**EXEMPT RESEARCH INFORMATION SHEET AND HIPAA AUTHORIZATION TEMPLATE INSTRUCTIONS**

This template should be used for exempt studies only.

The templatecontains language that meets OHRP and HIPAA requirements. There are some additional elements that may or may not apply to your study. We note in this template where they should be inserted if they apply.

**Consent language.** We have provided suggested language for required and additional consent elements, but this language can be tailored to fit your specific study.

**Instructions for use of the template.**

* **DELETE THE INSTRUCTION PAGE BEFORE SUBMITTING THE CONSENT DOCUMENT TO THE IRB.**
* **DO NOT ADJUST THE MARGINS OF THE CONSENT TEMPLATE.**
* For new studies, use the most updated version of the consent template available on the IRB website.
* Instructions within the template appear as comment bubbles. If the complete text of the instructions does not appear, click on the to view the text.

…

* + Certain sections have **DELETE IF NOT APPLICABLE** in the comment bubble. Delete the not applicable sections.
  + Comment bubbles will not appear in the IRB-stamped document and may be left in the document.
* The places you must insert your own study-specific language are in **bolded** in brackets **[like this]**

**ALBERT EINSTEIN COLLEGE OF MEDICINE**

**MONTEFIORE MEDICAL CENTER**

**BURKE REHABILITATION HOSPITAL**

**BURKE MEDICAL RESEARCH INSTITUTE**

**JACOBI MEDICAL CENTER**

**NORTH CENTRAL BRONX HOSPITAL**

**YESHIVA UNIVERSITY**

**WHITE PLAINS HOSPITAL**

**INFORMATION SHEET FOR EXEMPT RESEARCH AND HIPAA AUTHORIZATION**

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| --- | --- |
| The researcher in charge of this project is called the “Principal Investigator.” **[**His/Her**]** name is [name]. You can reach Dr. **[**name**]** at:  **Office Address:**  **City, State Zip**  **Telephone #:**  For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB. | The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at [irb@einstein.yu.edu](mailto:irb@einstein.yu.edu), or by mail:  Einstein IRB  Albert Einstein College of Medicine  1300 Morris Park Ave., Belfer Bldg #1002  Bronx, New York 10461 |
| Support for this research study is provided by **[Specify who is paying for the study including treatments, medications and tests]** |

We would like to talk to you about a research study on **[topic of the study]**. You are being asked to be in this research study because **[list criteria].** You will be one of about **##** people who will be participating in this study.

This study is designed to learn more about **[one or two words].**

If you join the study, you will **[list what they need to do].**

You have a choice about being in this study. If you decide to take part, you are free to stop participating at any time without giving a reason.

You may feel uncomfortable answering questions about…. You can choose not to answer questions that make you feel uncomfortable.

Possible discomforts or risks include **[list what the discomforts or risks may be].** There may be risks the researchers have not thought of.

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

You will receive a total of [**amount, e.g. $100**] for [**number e.g. 10**] study visits. If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed.

Participants in this study may receive more than $600 in a calendar year for their participation. The IRS requires that we report this as income. Therefore, you must provide your social security number if you wish to receive these payments.

It will not cost you anything to be in this study, and you will not experience any direct benefit personally from participating. However, we hope you will participate because the study will generate important information about **[insert]**.

Every effort will be made to protect your privacy and confidentiality by **[list how]**

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc. In addition, the researchers wish to review information pertaining to your [CHOOSE APPLICABLE RECORDS: HIV records/substance abuse treatment records/psychiatric treatment records]. By law, you must specifically authorize access to these records:

Yes, I authorize the use and disclosure of my information pertaining to HIV testing and HIV status.

Initial: \_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_

Yes, I authorize the use and disclosure of my information pertaining to substance abuse treatment.

Initial: \_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_

Yes, I authorize the use and disclosure of my information pertaining to psychiatric treatment.

Initial: \_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

* Researchers and other individuals who work with the researchers
* Organizations and institutions involved in this research, including those that fund the research, if applicable
* Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

Information about your participation in this study will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, the information will be available to all of your providers who participate in the EMR system. The purpose of this entry is to provide research information that has the potential to impact your medical care.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

**Certificate of Confidentiality**

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

A description of this clinical trial will be available on [www.ClinicalTrials.gov](file:///C:\Users\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\DO400VI2\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.

If you have questions, you can call **[insert contact name],** at **[insert phone number].** You can call and ask questions at any time.

You may have questions about your rights as someone in this study. If you have questions, you can call the Einstein Institutional Review Board. Their number is 718-430-2237.

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| **CONSENT AND AUTHORIZATION TO PARTICIPATE**  I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form. | | | | | | |
|  |  |  |  |  | | |
| Printed name of participant |  | Signature of participant |  | Date |  |  |
|  |  |  |  |  | | |
| Printed name of the person conducting the consent process |  | Signature |  | Date |  |  |