

# Genesys Health System

## Request for Waiver of HIPAA Authorization for Research Purposes

Name of Research Project (“**Research Study**”): \_\_\_\_\_

Name of Principal Investigator (“**PI**”): \_\_\_\_\_

### **I. PURPOSE**

The purpose of this form is to facilitate the request to use/disclose protected health information (“**PHI**”) by submitting to the Genesys IRB for review and approval for a waiver of (or altered) HIPAA authorization. Please read the information below carefully and answer the questions presented.

### **II. APPLICATION**

A. This application is to request the following: (Mark one box)

- A complete waiver of authorization** (*i.e.*, you are requesting a waiver of authorization for **all** uses and discloses of PHI related to your Research Study)
- Partial waiver of authorization** (*i.e.*, you are requesting a waiver of authorization for some, but not all, of the uses and disclosures of PHI related to your Research Study. For example, you are requesting a waiver or authorization for the purpose of contacting and recruiting individuals into your Research Study)
- Altered authorization** (*i.e.*, your are requesting that the Genesys IRB alter some, but not all, of the required elements of the HIPAA authorization. For example, you are asking that the IRB remove the HIPAA Authorization element that describes each purpose of the requested use or disclosure. If you are requesting an altered authorization, please provide copies of your altered authorization form)

B. Please describe the PHI that is needed for your Research Study. Indicate (i) the source of the desired PHI (*i.e.* physician/clinic records, lab results, billing records, etc. . .), and (ii) the PHI to be used or disclosed (*i.e.* refer to the “identifiers” listed on page 4).



E. Describe why the Research Study cannot practicably be conducted without an IRB waiver or alteration. Relevant information includes, without limitation:

1. The number of individuals whose PHI will be used or disclosed;
2. The difficulty of obtaining an authorization from each individual;
3. Time constraints related to obtaining authorization;
4. The costs associated with obtaining authorization;
5. Whether the Research Study is using existing PHI;
6. Whether requesting authorization from the individuals could alter their behavior and bias the Research Study results;
7. Whether obtaining an authorization overly burdens the individual from whom the PHI was collected.

F. Describe why the Research Study cannot practicably be conducted without access to and use of the PHI. Explain why it is essential that you access the desired PHI without authorization at this point of your Research Study.

**ASSURANCE.**

By signing this document, I assure that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted under the HIPAA regulations.

PI Signature: \_\_\_\_\_

Dated: \_\_\_\_\_

Print name: \_\_\_\_\_

## List of Personal Identifiers

1. Names
2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (i) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (ii) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is 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
4. Telephone numbers
5. Fax numbers
6. Email Addresses
7. Social Security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Health plan beneficiary numbers
13. Account numbers
14. Certificate/license numbers
15. Vehicle identifiers and serial numbers, including license plate numbers
16. Device identifiers and serial numbers
17. Web Universal Resource Locators (URLs)
18. Internet Protocol (IP) address numbers
19. Biometric identifiers, including finger and voice prints
20. Full face photographic images and any comparable images
21. Any other unique identifying number, characteristic, or code