Diversity and Inclusion in Research Underpinning Prevention and Therapy Trials
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**BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC**

**Icahn School of Medicine at Mount Sinai**

**SUBJECT INFORMATION AND INFORMED CONSENT FORM – Aim 2**

**Protocol Title**: Diversity and Inclusion in Research Underpinning Prevention and Therapy Trials
**Protocol #**:
**Sponsor**: Stand Up To Cancer
**Principal Investigator**: Nina Bickell MD, MPH
**Institution**: Icahn School of Medicine at Mount Sinai
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**Key Information Statement**

The purpose of this study is to test whether giving educational materials about clinical trials and a list of clinical trials for which they are potentially eligible to patients with cancer increases (1) patient and doctor discussions about clinical trial participation, and (2) clinical trial offers to patients. Our goal is to work with patients and their doctors to increase the number of patients, particularly patients of color with cancer, who join cancer clinical trials.

We will ask patients who have been diagnosed with cancer to receive and view an informational sheet and educational materials (written &/or video) prior to the first visit with their doctor to discuss their cancer, then answer some questions about the materials. We will also provide to patients and their doctors a list of trials to which the patient may be potentially eligible to stimulate talk about clinical trials. Lastly, we will ask patients to complete a survey after the visit with their doctor in which they discussed the cancer treatment plan. Questions in the survey will ask patients about their experiences and relationship with their doctor and any discussions about clinical trials they might have had. This study may take up to 4 study visits. Participation is completely voluntary. For your participation in this study, we will offer a gift card valued at $20 after the second survey is completed. While we will do all we can to protect your information, the biggest risk of being in this study is the possible loss of confidentiality of your personal information collected for this study.

**If you are interested in learning more about this study, please continue to read below, where you will find additional information related to this study such as the risks, benefits, procedures, alternatives, and contact information.**

## INFORMED CONSENT FORM

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the Principal Investigator and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your cancer care physician. If you agree to take part in this research study, you must sign this consent form.

### DISCLOSURE OF FINANCIAL INTERESTS

Stand Up To Cancer, the sponsor of this study, is providing funds to Icahn School of Medicine at Mount Sinai to conduct this research study. There will be 2 additional cancer centers where this research study will be conducted – Montefiore Einstein Cancer Center and Herbert Irving Comprehensive Cancer Center, Columbia University and 2 affiliate sites for each cancer center.

### PURPOSE OF THE STUDY

The purpose of this study is to test whether giving educational materials about clinical trials and a list of clinical trials for which they are potentially eligible to patients with cancer increases (1) patient and doctor discussions about clinical trial participation, and (2) clinical trial offers to patients.

### NUMBER OF SUBJECTS AND LENGTH OF STUDY PARTICIPATION

About 1000 subjects are expected to participate in this study at 9 research sites (3 cancer centers and 2 affiliate sites per cancer center) in New York City region.

Your participation in this study is expected to last up to 4 visits.

### STUDY PROCEDURES

You will be asked to view an informational sheet and educational materials (written or video) prior to the first visit with your doctor to discuss your cancer then some answer questions about the materials. You may also be provided a list of trials to which you may be potentially eligible. Lastly, you will be asked to complete a survey after the visit with your doctor in which you discussed your cancer treatment plan. Questions in the survey will ask you about your experiences and relationship with your doctor and any discussions about clinical trials you might have had with him/her.

### RISKS AND DISCOMFORTS

This study poses no physical risk to you. It is a very low risk study. You will be asked to talk about your opinions of the study educational materials and your experience with clinical trial with your doctor. You do not have to answer any questions that may make you feel uncomfortable, and you are free to stop participating if you want to. If you wish to withdraw from the study, we will only use the information that has already been collected.

### BENEFITS

There is no direct benefit to you if you join this study, but you may learn about clinical trials and/or learn of a clinical trial to which you are eligible. The results may also help people with cancer in the future.

### COSTS OF PARTICIPATION

There will be no cost to the patient for participating in the study.

**REIMBURSEMENT**
After completion of the second survey, you will be offered at gift card valued at $20 for your time and effort participating in this study. Tax law may require the payer (e.g., research institution or third party) to report the amount of payment you receive from that payer to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting will take place if you receive $600 or more from the payer in a calendar year. You would be responsible for paying the taxes on the payment you received from the study.

**COMPENSATION FOR INJURY**

For medical emergencies, call 911. If you become ill or are hurt while you are in this study, contact your doctor immediately. The study doctor will assist you in obtaining appropriate medical treatment.

Because this study involves only the sharing of medical information and requires no specific procedures, tests, or treatments, no research-related injuries are expected. No financial compensation will be offered by the Icahn School of Medicine at Mount Sinai or the Biomedical Research Alliance of New York.

No other compensation will be offered by the Icahn School of Medicine at Mount Sinai or Biomedical Research Alliance of New York, including for things such as lost wages or discomfort. You are not waiving any legal right to seek additional compensation through the courts by signing this form

**ALTERNATIVE TO PARTICIPATION**
Your alternative to being in this study is to not take part.

**CONFIDENTIALITY**
To the extent allowed by law, every effort will be made to keep your personal health information confidential. However, information from this study will be submitted to the study sponsor. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION
Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study Principal Investigator must get your permission to use or give out any health information that might identify you. If you choose to be in this study, the Principal Investigator will get personal information about you. This may include information that might identify you. The study investigator may also get information about your health, including:

- Past and present medical records
- Records about phone calls made as part of this research

Information about your health will only be accessed by the study team. They might see the research information during and after the study. Your information may be given to the sponsor of

this research but would not be given so that it can be traced to identify you. “Sponsor” includes any persons or companies that are working for or with the sponsor or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- Stand Up to Cancer (the sponsor)
- The Institutional Review Boards
  Study team members that analyze your information in connection with these research activities.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the Principal Investigator at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Collection of Identifiable Private Information or Identifiable Biospecimens:

- Identifiers will be removed from your identifiable private information. After such removal, the information 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).

**VOLUNTARY PARTICIPATION AND WITHDRAWAL**

Your participation in this study is voluntary. You may decide not to participate, or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please inform the Principal Investigator.

**CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS**

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. Nina Bickell at 212-659-9567.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns, or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

**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 leave 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 and study information collected as part of this study by the sponsor 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 I would otherwise have if I were not in this study.

I voluntarily agree to participate in this study.

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