JEFFERSON—Office of Human Research

# REQUEST FOR WAIVER OF SUBJECT AUTHORIZATION TO COLLECT PROTECTED HEALTH INFORMATION

**Version Date – FOR OHR USE: 1/21/19**

**PI Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Department/Division \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The IRB may waive the requirement to obtain written authorization from the subject to use his/her protected health information (PHI), provided that the investigator meets the following HIPAA criteria. PHI is defined by HIPAA as individually identifiable health information (including *both identifiers and health information)* transmitted or maintained in any form (electronic, paper, oral communication) that relates to the past or future physical or mental health or conditions of an individual.

1. **Please list all data that will be collected for this study.** This includes all study data, protected health information (PHI) and associated identifiers. PHI is generally considered any healthcare information collected from or about an individual and can include specific diagnosis, medical history, test/image/questionnaire results, treatments and payment information. Identifiers include name, address (e.g., home, email), dates (e.g., date of birth, date of treatment) and any identifying numbers (e.g., social security, MR#, phone number). Please see the [OHR-5](http://www.jefferson.edu/university/human_research/irb/forms.html) for a complete list of identifiers.

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1. What are the specific sources of the data to be collected? (i.e., Dr. X’s outpatient records, hospital EMR, Pathology records, etc.)

3. The data will be collected by (check all applicable):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Chart/image/database review |  |  | Survey/questionnaire (in person) |  |
| Survey/questionnaire (mail) |  |  | Interview/group discussion |  |
| Survey/questionnaire (phone) |  |  | Observational/prospective review |  |
| Survey/questionnaire (online) |  |  | Other:  |  |

4. Investigators are required to adhere to the “minimum necessary” standard when obtaining PHI without written authorization. Please justify why the PHI you wish to obtain is the minimum necessary to achieve the goals of the research. (This requirement prohibits collection of PHI for which you will not have an immediate, defined use, according to the stated goals of your research study.)

5. The research could not practicably be conducted without the waiver of written authorization because (check all that apply):

|  |  |
| --- | --- |
|  | All subjects cannot be readily accessed due to relocation, lost to follow up, death. |
|  | Research is minimal risk and patients opting not to participate would skew results. |
|  | Research is minimal risk and informing subjects of data collection might bias their behavior and skew results. |
|  | Research does not involve face-to-face interaction. Consent may or may not be obtained by other means. |
|  | Time-frame of research does not allow for process of obtaining written authorization. |
|  | Subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm. Consent may or may not be obtained by other means. |
|  | Other reason (please explain): |

1. The research could not practicably be conducted without access to and use of PHI because:
2. The following steps must be taken to ensure that identifiable data remains confidential and secure. There are fields below to provide explanations and to describe deviations as well as additional measures.
	1. [ ]  A separate research chart must be maintained apart from the medical record/chart of the subject.
	2. [ ]  There are 18 identifiers described in 45 CFR 164.514 that make data identifiable. To be considered de-identified, data must not contain any of the identifiers (also see OHR-5 for list of identifiers).
	3. [ ]  When not in use, identifiable data should be stored in a locked cabinet or desk in a locked room.
	4. [ ]  Access to the data should be limited. Only the individuals who need the data should have access.
	5. [ ]  If hardcopies of identifiable data must be taken to another building, a locked container such as a banker bag should be used. The container should be marked with instructions for returning the container if misplaced.
	6. [ ]  If hardcopies of identifiable data must be mailed, there must be a contract in place which specifies the method of doing this. The data should be placed in one envelope inside of another envelope. Both envelopes should have tamper-evident seals and should be addressed to the specific recipient. Signatures should be required for receipt, or lockable mailboxes should be used.
	7. [ ]  If research data is stored on your Jefferson computer, encryption software must be installed on the computer. Contact IT if you are not sure if the encryption software is installed.
	8. [ ]  PHI may be emailed between Jefferson email addresses. Jefferson email must not be sent from or forwarded to a non-Jefferson email address such as your personal email.
	9. [ ]  Research data should not be stored on non-secured portable devices including laptops. If research data must be stored on a portable device, contact IT. Please see Jefferson University Policies 116.03 and 126.02 for more complete information.
	10. [ ]  External monitors will only be given access to subjects’ medical records as specified in the signed consent form.

If you have any explanations for, or deviations to the items listed above, please describe them:

If applicable, please describe any additional measures that will be taken:

1. Specify those individuals who will have access to identifiable subject data:
2. If a code that links to identifiers will be used, please describe the coding mechanism.

10. Identifiers and/or codes that can be linked to identifiers should be destroyed at the earliest possible time. Please describe your plans to destroy identifiers/codes. However, if there is a health or research justification, for retaining the identifiers/codes, or if it is required by law, please provide justification.

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11. If appropriate, how will subjects be provided with pertinent information after research? If not appropriate, please specify why.

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PI certifies to the following (please check boxes):

[ ]  The information listed in this waiver application is accurate, and all study personnel will comply with the HIPAA regulations and the waiver criteria. All study personnel have completed HIPAA training.

[ ]  I assure that the PHI obtained as part of this research will not be used or disclosed to any other person or entity other than those listed on this form, except as required by law. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entities, I will seek approval by the IRB before doing so.

Principal Investigator Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_