TITLE OF RESEARCH STUDY:

Title: **BIOLOGICAL CORRELATES OF PERSONALITY DISORDER**

DIAGNOSTIC AND PSYCHOLOGICAL TESTING

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: Dr. Harold Koenigsberg, M.D.

Physical Address: 130 W Kingsbridge Road, Bronx VA, MIRECC

Mailing Address: 1 Gustave Levy Place, Box 1227, New York, NY 10029

Phone: 212-241-4459

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.

PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to determine the relationship between personality disorder and certain psychological indicators of impulse, mood and thinking

You may qualify to take part in this research study because you do not meet exclusion criteria for any of the diagnoses we are studying.

Funds for conducting this research are provided by the Veterans Health Administration and the National Institute of Mental Health.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last for the period of several weeks up to several months. Your participation will be scheduled so as to be as convenient for you as possible.

The number of people expected to take part in this research study at The Icahn School of Medicine at Mount Sinai is approximately two thousand two hundred and forty (2,240) normal controls and four thousand seven hundred and sixty (4,760) patients diagnosed as having a personality disorder. The total number of people expected to take part in this research study is seven thousand (7,000).

DESCRIPTION OF WHAT'S INVOLVED:

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

In this study, all visits will be conducted in a private office on 1160 5th Ave, Suite #108. You will be administered several interviews and questionnaires by members of the research staff. Questionnaires may be administered electronically, or by pen and paper. You will be asked questions about problems and personality characteristics you may or may not have. These face-to-face interviews and questionnaires will be administered to you in a series of five study sessions at most. These sessions include an initial screening interview, diagnostic interviews, and questionnaires. Each study session can last up to 2-3 hours. You may be asked to give a urine specimen to screen for substances which might affect the validity of study results (including illegal drugs).

In addition to contacting you by phone, do you give us permission to contact you by e-mail or text message regarding future appointments for this study? Please initial your choice:

By phone: Yes_____ No_____
By e-mail: Yes_____ No_____
By text message: Yes_____ No_____

With your permission only, we will contact a person whose name you give us as someone who knows you well (for example a friend or relative) to ask them about your personality. This is optional. If you agree we will check with you before we contact this person to be sure you have let this person know that they would be contacted by our research team.

Do you give us permission to contact a friend or relative to ask about your personality?

Please initial your choice: **Yes_____** **No_____**

Depending on the results of your interviews, you may be offered additional studies to participate in.

If you enroll in this study you may be contacted to participate in future studies. If you consent to the future studies, the data gathered for research purposes from this study may be used in those future studies.

Do you give us permission to contact you in the future if new studies within our research group become available for which you might be eligible? Yes_____ No_____

Participating in future research:
If you are interested, you can be contacted in the future by other Mount Sinai researchers if there are new opportunities to participate in research studies. With your permission a researcher at Mount Sinai will call you or send you an email when they conduct new studies for which you may be eligible. At that time you will receive a complete description of the new study, and you will have the opportunity to decide if you want to volunteer. If you do not give permission for re-contact in the future it will not

affect your current study participation or your ability to receive care at Mount Sinai. The choice is completely up to you.

Would you like to be contacted in the future if there are new opportunities to participate in research studies with other Mount Sinai Researchers?

Please initial one: YES_____NO_____

If YES, please provide us with a phone number and/or email address at which we should contact you.
Phone: _____ Email: _____

Medical Evaluation:
If you are eligible for any of our studies after your interview(s), you may be asked to undergo a Medical Evaluation in order to ensure that you are medically healthy before participating. While the required medical tests vary between studies within our group, it may be the case that you are found to be eligible for more than one study that require the same medical clearance. Repetition of the same medical evaluation or tests will not be required within a 3-6 month timeframe as we will have access to your initial records and your results may be considered for both. It may also be the case that you are medically cleared to participate in one study, but not all for which you are considered to be eligible. As part of the medical evaluation, you will be asked to provide a urine sample to test for drugs and pregnancy, if applicable. This will be completed by a member of our research staff in our offices at 1160 5th avenue. The results of this test will not be placed in your clinical medical record, although the research team will keep the result on file in our offices.

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: You will be expected to attend scheduled visits and answer questions about your personality, personal history and family history in both interview and questionnaire form.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not incur any costs for participation in this study.

If you agree to take part in this research study, we will pay you up to $115 for your time and effort. We will pay you $25 for the initial screening interview. If you are further eligible, you may take part in further interviews for $40, and complete two additional questionnaire packets for $25 each. These payments will be made out in the form of a check which will be available for pick up or mailed to you. Checks require some time to be prepared and will be given to you as available. Should you be eligible for further appointments, you may also be compensated for your transportation in the form of a pre-paid one-trip MetroCard. If you elect to receive a pre-paid one-trip MetroCard, then an equivalent amount will be deducted from your total study reimbursement.

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.

POSSIBLE BENEFITS:

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 the advancement of care for psychiatric patients at some time in the future should the research procedures in this study add to our knowledge about psychiatric disorders.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

There are no known risks associated with these tests, but you may feel bored or embarrassed when you complete some of them. In addition, assessments may cause anxiety, anger, or other emotional distress. There always exists the risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you. Instead of being in this research study, the alternative is not to participate.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff.

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. More possible reasons for removal from the study include: If you do not follow through with this assessment and do not regularly keep your appointments.

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 212-241-4459.

If you experience an emergency during your participation in this research, contact 888-836-4443. If this number is unreachable, and you are experiencing a medical or mental health related emergency, please dial 911.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

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?

As part of this research project, the research team at the hospital(s) involved in the research will collect your Name, Address, Telephone number, and Social Security Number.

The researchers will also get information from your mental health record. In that case, however, we will request your permission specifically to obtain your records and will ask you for a separate authorization to do so. In some cases, we will request access to your history of alcohol or substance abuse records. In that case, however, we will request your permission specifically to obtain your records and will ask you for a separate authorization to do so.

During the study the researchers will gather information by:

- completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

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.

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

- 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: The National Institutes of Health through a grant to the General Clinical Research Center at Mount Sinai School of Medicine.
- United States Department of Health and Human Services and the Office of Human Research Protection.

In all disclosures outside of Mount Sinai, the Bronx Veterans Affairs Medical Center, 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, 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?

Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

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

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 you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

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.

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 → **8/31/20**

Signature of subject	Date
Printed name of subject	Time

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,, document below (for example, subject is illiterate or visually impaired, or this accompanies a short form consent):

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