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NYU Langone MEDICAL CENTER

Research Subject Informed Consent Form

Title of Study:	Predicting poor vaccine responders to Hepatitis B vaccination
Principal Investigator:	Ramin Herati, MD Division of Infectious Diseases and Immunology 430 E 29th Street, 3rd Floor room 308 New York, NY 10016 646-477-9086 Ramin.herati@nyulangone.org
Emergency Contact:	Vaccine Center physician on-call 877-919-2822

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to understand how the immune system learns from the hepatitis B vaccine and why some people do not respond to the vaccine. Approximately 5-50% (5-50 in 100) of people who need hepatitis B vaccine do not develop immunity despite getting three doses of the classic vaccine. The immune system “learns” from a vaccine through the actions and changes to T and B cells (types of cells in your immune system), but there are many details that we do not understand. For example, we do not know how long T and B cells survive, how booster doses affect these cells, and whether we could predict who will ultimately respond well (or poorly) to a vaccine series based on just what we can learn from the blood. Understanding how people respond to different versions of the hepatitis B vaccine will help us understand how to design better, more effective vaccines.

You are being asked to participate in this study either because you have never been vaccinated against hepatitis B or because you have previously completed a hepatitis B vaccine series.

3. How long will I be in the study? How many other people will be in the study?

Depending on the randomization, you may have as few as 3 study visits (total ~1 month) or as many as 8 visits (total ~6 months). This study will include approximately 200 participants.

4. What will I be asked to do in the study?

If you decide to join this study you will be asked to sign this consent form. After you sign consent, you will be asked a series of questions to determine your eligibility. This may be in person with a coordinator or done over the internet.

If you are eligible, your samples will be collected at the NYULVC Research Clinic on the 4th floor Room 4-200 of the Medical Sciences Building (MSB) at 550 1st Avenue, New York, NY, 10016.

If you have never been vaccinated against hepatitis B before
You will be randomly assigned (by chance, like flipping a coin) to one of two groups. Most people (4 out of every 5 people) will receive the classic hepatitis B vaccine (Engerix-B) series, and a small number (1 out of every 5 people) will receive the adjuvanted hepatitis B vaccine (Heplisav) series. Each of these hepatitis B vaccines is Food and Drug Administration (FDA) approved for the prevention of infection caused by the hepatitis B virus. Both vaccines series will be used as directed by the package insert. Each vaccine series consists of either 3 doses (Engerix-B) or 2 doses (Heplisav) spread out over time. Vaccines will be given by study personnel qualified to perform vaccination, such as a nurse or physician, by disinfecting the skin with alcohol then administering the vaccine into the deltoid muscle (uppermost part of your arm). For the 3-dose series, the first two doses will be given in the same side (for example, both doses into the left shoulder), and then the third dose will either be given in the same side (for example, again into the left shoulder) or into the opposite side (for example, into the right shoulder).

If you have previously been vaccinated against hepatitis B virus
You will be given a single dose (booster shot) of the classic hepatitis B vaccine (Engerix-B) to see how well you have maintained immunity over time, compared to when you were originally vaccinated. To do this, we will give you one dose of the vaccine and draw your blood as described above. Although booster shots are routinely administered to people whose immunity to Hepatitis B virus over time, the FDA has not specifically approved a booster dose in people who have previously been vaccinated against hepatitis B. Therefore, in this study, the booster shot is considered ‘off-label’ or experimental.

Study Visits
Each visit will last approximately 1 hour or less. In the first visit, you will review the consent form with a study team member. We will ask you a few questions to verify your eligibility, collect demographics, record relevant medical history, and assess height and weight. Next, you will be asked to provide your blood sample. Approximately 75 mL of blood (~ 15 teaspoons) will be drawn by disinfecting the skin then placing a small needle into a vein in the arm. Blood samples will be analyzed in the lab to understand how hepatitis B immunity develops. Both vaccines are thought to protect equally well against hepatitis B virus infection. If you have not been vaccinated previously, you will be randomly assigned to receive either the classic hepatitis B vaccine (3 doses) or the newer adjuvanted vaccine (2 doses).

At each visit, you will meet with a study team member. We will ask you about your symptoms, any side effects from the vaccine, and ask you about your recent medical history.

Classic hepatitis B vaccine (Engerix-B)

Vaccine cycle	**1 (start)**		**2 (at 1 month)**			**3 (at ~6 months)**		
Time point	**Week 0**	**Week 1**	**Week 0**	**Week 1**	**Week 4**	**Week 0**	**Week 1**	**Week 4**
Urine pregnancy test	X		X			X		
Immunization	X		X			X		
Blood draw (in teaspoons)	15 tsp	15 tsp	15 tsp	15 tsp	15 tsp	15 tsp	15 tsp	15 tsp

CpG-adjuvanted hepatitis B vaccine (Heplisav)

Vaccine cycle	**1 (start)**		**2 (at 1 month)**					
Study Windows	**Week 0**	**Week 1**	**Week 0**	**Week 1**	**Week 4**			
Urine pregnancy test	X		X					
Immunization	X		X					
Blood draw (in teaspoons)	15 tsp	15 tsp	15 tsp	15 tsp	15 tsp			

Previously immunized against hepatitis B vaccine (Engerix-B)

Vaccine cycle	**1 (start)**							
Study Windows	**Week 0**	**Week 1**	**Week 4**					
Urine pregnancy test	X							
Immunization	X							
Blood draw (in teaspoons)	15 tsp	15 tsp	15 tsp					

Optional visit #1: One additional visit for blood draw will be permited at 1-3 days after any dose of the vaccine. Although the primary goal of the study is to find out what happens to the immune system starting at about 1 week after vaccination, there are particular changes to certain “first-responder” cells in the immune system that can only be studied soon after vaccination. To study these cells, an optional visit will consist of blood draw of 15 teaspoons, performed the same way as the other study visits. This optional visit can occur up to once during the course of the protocol. This optional visit is not required for study participation.

Please mark your initials next to one of the options below:

_____YES: I agree to participate in the additional, optional visit as described above.

_____NO: I DO NOT want to participate in the additional, optional visit as described above.

Optional visit #2: Although we rely on the cells in the blood to tell us about the immune system, the immune system's home is in the lymph nodes of the body. Lymph nodes are the round "bumps" you may feel in your armpit such as when you have had an infection. Lymph nodes are where the immune system "learns" about how to defend against germs. We want to study the cells from the lymph nodes directly, since this will give us the clearest view of what is happening after you get a vaccine.

Lymph nodes are usually found just below the skin and can be as small as a pea or as a big as a marble. To find the lymph nodes, a trained interventional radiologist will use an ultrasound machine, which is the standard way to locate these nodes. Then, the radiologist will thoroughly disinfect the skin, numb the skin with a local anesthetic, then place a needle into the lymph node using the ultrasound machine for guidance. Then the radiologist will perform a biopsy to take a small sample of the node. The lymph node itself is not removed. Afterwards, the team will monitor for signs of bleeding or other problems. This procedure is not a surgery and you will not need sedation or general anesthesia and takes a couple of hours in total. The procedure is routinely performed for medical care when there is a need to look into the lymph nodes directly, so our physicians have the training and experience needed to do this procedure.

This optional lymph node biopsy can occur one time during the course your participation in our study following any of the vaccinations. This optional visit is not required for study participation.

Please mark your initials next to one of the options below:

_____YES: I agree to participate in the additional, optional visit for lymph node biopsy.

_____NO: I DO NOT want to participate in the additional, optional visit for lymph node biopsy.

What if I can't come back to the clinic for some visits?
We understand that your time is valuable and that it is not always possible for you to return to the clinic frequently. Unfortunately, all visits involving vaccinations need to be performed in the Vaccine Center clinic to make sure we give you the right vaccine and under the right conditions.

However, for visits in-between, such as the Week 1 visits, you have the option to have a trained phlebotomist (person who draws blood) to come to you to draw the blood samples. If you choose this, we will communicate your name and contact information to an NYU-approved 3rd party service, Bruen Medical Partners, who then will contact you to set up a time and a place to meet. The service provides trained phlebotomists who can draw your blood safely and who will ensure the blood samples are packaged appropriately and sent back to the Vaccine Center. This research service, called mobile phlebotomy, is provided at no cost to you. With these visits, we will contact you by phone to check in and ask you about any side effects.

To make it easier to complete the visits, we offer windows of time:

- Week 1 visits may be completed between 5 and 14 days after the preceding vaccination;
- Week 4 visits may be completed between 3 and 5 weeks after the preceding vaccination;
- Vaccination #2 cannot occur less than 4 weeks after the initial vaccination*
- Vaccination #3 cannot occur less than 6 months after the initial vaccination*

*Not all participants will receive Vaccinations #2 or #3, depending on randomization.

What will happen to my samples?
We will analyze your blood sample to test for antibodies (proteins made by your immune system in response to your body fighting a disease or infection) and white cells responding to the vaccine. White blood cells will be separated and studied using typical immunology laboratory tests to understand how your body has responded to the vaccine across multiple doses. We may also examine your immune responses to prior vaccines and/or infections. For this reason, we'll ask you to answer a few questions regarding your infectious disease history before sample collection.

Some scientific questions may arise after data analysis that we did not anticipate when starting the trial, and these questions may be beyond the scope of the current trial. Use of the stored, leftover samples will permit these questions to be addressed. Samples may only be used for scientific health-related research to find new ways to prevent or treat health problems. Sample storage for future research is optional, and you can still participate in the study if you decide not to allow sample storage for future research. Samples banked in the NYULVC repository will be stored indefinitely. Samples will be labeled with a unique alphanumeric (containing letters and numbers) identification code. The linking key will be securely maintained on a NYULH computer and accessible only by study personnel. Samples will become the property of NYULH, and the study participant will give up all rights to any future financial compensation, inventions, discoveries, or access to the donated specimens.

Your participation in future research is voluntary. You are entitled to withdraw your consent for future research at any time, without giving a reason and without a negative effect on your standard of medical care. If you wish to withdraw, please inform the study Principal Investigator (Dr. Ramin Herati, ramin.herati@nyulangone.org). There will not be any penalty or loss of benefits to which you are otherwise entitled if you decide not to take part or if you withdraw early. You may continue to participate in the clinical study even if you choose to withdraw from future research. If you withdraw from future research, your coded data and biosamples will not be used for future research and your samples will be destroyed as soon as possible. Your coded data (either copied from the clinical study database or newly generated) will also be destroyed unless this information is already included in analyses or used in scientific publications or if the coded data been anonymized and therefore we can't identify your data or biosamples.

Please mark your initials next to one of the options below:

_____YES: I will permit samples to be used for future research.

_____NO: I DO NOT want samples to be used in future research.

Research using your samples is important for the study of vaccines and, more broadly, virtually all infectious diseases. NYULVC clinical and research personnel will have access to the samples and results collected under this study protocol. Additional investigators – at NYULH and outside academic institutions – may request access to these results and specimens. If these researchers are conducting relevant, significant research and have all required IRB and biosafety requirements in place, these researchers may receive coded specimens from this protocol. The study Principal Investigator, Dr. Ramin Herati, will oversee the transfer of any specimens outside of the NYULVC.

Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to

health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes.

Identifiers will be removed from the identifiable specimens. After such removal the specimens may be used for future research studies or shared with other researchers, and we will not request additional informed consent from you to use these specimens as we have noted here.

5. What are the possible risks or discomforts?

This section describes the risks we know about. There may be other risks, discomforts or side effects that are currently unforeseeable.

Risks of Hepatitis B vaccination
There are two forms of the hepatitis B vaccine that are being used in this study:

Traditional HBV vaccine (tradename Engerix-B) - In healthy adults, 15-30% (15-30 in 100) reported pain at the injection site, and 1% (1 in 100) had redness or swelling at the injection site. Approximately 10-15% (10-15 in 100) reported systemic reactions including feeling rundown or tired, headache, fever, nausea, or diarrhea.

CpG-adjuvanted HBV vaccine (tradename Heplisav) - In healthy adults, 20-37% (20-37 in 100) reported pain at the injection site, and 1-5% (1-5 in 100) had redness or swelling at the injection site. Approximately 10-15% (10-15 in 100) reported feeling rundown or tired, headaches, feeling ill, or fever.

Risks of Blood Collection
The risks of blood collection through venipuncture include temporary discomfort, bleeding, bruising, and, in rare cases, infection.

Risks of lymph node core needle biopsy
Lymph node biopsy is more complex than taking blood from a vein, so there are some additional risks. The lymph node biopsy is performed by the Interventional Radiologists at NYULH who are board-certified and perform this procedure routinely. The lymph nodes of the armpit are first visualized using an ultrasound machine, which is safe and carries no risk of harmful radiation. If a lymph node is found, then the armpit skin is disinfected and a biopsy needle inserted using the ultrasound for guidance. The biopsy itself can cause temporary pain or discomfort. Uncommonly, bruising, bleeding, or infection could occur (~1%). Extremely rarely (much less than 1%), there could be injury to the nerves or the lymphatic vessels in the armpit leading a condition called lymphedema. *Risk to Confidentiality*
In addition, there is the risk of loss of confidentiality. Your samples will be coded with a study number that does not contain any personal identifiers. The key to the code will be maintained on a secure server with limited access and protected by a computer security system. No information will ever be released or published in a way that will identify a specific individual. Although every effort will be made to protect the confidentiality of your records, this cannot be guaranteed. In the event of technological malfunction, data will be collected on a paper instrument and secured in a locked cabinet within the locked office of the Principal Investigator or designee. All signed informed consent documents will be maintained in a locked cabinet within the locked office of the Principal Investigator or designee. The researchers who request specimens from this specimen collection protocol will receive de-identified specimens only if they are conducting relevant, significant research and have all required IRB and biosafety requirements in place. There is the risk that information about you may become known to people outside this study.

If you choose to have your blood drawn by mobile phlebotomy, we will send your name and contact information to the NYU-approved 3rd party company, Bruen Medical Partners. Only the minimum required information will be sent to this service so that they can provide the blood draw service.

Other Risks

You may get tired or bored when we are asking you questions. You do not have to answer any question you do not want to answer.

NYU Grossman School of Medicine Students: Your decision to participate, decline, or withdraw from the study will have no impact on your grades or academic standing. Participation in this study cannot be linked to your academic record.

NYU Grossman School of Medicine and NYU Langone Health Employees: Your decision to participate, decline, or withdraw from the study will have no impact on your employment, salary, or performance evaluation.

6. Can I be in the study if I am pregnant or breastfeeding?

There are no data on the safety of the adjuvanted hepatitis B vaccine during pregnancy. Thus, if you are currently pregnant, we ask that you not participate in the study. Women who are breastfeeding may participate in the study. Women of child-bearing potential will have a pregnancy test done in-clinic prior to each vaccination, because we do not have enough safety data on some of the vaccines during pregnancy to be able to guarantee safety.

7. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

8. What are the possible benefits of the study?

Immunization can directly provide you with long-term protection against against hepatitis B infection. Indirectly, people may benefit in the future from information learned in this study. You may get a feeling of personal satisfaction from being part of a study that contributes scientific findings and discoveries for better vaccines Science and NYULH scientists will benefit because specimens will be made available to advance research projects.

9. What other choices do I have if I do not participate?

You can choose whether or not to join this study. You can receive a hepatitis b vaccine without participating in this study. Your decision is voluntary. Your care at NYU Langone Medical Center will not be affected. You will not lose any benefits or rights you would normally have if you refuse to join this study or if you leave it after you have joined.

10. Will I be paid for being in this study?

You will be compensated $50 per completed blood-draw visit on-site and $30 for completed visits via mobile phlebotomy. If you participate in the one-time lymph node biopsy and the biopsy is successfully done, you will be compensated $500. If the ultrasound is done but the lymph nodes cannot be biopsied, you will still be compensated $200. For each group, the total amount you can receive if you complete all visits in-person (including the one optional visit and one optional lymph node biopsy) will be:

- Traditional HBV vaccine $950
- CpG-adjuvanted HBV vaccine $800
- Known HBV immunity $700

You will be reimbursed for travel costs if traveling ≥ 50 miles each way to/from NYU Langone Health for study participation. Reimbursement schedule summarized below.

Travel between 50-199 miles each way to/from NYU Langone Health:

1) Round trip coach train fare or mileage reimbursement

You will be asked to provide receipts and proof of mileage prior to reimbursement.

As is required by the laws that apply to NYU Langone, in order for you to receive a payment (i.e. check, Clincard or bank gift card), you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

You are required to track all payments made to you by NYU Langone for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please advise Dr. Ramin Herati (ramin.herati@nyulangone.org) and we may need to collect your Social Security number or Taxpayer Identification number. This is because NYU Langone is required to report to the Internal Revenue Service (IRS) any amounts that are paid to research participants that are equal to or greater than $600.00, and you may be taxed on these research payments above $600.00. If you do not have either of these numbers, you may be in the study but will not receive any payment.

11. Will I have to pay for anything?

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility. You will not be held responsible for payment of the optional research related lymph node biopsy if your insurance does not cover this procedure.

12. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form. We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

13. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the study sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

14. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.
You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this

research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results may be included in your NYU Langone Health electronic medical record.

In order to allow researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that analyze data and collect the results of whole genome studies. These banks may also analyze and store DNA samples, as well. These central banks will store your genetic information and samples and give them to other researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your samples and whole genome information with these banks. However, we cannot predict how genetic information will be used in the future. The samples and data will be sent with only your code number attached. Your name or other directly identifiable information will not be given to central banks. There are many safeguards in place to protect your information and samples while they are stored in repositories and used for research.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: The National Institute of Allergy and Infectious Diseases (NIAID)
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA)
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Bruen Medical Partners (only for mobile phlebotomy visits)

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of: doctors, nurses, non-scientists, and people from the community.

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date