Walter Reed National Military Medical Center

REQUEST FOR WAIVER OF HIPAA AUTHORIZATION FOR RESEARCH USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION

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TITLE OF PROJECT Metabolic effects after eradication of hepatitis C infection with NS5B inhibitor (Sofosbuvir), NS5A inhibitor (Ledipasvir) or protease inhibitor (Simeprevir)
PROTOCOL NUMBER

INSTRUCTIONS TO INVESTIGATOR

This form must be completed if you wish to obtain and use identifiable "protected health information" for a study without obtaining written approval ("authorization") from the subject for the use of the data.

The federally required criteria for approving a waiver of authorization are included as an attachment to this Request Form. The criteria are similar to the criteria for waiver of informed consent to participate in the study. If the subjects in this study will be required to give their informed consent to participate, it is unlikely that a request for a waiver of authorization under the HIPAA regulations will be approved.

If a waiver of authorization is approved, the covered entity (such as a hospital or treating physician) that provides the protected health information for this study will need to account for all disclosures made to persons other than members of its own workforce, if the subject asks for an "accounting" under the federal HIPAA regulations (if study consists of sample size of less than 50). The accounting must include subject name, purpose, date, recipients, and a description of information provided. Some covered entities may have systems in place that will capture this information at the time of disclosure; other covered entities may expect the study personnel to maintain a log of all such disclosures and provide a copy to the respective data managers.

PURPOSE OF STUDY: [Summarize the protocol, and attach a copy of the full protocol to this Request Form.] This research will be a retrospective chart review to study the association between patients treated with Sofosbuvir, ledipasvir and Simeprevir and hemoglobin A1C/lipid panel pre and post therapy. We will review the pharmacy drug usage data to look for patients treated from January 2014 to February 2015. This list encompasses all patient treated with these agents from January 2014 up to February 2015. We anticipate approximately 160 patients, but will not know for sure until the actual list is obtained. From this list, AHLTA will then be used to access clinical data regarding

DESCRIBE THE ACCOUNTING METHOD [Describe how disclosures will be accounted for, by subject name, purpose, date, recipients, and a description of information provided.] No disclosures to report

TO WHOM, IF ANYONE, OUTSIDE OF WRNMMC, WILL THIS DATA BE DISCLOSED. IF NO ONE, STATE NO ONE. No one

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INVESTIGATOR'S ASSURANCES:

By signing this package in IRBNet, I assure the IRB that the protected health information for which I have requested this Waiver of Authorization will not be reused or disclosed to any person or entity other than those listed above, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

The IRB Approval of Waiver of Authorization for Use or Disclosure of Protected Health Information in Research - 45 CFR §164.512

Waiver criteria. A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) 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;

(2) 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; and

(3) 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 study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

- 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

11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying numbers, characteristics, or cod

(B) The research could not practicably be conducted without the waiver or alteration, and

(C) The research could not practicably be conducted without access to and use or the protected health information.

IDENTIFIERS

1. Names
2. All geographic subdivisions smaller than a State, including:
   - Street address
   - City
   - County
   - Precinct

   Zip codes 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: (1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. Telephone numbers
4. Fax numbers
5. E-mail addresses
6. Social Security numbers
7. Medical record numbers
8. Health plan beneficiary numbers
9. Account numbers
10. All elements of dates (except year) for dates related to an individual, including:
    - Birth date
    - Admission date
    - Discharge date
    - Date of death

each subject. Each subject on the list will be assigned a research number, and all clinical data for each case will be recorded under this number. The relevant data will be extracted by a physician investigator and recorded on a spreadsheet for further analysis.

DESCRIPTION OF PROTECTED HEALTH INFORMATION THAT IS NEEDED FOR THIS STUDY [Include the anticipated data locations as well as the type of information that will be required]: We will review the pharmacy drug usage data to look for patients treated with the new anti-viral therapies (Sofosbuvir, Ledipasvir, Simeprevir). From this list, AHLTA will then be used to access clinical data regarding each subject. Each subject on the list will be assigned a research number, and all clinical data for each case will be recorded under this number. The relevant data will be extracted by a physician investigator and recorded on a spreadsheet for further analysis.

DESCRIBE WHO WILL HAVE ACCESS TO THE PROTECTED HEALTH INFORMATION [Includes each person and organization by name or category. Examples include the research sponsor, the investigator, the research staff, and all research monitors.]: The principal and associate investigators.

DESCRIBE THE RISKS TO PRIVACY INVOLVED IN THIS STUDY: [Include a description of what identifiers[1] will be obtained, collected and stored, who will have access to identified information; how access to study data is controlled, who will monitor access to study data; where will identified information be stored] Identifiers that will be collected are last name and last four of SSN. Data will be recorded on a password protected spreadsheet on the secure Gastroenterology Clinic hard drive.

PLAN FOR DESTROYING IDENTIFIERS: [Describe how, by whom and when identifiers will be destroyed] All files will be deleted three years after publication. The spreadsheet with the link to PHI will be destroyed at this time.

EXPLAIN WHY THESE RISKS ARE NO MORE THAN "MINIMAL RISK": Data will only be stored in one location in a secure spreadsheet and a plan exists to destroy that data.

IMPRACTICABILITY OF OBTAINING AUTHORIZATION: [Describe why it would be impracticable to obtain the subjects' authorization for use/disclosure of this data.] The waiver will not adversely affect the rights and welfare of the subjects. Given the retrospective length of time, the research could not practicably be carried out without the waiver. Due to the need to retrospectively identify data, the research could not practicably be conducted without access to and use of PHI.

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[1] "Identifiers" include any one of the items listed on the attachment to this Request Form.
2 "Minimal risk" means the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The IRB will determine whether a risk to privacy associated with a proposed study is "minimal" based on the investigator's plan to protect the identifiers from improper use and disclosure, to destroy the identifiers at the earliest opportunity consistent with the conduct of the research and to prevent the reuse or disclosure of protected health information beyond what is required for the proposed research.