicable) may continue to use and disclose the information they have already collected.

*[For blinded studies, please add:]* To maintain the integrity of this research study, you generally will not have access to your protected health information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to this information.

### 9. Will I get paid or be given anything to take part in this study?

*Choose as appropriate:*

You will not receive any payment or other reward for taking part in this study.

*or*

*If compensated:*

We will give you [*insert specifics i.e. amount given in cash or gift cards*] to pay you for your time. *[If more than one study visit]* You will receive [*insert specifics]* at each visit.

*If payment will be by check:*

A check will be mailed to you about [*insert number*] weeks after your participation in the study has ended. You will need to provide your Social Security Number for payment.

*If applicable, i.e., a series of subject payments will result in total compensation greater than $600, please add:*

According to the rules of the IRS, compensation payments totaling more than $600 in a calendar year are considered taxable income and will be reported to the Internal Revenue Service (IRS).

*or*

*If reimbursed for travel expenses:*

We will reimburse you up to $ [*insert amount*] per visit for reasonable travel and parking expenses.

*[If by check]* You will need to provide the original receipt and your Social Security Number for reimbursement.

### 10. Will I incur costs if I take part in this study?

There will be no costs to you for being in this study.

or

If there will be costs to the participant:

The study will pay for services that you will receive only if you are in the study [list what will be paid for, e.g. blood tests, study drug].

**11. What are my rights if I take part in this study?**

Taking part in this study is your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not change the treatment you receive from doctors and staff at Columbia University Medical Center [add, if applicable] and New York-Presbyterian Hospital.

If applicable, please add:

Please tell one of the Researchers listed in Section 2 of this consent form if you decide to leave the study before it is finished.

If applicable, please add:

Your participation will also end if the Researchers or the study Sponsor stops the study earlier than expected or if you do not follow the study procedures.

### 12. Who can I call if I have questions?

## You may call [*insert name of Principal Investigator or study contact*] at telephone # [*insert phone number*] if you have any questions or concerns about this research study.

If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact the Institutional Review Board listed below.

Institutional Review Board

Columbia University Medical Center

154 Haven Avenue, 1st Floor

New York, NY 10032

Telephone: (212) 305-5883

[irboffice@columbia.edu](mailto:irboffice@columbia.edu)

### 13. Statement of consent and signatures

*When finalizing this document, please make sure the statement of consent and signatures are on the same page.*

**Statement of consent and HIPAA authorization**

I have read this consent and HIPAA authorization form. The research study has been explained to me. I agree to be in the research study described above.

A copy of this consent form will be provided to me after I sign it. *[Add, if an inpatient]* Another copy will be placed in my medical record.

By signing this consent and HIPAA authorization form, I have not given up any of the legal rights that I would have if I were not a participant in the study.

**Signatures**

*Omit signature lines that do not apply to your study. If the signature line remains, the expectation is that it will be used at the time of each enrollment.*

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**Research Participant** Date

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Print Name of Research Participant

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*If this consent also serves as the parental permission, please include a parent/Guardian signature line.*

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**Parent/Guardian** Date

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Print name of Parent/Legal Guardian

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*If this consent also serves as the permission from a surrogate, please include a “legally-authorized representative” signature line.*

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**Legally Authorized Representative** Date

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Print name of Legally Authorized Representative

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**Person Obtaining Consent** Date

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

Print Name of Person Obtaining Consent

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**Witness** Date

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Print name of Witness

The signature of a witness is only required for minimal risk studies when obtaining consent from:

* a Non-English Speaking Research participant using the short form process, or
* a person who is physically not able to read, talk or write.