

National Jewish Health ICF requirements

1.) NJH logo on first page only



2.) ICF Title to include:

“Informed Consent and HIPAA Authorization Form”

3.) Contact information listed on page one only. Other ICF sections regarding contact can refer to page 1. This will need to be provided by NJH:

Phone number: ###-###-#### (Office hours)
 ###-###-#### (After-hours messages)
 <For study greater than minimal risk, also include the following>
 ###-###-#### (24-hour contact for urgent matters)
 In an emergency, dial 911

4.) No subject initials in the footer

5.) Sponsor pays National Jewish Health to perform the study (not the study doctor)

6.) Per Colorado State law, positive pregnancy tests may only be shared with the pregnant female. For pediatric studies, following statements:

- In parental ICF: “If a pregnancy test for a minor female is positive, only she will be told”
- In the assent form: “If your pregnancy test is positive, only you will be told. The study doctor will offer to tell your parents.”

7.) For studies involving testing for HIV, Hepatitis B, Hepatitis C and/or TB, the following needs to be clear:

“positive results will be reported to the Colorado Department of Health”

8.) Clinically Relevant Research Results

When applicable:

“Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have

meaning for your health, and to which we have access and will analyze, the researchers will contact you to let you know what they have found.”

When applicable:

“If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.”

9.) Site will need to confirm/provide subject compensation dollar amounts. Mandatory payment language:

“You be paid \$XX for each completed study visit (or table breaking down amount per visit)

A payment schedule that best fits your needs will be agreed upon at study enrollment. If you do not complete all study visits, you will be paid for the visits you completed.

Important Tax Information

It is important to know that any payment for participation in a study is considered taxable income, regardless of the amount or form of payment, including check, cash, gift card, gift certificate, money order, or non-cash items. National Jewish Health is required by the Internal Revenue Service to report any payments that exceed \$600 per person per year. If you are Nonresident Alien, for tax purposes, all payments made to you, including those for your participation in this study, are subject to a 30% tax withholding. All withholdings and payments will be reported to those in charge of taxes (IRS) by NJH. Reimbursement for expenses you have already paid are not considered income and are not taxable. You may be required to complete a W-9 form to provide accurate information for this purpose. However, patient confidentiality will be protected in accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA). Please contact your coordinator if you do not wish to be paid for your study participation.”

When applicable:

“With pre-approval from the sponsor, you may be reimbursed for travel expenses. The study sponsor may offer a travel agent or other vendor to assist you in travel arrangements and/or reimbursement. Please see your research coordinator for more information.”

10.)GINA language for all studies involving DNA and RNA testing of samples:

There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers (except those with fewer than 15 employees) 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.

11.) Injury Compensation language

“If you have an injury while you are in this study, you should call the study doctor immediately. Contact numbers are listed on page one of this consent form.”

Either, for all NIH-funded studies, investigator initiated studies, foundation funded studies and extended compassionate use studies:

“We can help arrange to get you medical care if you have an injury that is caused by this research. National Jewish Health does not offer financial compensation or payment for injuries due to participation in this research.”

Or, for all industry-sponsored:

“In the event of an injury or illness resulting from your participation in the research study, your study doctor can help arrange for you to receive appropriate health care, including first aid, emergency treatment and follow-up care either at National Jewish Health or another appropriate health care facility. In accordance with general NJH policy, we make no commitment to provide free medical care or other compensation for injury or illness resulting from your participation in this study. Medical treatment, paid for by the study Sponsor, will be provided at no cost to you or your insurance company for a research-related injury. The sponsor and the study doctor will determine if your injury or illness is research-related. The term “research-related injury” means physical injury caused by medications, devices, interventions, procedures, or tests required by the study which are different from the medical treatment you would have received if you had not participated in the study.

The Sponsor is not responsible for expenses that are due to pre-existing medical conditions, underlying disease, or your negligence or willful misconduct. In addition, the Sponsor will not pay for expenses that result from National Jewish Health’s negligence, misconduct or failure to follow the study protocol or the study doctor, study staff or an employee of the Institution’s negligence, misconduct or failure to follow the study protocol. If the cost of treating your research related injury was incorrectly billed to your insurance company or a government program by National Jewish Health, the payment will be returned and the Sponsor will be billed. By signing and dating this form, you have not given up your legal rights.

If you experience a research-related injury that requires Sponsor to pay for your medical expenses and you are a Medicare recipient, you will be asked to provide Sponsor with your name, date of birth, gender and Medicare number for Medicare reporting requirements.”

12.)HIPAA to be placed within text of the ICF, before the signature blocks:

How will my protected health information be used and disclosed?

National Jewish Health has rules to protect information about you. Federal and state laws, including the Health Insurance Portability and Accountability Act (HIPAA), also protect your privacy. This part of the informed consent form tells you what information about you may be collected in this study and who will use, share, copy and disclose it.

The institutions and healthcare providers involved in this study include:

- National Jewish Health
- Other (name; use this space for other affiliated institutions only, such as University of Colorado, Saint Joseph Hospital, etc.)

We cannot do this study without your permission to see, use and give out your information. You do not have to give us permission. If you do not, then you may not join the study. We will see, use, share and copy your information only as described in this form and in our Notice of Privacy Practices; however, people outside National Jewish Health may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and sharing of your information has no time limit. You can withdraw your permission to use and share your information at any time by contacting the study doctor in writing at the address listed on page one. If you do withdraw your permission, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected for the study.

The study doctor (or staff acting on behalf of the study doctor) will use your information for the research outlined in this consent form. They may also make all or some of the following health information about you collected in this study available to:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- the IRB of Record
- [if applicable, if NJH is not the IRB of record] NJH HRPP/Research Regulatory Affairs Office in conjunction with Biomedical Research Alliance of New York IRB (BRANY) who are acting as the NJH Privacy Board
- The study doctor and the rest of the study team (including collaborators outside of NJH)
- <Insert sponsor name>, the company or organization paying for this research study and its affiliates
- Officials and authorized personnel at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in medical journals or medical magazines, but we will always keep the names or other information that could identify you private.

You have the right to request access to your personal health information related to the study. [To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed – if applicable].

[Include if the research may involve whole genome sequencing.] The research might include whole genome sequencing (determining the order of DNA building blocks (nucleotides) in your genetic code).

[if applicable] Some of the research procedures involve genetic testing or the use of your genetic information. Your genetic information [choose one <will/will not>] be released to others.

Information about you that will be seen, collected, used and disclosed in this study:

[check all that apply]

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Your social security number for payment purposes
- Your Medicare number for reporting requirements if you have a study related injury and are a Medicare recipient
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Data from Research-related activities and procedures
- Data from Biologic samples such as Blood/Urine/Saliva
- Psychological and mental health test results
- Information related to Alcoholism or Alcohol/Drug abuse
- Testing for or infection with diseases reportable to the Public Health department, including but not limited to: Human Immunodeficiency Virus (HIV), hepatitis (all forms) tuberculosis, or other sexually transmitted diseases
- Testing for sickle cell
- Data from future Genetic research if you opt in
- Other (please specify): _____

13.)Signature section to include:

“Consent and Authorization”

No required dating formatting