|  |  |
| --- | --- |
| Principal Investigator: | Last name , First name |
| SpartaIRB Study Number: | STUDYXXXXXXXX |
| Study Title: | Click here to enter text. |

***Under the federal HIPAA privacy rule, research use or disclosure of an individual’s protected health information (PHI) requires the individual’s authorization unless the IRB determines the use or disclosure qualifies for a waiver.***

[ ]  **Requesting a partial waiver of HIPAA (pre-screening)**

[ ]  **Requesting a full waiver of HIPAA** **between dates:**

 Click here to enter a date. and Click here to enter a date.

* **Indicate the identifiers for which you are seeking a waiver of Authorization:**

[ ]  Name

[ ]  Address *(e.g., Zip code, other geographical designation, etc.)*

[ ]  Dates related to an individual *(e.g., Date of admission, birth, surgery, etc.)*

[ ]  Telephone number

[ ]  Fax number

[ ]  Email address

[ ]  Social security number

[ ]  Medical record number

[ ]  Health plan beneficiary number

[ ]  Account number

[ ]  Certificate/license number

[ ]  Any vehicle or other device serial

[ ]  Device identifiers or serial numbers

[ ]  Web URL

[ ]  Internet protocol (IP) address

[ ]  Finger or voice prints

[ ]  Photographic images

[ ]  Other: Any characteristic that would uniquely identify the individual

* **Under the federal regulations, the investigator may obtain only the minimum necessary PHI to achieve the goals of the research.**
	+ Is the PHI described in the previous question the minimum necessary to achieve the goals of the research?

[ ]  Yes [ ]  No – Please explain

* Describe why patient identifying information is needed to complete this research.

Click here to enter text.

**The use or disclosure of the 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. **Provide a plan to protect the identifiers from improper use and disclosure.**

[ ]  Identifiable information will **not** be used or disclosed by anyone other than the research team.

[ ]  Identifiable information will be used or disclosed to: Click here to enter text.

* + Detail how this will be accomplished including limitations of physical or electronic access to the information and other protections.

Click here to enter text.

[ ]  Confidentiality agreements with study staff.

[ ]  Policies and procedures relating to privacy and confidentiality.

[ ]  Initial and continuing staff education on the HIPAA Privacy & Security Rule and/or subject privacy and confidentiality

[ ]  Other – Please explain

1. **What steps have been taken to ensure that the PHI will not be reused or disclosed to any other person or entity?**

[ ]  Limited access to only individuals who need to know the information.

[ ]  Electronic safeguards where only study staff has access to electronic study information. Describe the electronic safeguards in place (e.g., password protection, data encryption, firewall, etc.)

[ ]  Physical safeguards where only study staff has access to areas with study information. Describe the physical safeguards in place (e.g., locked cabinets, locked filing room, security system, etc.)

[ ]  Other: Please explain

1. **Identifiers must be destroyed at the earliest opportunity. When and how will identifiers of subjects be destroyed?**

[ ]  Identifiers will be destroyed with the study records, as defined by federal, state, and/or local laws and regulations.

[ ]  Identifiers will be destroyed after health information has been collected for the study and a code (containing no HIPAA Identifiers or derivative(s) thereof) has been assigned to the study data.

[ ]  Identifiers will not be destroyed. Provide a health, research, and/or regulatory/legal justification for retaining the identifiers as well as a timeframe.

 [ ]  Other:Please explain

* + Describe how long identifiers will be kept for in relation to study length and data collection and analysis.

Click here to enter text.

1. [ ]  **I attest that protected health information (PHI) collected for purposes of this research study will not be reused or disclosed to any other person or entity, except (i) as required by law, (ii) for authorized oversight of the research study, or (iii) other research for which a waiver of HIPAA Authorization has been obtained or as otherwise permitted under 45 CFR 164.512.**
* **Describe why the research could not be completed without the waiver or alteration.** *Practicability (feasibility) should not be determined solely by considerations of convenience, cost, or speed.*

[ ]  Scientific validity would be compromised if Authorization is required.

[ ]  Sample size is so large that including only those samples/records/data for which Authorization can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.

[ ]  Subjects for whom records will be reviewed will not be available to come to the study site to sign an Authorization.

[ ]  Subjects for whom records will be reviewed are no longer being followed and/or are lost to follow-up.

[ ]  Ethical concerns would be raised if Authorization is required.

[ ]  A possibility exists of creating additional risks to privacy by linking otherwise de-identified data with nominal identifiers in order to contact individuals to seek Authorization.

[ ]  A risk exists of inflicting psychological, social, or other harm by contacting individuals or families.

[ ]  Study relates to completed care only.

[ ]  Other: Click here to enter text.

* Please describe and provide additional details or supporting information.

Click here to enter text.

* **Describe why the study could not be completed without access to and the use of the protected health information.**

Click here to enter text.

**For Research IT purposes, if you have also applied for a waiver of consent, please indicate the non-identifiable data elements you will be collecting:**

Examples: diagnoses, lab results, any non-identifiable data that would be included on a data collection sheet for a chart review