**Supplement Form H**

 **Request for Waiver or Alteration of HIPAA Authorization**

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| **PI Name:**  | **Date**  |
| IRB#/Title:  |

The IRB may waive or alter the requirement to obtain written authorization from research subjects for the use or disclosure of their Protected Health Information (PHI) when the investigator justifies, and the IRB agrees, that specific criteria have been met.

**Note:** *Authorization must be obtained for the use or disclosure of psychotherapy notes. 45 C.F.R. §164.508(a)(2)*

**HIPAA identifiers that will be accessed, used or disclosed for this waiver request *(check all that apply):***

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| --- | --- | --- |
| 1. [ ]  Names.
2. [ ]  All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
	1. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
	2. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. [ ]  All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
 |   | 1. [ ]  Telephone numbers.
2. [ ]  Facsimile numbers.
3. [ ]  Electronic mail addresses.
4. [ ]  Social security numbers.
5. [ ]  Medical record numbers.
6. [ ]  Health plan beneficiary numbers.
7. [ ]  Account numbers.
8. [ ]  Certificate/license numbers.
9. [ ]  Vehicle identifiers and serial numbers, including license plate numbers.
10. [ ]  Device identifiers and serial numbers.
11. [ ]  Web universal resource locators (URLs).
12. [ ]  Internet protocol (IP) address numbers.
13. [ ]  Biometric identifiers, including fingerprints and voiceprints.
14. [ ]  Full-face photographic images and any comparable images.
15. [ ]  Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.
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1. **Indicate which of the following you are requesting *(check all that apply):***

[ ]  **Full Waiver** – Authorization will not be sought from any subjects

[ ]  **Partial Waiver** – Authorization will not be sought from some subjects (e.g., historical cohort) or for some activities (e.g., screening or recruitment) *Complete 1a below*

[ ]  **Alteration** – Authorization will be sought but one or more required elements will be eliminated or altered (e.g., requirement for signature) *Complete 1b below*

* 1. **If the request is for a Partial Waiver, explain what you are requesting and why:**

[ ] **Partial Waiver for Recruitment *(check all that apply):***

[ ]  PHI for interested parties will be accessed by the study team from either the NJH EMR or through the NJH RDB. This PHI may be used for identification of NJH patients as potential research participants, through treatment relationship, physician request referral, HIP-201 and/or scheduling.

* + 1. Will you require names of treating physicians?

 [ ] No [ ] Yes, explain:

* + 1. Will highly sensitive information be collected (HIV, substance abuse etc.)?

[ ] No [ ] Yes, explain:

[ ]  Study personnel will have contact with the potential subjects through office visits, phone calls, mailings, and/or emails to provide study information using the IRB approved consent form as a guide and to assess interest and eligibility. The study team may mail/email of the IRB approved consent form for future screening and recruitment purposes, however the consent process will be conducted as outlined in the IRB approved New Protocol Application/protocol.

[ ]  If a subject does not participate, is ineligible for this study and an Authorization for Future Contact is not obtained within 30 days, PHI will be destroyed.

[ ]  PHI will be collected prior to potential subjects visit at National Jewish Health to determine interest and eligibility. This is to ensure the time spent with the potential subject at National Jewish Health is focused on health care and suitable research options.

[ ]  The determination of study interest and eligibility by inclusion /exclusion criteria prior to subject visit to National Jewish Health is more practical than requesting subjects come to the study site. This study could not be performed without the pre-screening of interested potential study subjects.

 [ ]  Other:

[ ]  **Partial Waiver for purpose other than recruitment**

Explain:

* 1. **If the request is for an Alteration, explain which elements you are requesting to eliminate or alter and why** (a list of required elements is provided at the end of this form for your reference):

1. **Provide justification for how each of the following criteria for a waiver or alteration are satisfied:**
	1. **The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:**
		1. An adequate plan to protect the identifiers from improper use and disclosure.

Please explain:

Partial waiver for recruitment - Indicate if any of the following apply: [ ] NA

[ ]  Paper Based Documents: PHI for study recruitment will be kept in a locked office or suite, and only be accessed by study team members.

[ ]  Electronic Data: Any use of PHI in emails will be encrypted, all PHI will be stored on NJH Shared Drives and/or in accordance with the IRB approved New Protocol Application/protocol

[ ]  Other

* + 1. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Please explain:

Partial waiver for recruitment - Indicate if any of the following apply: [ ] NA

[ ]  Paper Based Documents: PHI will be shredded or discarded in Dataguard bin when no longer needed for recruitment purposes by the study team.

[ ]  Electronic Data: PHI will be deleted when no longer needed for recruitment purposes by the study team.

[ ]  PHI will not be destroyed. Explain:

* + 1. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by HIPAA. Please explain:
	1. The research could not practicably be conducted without the waiver or alteration. Please explain:
	2. The research could not practicably be conducted without access to and use of the protected health information. Please explain:

**HIPAA Authorization Required Elements & Statements**

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| **Core Elements** 45 C.F.R. §164.508(c)(1) |
| [ ]  | A description of PHI to be used or disclosed (identifying the information in a specific and meaningful manner) |
| [ ]  | The name(s) or other specific identification of person(s) or class of persons authorized to make the requested use or disclosure. |
| [ ]  | The name(s) or other specific identification of person(s) or class of persons authorized to make the requested use or disclosure. |
| [ ]  | A description of each purpose of the requested use or disclosure.  |
| [ ]  | Authorization expiration date or event that relates to the individual or to the purpose of the use or disclosure (the terms "end of the research study" or "none" may be used for research, including for the creation and maintenance of a research database or repository). |
| [ ]  | Signature of the individual and date. If the Authorization is signed by an individual's personal representative, a description of the representative's authority to act for the individual. |
| **Required Statements** 45 C.F.R. § 164.508(c)(2) |
| [ ]  | The individual's right to revoke his/her Authorization in writing and either (1) the exceptions to the right to revoke and a description of how the individual may revoke Authorization or (2) reference to the corresponding section(s) of the covered entity's Notice of Privacy Practices. |
| [ ]  | Notice of the covered entity's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and, if applicable, consequences of refusing to sign the Authorization. |
| [ ]  | The potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule. This statement does not require an analysis of risk for re-disclosure but may be a general statement that the Privacy Rule may no longer protect health information. |