Changes to boilerplate template language tracked for 4/1/15 version. Changes made in 9/2/14 version highlighted. Changes in instructional text have not been tracked or highlighted in this document.

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION

[Remove any sites not engaging in the research] Icahn School of Medicine at Mount Sinai, Mount Sinai Beth Israel, Mount Sinai St. Luke’s-Roosevelt, New York Eye & Ear Infirmary of Mount Sinai

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Study ID #: [GCO# or HSM#] Form Version Date: [Do not leave blank]

TITLE OF RESEARCH STUDY:

[Follow all instructions in blue. Delete optional text that does not apply to your study and delete all instructions from the completed consent document]

Title:

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name:

Physical Address: [Hospital/clinic name; Annenberg 22nd Floor, Room XXX; This will usually the location where the subject should go for study visits; otherwise it can be the PI’s office address]

Mailing Address: [e.g. One Gustave L Levy Place Box XXXX, NY, NY 10029]

Phone: [e.g. 212-XXX-XXXX; this number should reach the research team directly, not be just a general clinic or department number]

WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don’t know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care within the Mount Sinai Health System.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

[For any study that will be registered on ClinicalTrials.gov, please add the following paragraph:]

Basic information about this study will appear on the website http://www.ClinicalTrials.gov. There are a few reasons for this: the National Institutes of Health (NIH) encourages all researchers to post their research; some medical journals only accept articles if the research was posted on the website; and, for research studies the U.S. Food and Drug Administration (FDA) calls “applicable clinical trials” 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.

PURPOSE OF THIS RESEARCH STUDY:

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IRB Form HRP-502a
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The purpose of this study is [Tell the subject the purpose of the research. Explain the background of the research problem IN LAY TERMINOLOGY. For example, explain to the subject the current therapies for the disease and why they are not satisfactory. For non-therapeutic studies, explain the scientific problem. Describe how this research will attempt to solve the problem.]

You may qualify to take part in this research study because [Fill in the circumstance or condition that makes subjects them eligible for the research, for example, “you are a healthy individual.” “you have diabetes and you take insulin.” These descriptions should be brief and not the entire inclusion/exclusion criteria.]

Funds for conducting this research are provided by [indicate name of financial sponsor(s) [or, for unfunded studies, Mount Sinai] as applicable, and indicate the relationship of the financial sponsor to the study if any (e.g., manufacturer of the drug or device).]

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last [months/weeks/years, until a certain event.]

The number of people expected to take part in this research study at [specify by site within MSHS] this site is ……. [if it is multisite study, also indicate:] The total number of people expected to take part in this research study is….

DESCRIPTION OF WHAT’S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

[Tell the subject what to expect using lay language and simple terms. As appropriate, include the following items:

- The site where the research activities will take place (begin with the appropriate Mount Sinai site. If the subject will need to go/or can choose to go to more than one location for different study visits, make that clear. If this study will take place at more than one site within the MSHS, the study needs to be approved through the MSHS reciprocal IRB reliance agreement.)

- What is being performed as part of the research study

- List experimental procedures and therapies and identify them as such

- List frequency of procedures and tests. Consider providing a time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for studies that require more than 1 or 2 steps/visits

- Protocol-dictated drugs or biologics to be used

- Protocol-dictated devices to be used

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- Hospitalizations, outpatient visits and telephone or written follow-up
- Length and duration of visits and procedures
- If blood will be drawn, indicate the amount in teaspoons, tablespoons, or ounces
- With whom the subject will interact
- Where the research will be done
- When the research will be done
- What is being performed according to the standard of care, when providing context is necessary
- What procedures are part of regular medical care that will be done even if the subject does not take part in the research, when providing context is necessary

[Timing and use of birth control is generally dictated by protocol. If this study requires use of contraception, please insert the appropriate language on birth control.]

For Women:

Since you are participating in a study that involves drugs or investigational treatment with potential risks to a developing fetus, it is recommended, for your protection, that you not become pregnant for the duration of the study. Also, you should not participate if you are breastfeeding. Therefore, practicing effective contraception is important. No individual contraceptive is 100% effective.

Recommended methods of birth control are:

- The consistent use of an approved hormonal contraception (birth control pill/patches, rings),
- An intrauterine device (IUD),
- Contraceptive injection (Depo-Provera),
- Double barrier methods (Diaphragm with spermicidal gel or condoms with contraceptive foam),
- Sexual abstinence (no sexual intercourse) or
- Sterilization.

[Some study drugs interact with hormonal contraceptives and make them less effective or they should not be used with the disease/condition under study. If that is the case, delete the hormonal methods listed above and state why they are not recommended while taking part in the study.]

Hormonal contraceptives, implants, and injections are only considered effective if used properly and started at least one month before you begin the study, continuing throughout the study and for one month [OR insert a longer period of time if required by the protocol] after the end of the study. You should ask your study doctor if you should continue birth control for longer than 30 days [OR insert a}
longer period of time if required by the protocol] after the end of the study. If you are unsure whether the method of birth control you use is acceptable to use while participating in this study, you should ask your study doctor before you begin the study. If you are less than one year post-menopausal, there is the potential that you could become pregnant. If you or your partner becomes pregnant or thinks either of you may be pregnant at any time during the trial [or in the “month” [OR insert a longer period of time if required by the protocol] following it], it is important that you tell your study doctor immediately. The trial drug may be stopped and a referral will be made to an obstetrician/gynecologist for follow-up. If you plan to become pregnant in the year following a clinical trial, speak with your study doctor.

If you have any questions about birth control, your study coordinator or study doctor will be able to answer your questions and give you advice.

Should you become pregnant, regardless of the outcome, the sponsor may ask for information on your pregnancy, even if you are withdrawn from the study. Your written consent will be obtained separately in the case that this happens.

For Men:

Since you are participating in a study that involves drugs or treatment with potential risks to a developing fetus, it is recommended that you use a condom and not father a child or donate sperm while you are taking the study drug. Also, it is recommended that you use a condom and not father a child and/or donate sperm for 90 days [OR insert a longer period of time if required by the protocol] after you stop taking the study drug. This is because levels of the study drug may be present in the sperm and/or seminal fluid even after you stop taking the study drug. Continuing to use a condom and not donating sperm during this 90 day period [OR insert a longer period of time if required by the protocol] may allow time for any study drug that is still present in sperm and/or seminal fluid to be eliminated from your body before you attempt to father a child or donate sperm. You are encouraged to tell your female partner(s) and/or their doctor(s) that you are participating in a clinical trial.

List an exact length of time if the protocol recommends that men refrain from fathering a child and/or donating sperm for a longer period of time than 90 days, for example, 180 days or 6 months. Do not list a range of time, for example, 3 to 4 months.

[For research involving pregnancy testing, customize the statement below for this study]

A pregnancy test (specify either blood or urine) will be done before you begin the study and will be repeated at [insert Week and/or Visit time points]. Or, insert similar wording as required by the protocol.
YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things: [Describe the subject's responsibilities. Explain what commitment you expect from the subject. For example: taking prescribed medications, using birth control methods as described in the Description of What's Involved section, avoiding certain medications, attending study visits, etc.]

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

[If there are no anticipated costs or payments to the subjects, add:] You will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you. [If time or travel costs to be assumed by subjects, add:] You will not be reimbursed for your travel or time that may be required for study visits.

[If the research may result in additional costs to the subjects, add:] Taking part in this research study may lead to added costs to you. [Describe what these costs are, if known]

[When subjects will be paid, add:] If you agree to take part in this research study, we will pay you [indicate amount] for your time and effort. [Indicate if the amount is pro-rated for research visit completion and what form the form of the payment will be (e.g. cash, gift card, check). Provide a general indication of when the payment will be provided (e.g. at each visit, at the end of their participation in the study). Be sure the timeframe is general and realistic. If the payment will be provided in the form of a check generated by the Mount Sinai Finance department, please include a statement such as:] Checks require some time to be prepared and will be given to you as available.

[Only if NO payment of any kind will be provided to subjects as part of their participation may this statement be removed:] Tax law may require the Mount Sinai Finance Department to report the
amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally this reporting would take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

[If any reimbursement will be provided for expenses the subject will incur, such as transportation, indicate what evidence of the expenses the subject needs to provide (receipts). Further guidance is available from the Finance Department.]

[For Department of Defense (DOD) research which targets military personnel and where subjects will be paid, add:] You should check with your supervisor before accepting payment for participation in this research.

[For studies involving prisoners, add:] If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you and/or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

POSSIBLE BENEFITS:

[If there are possible benefits to individual subjects from the research, add:] It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be … … . [Describe the potential benefits of participation but do not overstate them. First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, explain that here. For example, an investigational drug provided at no cost during a study may not be available at the end of the research or may no longer be provided at no cost to subject if the drug becomes available for marketing. Monetary reimbursement for participation is not considered a benefit and should be described in the Costs/Payments section.]

[If there are no expected benefits to individual subjects from the research, add:] You are not expected to get any benefit from taking part in this research study. Others may not benefit either. However, possible benefits to others include … [Describe potential benefits to others but do not overstate them]

[For studies involving prisoners, add:] Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

[Describe each of the following risks and discomforts, as appropriate. The risks of therapies or procedures may be presented in a table form if it provides further clarity.]

- Physical risks (for example, medical side effect)
Psychological risks (for example, embarrassment, fear or guilt)

Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

Legal risks (for example, being reported for child abuse)

Social risks (for example, damage to your social standing or reputation; possible discrimination)

Economic risks (e.g. having to pay money out of pocket for research or medical expenses, loss of health insurance, missing work, being unable to obtain a job)

[If the research involves the research use of genetic testing to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disability in the subject or the subject's offspring, add the following:] There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers of over 15 people to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

[Describe risks for each relevant procedure (For example, computerized tomography, MRI, survey, etc.) and for each drug, device or biologic that is being studied by the investigation.]

[Include relevant risks based on animal and in vitro studies, particularly for Phase I or II trials.]

[Describe the probability of risks (frequently, occasionally, or rarely expected). For high-magnitude risks (ones that are life-altering or potentially life-altering, such as visual loss, anaphylaxis, paralysis, and aplastic anemia) explain the ramifications, even if these risks are rarely expected (for example, indicate what might happen to the subject if liver enzyme tests indicate an abnormality.]

[Describe risks to those other than the subject, along with corresponding instructions. For example, risk to a nursing infant if the mother is the research subject, risk to sexual partners or family members etc.]

[If this study includes blood draw by needle stick, include the following statement] The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.

[For research that involves known risks to an embryo or fetus, add:] This drug may harm a pregnancy or unborn child in the following ways: [include any known risks here] You should not become pregnant or father a baby while on this research study. Please read the acceptable methods of birth control found under the Description of What's Involved section of this document.

[If the research involves an investigational product or procedures whose risk profile is not well known, add:] In addition to these risks, this research may hurt you in ways that are not known. The unknown risks might be minor or might be major (death).
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If you decide to stop being in the research study, please contact the Principal Investigator or the research staff. If procedures for orderly termination of participation by the subject are necessary, describe them. For example, subjects on an investigational drug to treat their diabetes may be switched to an approved drug, subjects in a study of high dose corticosteroids may have their steroid doses tapered, etc. Include any specific withdrawal procedures described in the protocol. If applicable, add and customize. At that point...

If there are possible adverse consequences to withdrawing from the research, add: If you decide to stop being in the research study, the following may occur: [Describe the adverse consequences that subjects may experience by unilaterally withdrawing from the research. For example, subjects on a drug to treat their diabetes may experience elevated blood sugars unless they switch to another drug. Subjects in an oncology trial who were getting benefit from the study drug may experience progression off the drug. Subjects in a study of high dose corticosteroids may experience life-threatening symptoms unless the steroid doses are tapered.]

[If there are possible adverse consequences to withdrawing from the research, add:] If you decide to stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. [Note: The consent document cannot give the subject the option of having data removed.] You may be asked whether the investigator can collect information from your routine medical care. If you agree, this data will be handled the same as research data. [Note: If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject’s medical record or other confidential records requiring the subject’s consent. However, an investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.]

[If samples are being banked from this research, describe if and how samples can be withdrawn or destroyed.] [If the research involves a data or specimen registry, explain what withdrawal means, e.g. the sample will be returned, destroyed, anonymized, or no new information will be collected]

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent. [If applicable add:] More possible reasons for removal from the study include... [add additional reasons why the subject may be withdrawn. Include all withdrawal criteria listed in the protocol. For example, if the

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protocol states that subjects will be removed from the research if they become pregnant, have tumor progression, or experience certain adverse events, list these here

CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at phone number...... [e.g. 212-659-xxxx; this number should reach the research team directly, not be just a general clinic or department number]

[If applicable, add:] If you experience an emergency during your participation in this research, contact...... [customize as appropriate: e.g. provide an attending physician’s number, instruct subjects to call 911 or go to the emergency room, etc]

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Deleted: HOSPITAL

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[2. For studies where an investigator holds a financial interest in the company, or in the drug/device
under investigation, that could benefit from the trial the consent form should state:] One or more
researchers has a financial interest that could be affected by the outcome of this research study.

[3. For studies where the PI's Department has a financial interest in the drug or device under
investigation or in a company that could benefit from the study findings, or receives significant support
from the study sponsor, the consent form should state:] The Principal Investigator's Department has a
financial interest that could be affected by the outcome of this research study or receives significant
support from the research study sponsor. [Statements #2 and #3 may be combined in a single
statement, when applicable.]

[4. For studies where investigators or their Departments are paid on a per-patient enrolled basis, the
consent form should state:] The costs of doing this research are paid based on the number of patients
enrolled.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use
and share some of your private protected health information. Consistent with the federal Health
Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use
and share that information.

What protected health information is collected and used in this study, and might also be disclosed
(shared) with others?

[The following paragraphs must be precise and customized as appropriate.]

As part of this research project, the research team at the hospital(s) involved in the research will
collect your… … [At a minimum you should include any of the following if collected: name, address,
telephone/fax numbers, dates directly related to the individual (birth, admission, discharge, date of
death, etc.), e-mail/internet protocol (IP) addresses or web universal resource locators (URL’s), social
security number, medical records number, health plan numbers, account numbers, certificate/license
numbers, vehicle identifiers, device identifiers, biometric identifiers, photographic images, other
unique codes]

The researchers will also get information from your medical record [include where these records will
come from, for example, which hospital or clinic, your private doctor, etc.]

During the study the researchers will gather information by: [choose and modify as needed. The first 2
bullets do not need to be included here if they are adequately covered in the description section of the
consent]

− taking a medical history (includes current and past medications or therapies, illnesses,
  conditions or symptoms, family medical history, allergies, etc.)
− doing a physical examination that generally also includes blood pressure reading, heart rate,
  breathing rate and temperature

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− completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
− reviewing HIV-related information, which includes any information indicating that you have had an HIV related test, or have HIV infection, HIV related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV
− reviewing genetic tests
− reviewing mental health records [If you include this, your protocol needs to explicitly address this special class of records and appropriate access]
− reviewing alcohol and/or substance abuse records [If you include this, your protocol needs to explicitly address this special class of records and appropriate access]
− reviewing psychotherapy notes [If you include this, your protocol needs to explicitly address this special class of records and appropriate access]

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

[Include this statement if applicable, otherwise delete it:] [Unless sharing of research information is not permitted as outlined above, (for example, the results of an experimental test)] The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System (“Mount Sinai”) workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School’s Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the

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list during this research study; you may request an up-to-date list at any time by contacting the
Principal Investigator.)

[Modify this list as appropriate- delete or add items as necessary. For EACH LISTING include a brief
description of WHY they will receive the information (the examples below are suggestions only)]

- Other collaborating research center(s) and their associated research/clinical staff who are
  working with the investigators on this project: [List all sites; if greater than 6, list the first 6
  and add “and other sites available on request.” It is also permissible to reference at this
  point a website that maintains a current list of sites, as long as the list is printed out and
given to the subject at the time this authorization is signed]

- Research data coordinating office and/or their representative(s) who will be responsible for
  collecting results and findings from all the centers: [name that group or company]

- Outside laboratory who will be performing laboratory analysis for all the research centers
  involved in this project: [name that company or organization]

- The commercial sponsor and/or their representative (who will use the results for
  submissions to the Food and Drug Administration): [name that group or company]

- The sponsoring government agency and/or their representative who need to confirm the
  accuracy of the results submitted to the government or the use of government funds:
  [name that agency]

- Contract Research Organization (whose job is to help organizations fulfill their
  responsibilities in the research and development process): [name that company]

- A Data Safety Monitoring Board or other committee that will monitor the study on an
  ongoing basis for safety.

- [leave in if FDA regulated research] The United States Food and Drug Administration

- [always leave this statement] The United States Department of Health and Human Services
  and the Office of Human Research Protection.

- [For studies involving prisoners:] If you are a prisoner, your medical and/or research
  records may also be given to officials and agencies within the criminal justice system when
  necessary and permitted by law.

- Others: [name other groups who might receive the PHI, and why; examples may include
  foreign regulatory agencies, outside firms doing telephone polling, internet hosts, etc.]

[The following paragraph must be precise and customized to fit this study] In all disclosures outside of
Mount Sinai, you will not be identified by [name, social security number, address, telephone number,
or any other direct personal identifier] unless disclosure of the direct identifier is required by law.
Some records and information disclosed may be identified with a unique code number. The Principal
Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored
electronically. The code will not be used to link the information back to you without your permission,

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unless the law requires it, or rarely if the Institutional Review Board allows it after determining that
there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a
data coordinating office, a contract research organization, may come to inspect your records. Even if
those records are identifiable when inspected, the information leaving the institution will be stripped of
direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human
Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food
and Drug Administration (FDA) will be granted direct access to your medical records for verification of
the research procedures and data. OHRP and FDA are authorized to remove information with
identifiers if necessary to complete their task. By signing this document you are authorizing this
access. We may publish the results of this research. However, we will keep your name and other
identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information? [A specific
duration can be given, but has to be consistent with FDA, faculty handbook, and other guidelines.
Otherwise, just insert this sentence:] Your authorization for use of your protected health information
for this specific study does not expire.

Will you be able to access your records?

[Use this paragraph for blinded studies or other studies where access will be denied in order to protect
the integrity of the research; otherwise delete it:] During your participation in this study, you will not be
able to access your medical records. This will be done to prevent the knowledge of study results from
affecting the reliability of the study. Your information will be available should an emergency arise that
would require your treating physician to know this information to best treat you. You will have access
to your medical record and any study information that is part of that record when the study is over or
earlier, if possible. The investigator is not required to release to you research information that is not
part of your medical record.

[Use this paragraph for open label studies and other studies for which access will not be denied;
otherwise, delete it:] During your participation in this study, you will have access to your medical
record and any study information that is part of that record. The investigator is not required to release
to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign this
form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect
your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for
research, but you must do so in writing to the Principal Investigator at the address on the first page.
Even if you withdraw your permission, the Principal Investigator for the research study may still use
your protected information that was already collected if that information is necessary to complete the
study. Your health information may still be used or shared after you withdraw your authorization if you
should have an adverse event (a bad effect) from being in the study. If you withdraw your permission

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to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

_________________________________________________________________________________
Notice Concerning HIV-Related Information
If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

_________________________________________________________________________________
[If your study does not involve a Certificate of Confidentiality, delete this section. For studies involving a Certificate of Confidentiality, replace the paragraph in the HIPAA section beginning with "In all disclosures outside of Mount Sinai with the paragraph below:

In almost all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will

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ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential. 

Certificate of Confidentiality: To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This Certificate does not mean that the Department of Health and Human Services approves of this research. Rather, it is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above. The research staff will not share any of your research information with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

[Omit the signature page if there is no written documentation of consent.]
THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION

[Remove any sites not engaging in the research] Icahn School of Medicine at Mount Sinai,
Mount Sinai Beth Israel, Mount Sinai St. Luke’s-Roosevelt,
New York Eye & Ear Infirmary of Mount Sinai

Study ID #: [GCO# or HSM#]     Form Version Date: [Do not leave blank]

**Signature Block for Capable Adult**

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

**DO NOT SIGN THIS FORM AFTER THIS DATE**

__________
Signature of subject
__________
Date

__________
Printed name of subject
__________
Time

[required if used for FDA documentation purposes]

**Person Explaining Study and Obtaining Consent**

__________
Signature of person obtaining consent
__________
Date

__________
Printed name of person obtaining consent
__________
Time

**Witness Section: For use when a witness is required to observe the consent process,**

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

__________
Signature of witness to consent process
__________
Date

__________
Printed name of person witnessing consent process
__________
Time

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