**Northwest Community Healthcare**

**Institutional Review Board**

**(ATTACHMENT II– Policy 142)**

**AUTHORIZATION TO USE AND DISCLOSE**

**PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES**

**Protocol Number:**

**Title of Protocol:**

**Principal Investigator:**

**Affiliation:**

**Address:**

**Study Sponsors:**

Note: References to “researchers” below includes the principal investigator and his or her staff members.

“Sponsor” refers to the sponsor(s), if any is listed above, and any of their representatives.

**AUTHORIZATION PURPOSE**

The purpose of this authorization is to obtain permission from you to collect and use personally identifiable information about you for the purposes of the above research study. This Authorization differs from an informed consent in that it explains privacy risks and states how your information will be collected, why it will be collected, and with whom your information will be shared with. An informed consent, on the other hand, provides you with information about the study you are participating in. Your signature on both documents are required in order for you to participate in the above study; however you may still receive non-research related care if you chose not to sign this document.

**INTRODUCTION**

State and federal laws protect the use and disclosure of your health and medical information so that it is kept private and confidential to the greatest extent possible. Protected Health Information (PHI) includes any information that we collect in relation to this research or the provision of care that can be used to individually identify you. Under these laws, Northwest Community Healthcare or your health care provider cannot release your health information for research purposes unless you give your permission through signing this form.

If you do notsign this form, you will not be allowed to enroll in the research study named above. Your choice about whether or not to participate in the study will not affect your regular treatment, payment or enrollment in any health plans or your eligibility or benefits for your medical care.

This authorization will not expire. There is no set date at which your information will be destroyed or no longer used. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be completed.

If you sign this Authorization, but wish to limit or withdraw the Authorization in the future, please notify the principal investigator above in writing. If you withdraw the Authorization, you will also be withdrawn from the study. Any information collected prior to your withdraw will still be used and maintained.

**What Personal Health Information will be released?**

Your signature on this form serves as your consent to permit Northwest Community Healthcare, its employees and affiliates to release documents and provide information containing the Personal Health Information indicated below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Name |  | Social Security Number |  | Telephone Number |
|  | Address |  | Date of Birth |  | Fax Number |
|  | Email Address |  | Medical Record Number |  | Health Plan Beneficiary (Insurance) Number |
|  | Account Number |  | Certificate or License Number: |  | Vehicle identifiers and serial numbers |
|  | Patient-Specific Dates (e.g., treatment dates) |  | Biometric Identifiers (finger or voice prints) |  | Device Identifiers and serial numbers |
|  | Web universe resource locators (URLs) or Internet Protocol (IP) addresses |  | Photographic images, including: |  | Other: |

The PHI will be collected from the following sources:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Hospital Medical Records |  | Physician or clinic records |  | Laboratory, pathology and/or radiology results |
|  | Biological samples |  | Interviews or questionnaires/health histories |  | Data previously collected for research purposes obtained from: |
|  | Other: |  |  |  |  |

The following information requires that you give special permission for us to release. Please read each request below that has a check mark next to it, and initial in the space provided to indicate you agree with the release of this information in the way that is described in this form.

\_\_\_\_\_\_\_\_\_(initials) I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

\_\_\_\_\_\_\_\_\_(initials) I agree to the release of HIV/AIDS testing information

\_\_\_\_\_\_\_\_\_(initials) I agree to the release of genetic testing information.

\_\_\_\_\_\_\_\_\_(initials) I agree to the release of information pertaining to mental health diagnosis or treatment.

\_\_\_\_\_\_\_\_\_(initials) I agree to the release of information pertaining to sexually transmitted diseases.

**Your health information may be disclosed to the following agencies that oversee the study:**

* Members and staff of Northwest Community Healthcares Institutional Review Board, and (*specify which external IRB’s are involved),* an external Institutional Review Board overseeing study
* The United States Food and Drug Administration
* Office for Human Research Protections (OHRP)
* National Institutes of Health
* National Cancer Institute (NCI)

These researchers, companies and/or organization(s) may also use, share and receive your health information in connection with this study:

* Health care facilities, research site(s), researchers, health care providers, or study monitors involved in this study: *[Insert name(s) or delete if the information will not be shared outside of NCH]*
* Private laboratories and other persons and organizations that analyze your biological samples and/or imaging and/or get copies of the results in connection with this study: *[Insert name(s) of organizations that analyze lab results or data or any collaborative groups that will have access to the data if applicable or delete]*
* The research sponsor and companies owned or connected with the sponsor: *[Insert name(s) of sponsor(s) and names of sponsors’ subsidiaries participating in the research if applicable or delete*]
* Contract Research Organization(s) who oversee and audit the study on behalf of the sponsor: *[Insert name of CRO or SMO if applicable or delete]*
* Independent data and safety monitoring boards and others who monitor the conduct of the study*: [Insert if applicable or delete]*
* Others: *[Insert if applicable or delete]*.

We will make every attempt to protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records once your name and other information that could be used to identify you has been released. Also, once your PHI has been removed, the information that remains is no longer subject to this Authorization and may be used and disclosed by the Researchers and the Sponsor as permitted by law, including for educational or other research purposes.

No publication or presentation of the research will reveal your identity unless you have given your specific written permission.

Notice is hereby given to the patient or legal representative signing this Authorization that Northwest Community Healthcare cannot guarantee that a third party receiving the requested health information will not re-disclose any or all of it to others. However, Northwest Community Healthcare agrees to protect your health information by using and disclosing it only as described in this Authorization. The limitations on the use of your health information continues even if you revoke this Authorization in the future.

While the research is in progress, you will not be allowed to see your health information that is created or collected in the course of the research. After the research is finished, however, you may see this information as described in the Notice of Privacy Practices available in the hospital, clinic, or office where the research was conducted.

You will be given a signed copy of this Authorization.

**Signatures**

I have read this form and have received answers to all of my questions.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Participant Date

**Research Representative’s Statement**

I have explained this authorization form to the subject and have answered any questions he/she had.

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Signature of Person Obtaining Consent Date

***Add any of the following that are applicable for this study and delete any that do not apply***

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Signature of Legally Authorized Representative (LAR) for **ADULTS NOT** Date

**CAPABLE of GIVING CONSENT** (*Persons from* *the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship of LAR to Participant (indicate why the LAR is authorized

to act as a surrogate health care decision-maker under Illinois Law)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Parent/Guardian Date

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Signature of Parent #2 (if 45 CFR 406 or 407 study) Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Child Participant (optional unless IRB required) Date

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Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required) Date