

**8.3.5 Model Request for a Waiver of the Requirements to Obtain HIPAA Authorization/Informed Consent to Access, Record, and Use Protected Health Information/Patient Medical Record Information for a Retrospective Research Study: Investigator(s) Who Accesses (Access) and Uses (Use) Such Information for Research is (are) Involved Directly in Providing Health Care to the Respective Patients**

Retrospective research studies involving investigator access to and the recording of identifiable medical record information are subject to both 1) the requirement for the respective patients' signed, written authorization in accordance with the HIPAA Privacy Rule; and 2) the requirement for the respective patients' signed, written informed consent in accordance with the Federal Policy regulations governing human research subject protections. The IRB will consider a waiver of the HIPAA authorization and informed consent requirements for retrospective research studies involving access to and the recording of identifiable medical record information under the circumstance wherein the researcher(s) who accesses (access) and use such information is (are) involved directly in providing health care to the respective patients. This consideration is based on the fact that there is no breach of privacy or confidentiality of the patients' (i.e., subjects') medical record information since the personal health care provider(s)-researcher(s) already has (have) knowledge of and access to this information.

In order for the IRB to grant such a waiver request, it must find that the researcher has addressed and appropriately justified each of the HIPAA criteria for granting a waiver of the written HIPAA authorization requirement and each of the Federal Policy criteria for granting a waiver of informed consent requirement for this minimal risk research activity. Below is a template for requesting a waiver of these requirements.

A. HIPAA Waiver Criteria and Respective Model Justifications

1. Criterion: "The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals based on (a) an adequate plan to protect the identifiers from improper use and disclosure; (b) an adequate plan to destroy the identifiers at the earliest opportunity consistent with the 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 (c) 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."

*Justification: Access to and the use of protected health information by the research investigator(s) who is (are) also involved directly in the care of the respective patients involves no more than a minimal risk to the privacy of these patients since these investigator(s) already has (have) knowledge of and access to the patients' identifiable health information. Moreover, the protected health information that will be accessed, recorded and used by this (these) investigator(s) will be limited to that information which is related to the investigator's (investigators') area of medical practice. To further ensure that the risk to the privacy of the involved patients remains minimal:*

- (1) *the protected health information collected for the purpose of this research study will be assigned a research code number and any*

*obvious patient identifiers (name, social security number, hospital record number) will be removed from this information. Both the anonymized health information and the information linking the research code numbers to the patients' identities will be stored in a secure manner (e.g., locked file cabinet, password protected database) accessible only to the research study investigator(s) who is (are) also involved directly in the health care of the respective patients. The information linking the research code numbers to the patients' identities will be stored separate from the anonymized health information.*

- (2) *the information linking the research code numbers to the patients' identities and the anonymized health information will be destroyed (1) immediately after a determination has been made to not publish the respective research study; or (2) at 5 years following the publication of the respective research study (i.e., in accordance with University policies).*

*I (We) hereby provide my (our) assurance that any protected health information recorded for the purpose of this research study will not be used by or disclosed to any other person or entity, except as required by law or for authorized oversight of the research study.*

2. Criterion: "The research could not practically be conducted without the waiver or alteration."

*Justification: It is not possible to conduct this research study without access to and the use of protected health information. In accordance with the Federal Policy regulations governing human subject protections, the process of accessing identifiable medical record information for the purpose of identifying eligible patients for this research study so as to permit the subsequent obtaining of their HIPAA authorization, itself, requires the prior informed consent of the involved patients. The patients, whose protected health information will be accessed under this waiver request, have not previously provided informed consent for this research activity. Thus, obtaining the HIPAA authorization of these patients for the research use of their health information is impractical. In the absence of obtaining the HIPAA authorization of the patients for the use of their protected health information for research, the IRB and UPMC recommend the involvement of an honest broker system/process to perform an independent (i.e., independent of the research investigators) collection of the protected health information and its subsequent de-identification (in accordance with HIPAA "safe harbor" or "limited data set" standards) prior to providing the information to the research investigators. Such involvement of an independent honest broker system/process is cumbersome and adds expense to the study, but is typically necessary so as to avoid a violation of the patients' privacy and medical record confidentiality by the research investigators. However, consistent with this waiver request, the research investigators who will access and use the protected health information are also involved directly in the care of*

*the respective patients, thus obviating the privacy and confidentiality concerns.*

*In summary, this research study could not practically be conducted without a waiver of the HIPAA authorization requirement.*

3. Criterion: "The research could not practically be conducted without access to and use of the protected health information."

*Justification: Access to and the collection and analysis of protected health information is necessary in order to conduct this research study. Consistent with the "minimum necessary standard" of the HIPAA privacy rule, I (we) will only access and collect the specific health information necessary to complete this research study.*

B. Federal Policy Criteria and Respective Model Justifications

1. Criterion: "The research involves no more than minimal risk."

*Justification: This research study is limited to accessing, collecting and analyzing existing medical record information. There are no physical or psychological risks to the human subjects (i.e., the respective patients) associated with the conduct of this research study.*

*Access to and the collection and analysis of identifiable medical record information for this research study involve no more than a minimal risk to the confidentiality of the respective patients private information based on (a) an adequate plan to protect the identifiers from improper use and disclosure; (b) an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research; and (c) adequate written assurances that the recorded medical record information will not be reused or disclosed to any other person or entity, except as required by law or for authorized oversight of this research study (see HIPAA Waiver Criteria and Respective Justifications).*

2. Criterion: "The waiver will not adversely affect the rights and welfare of the subjects."

*Consistent with this waiver request, access to and the recording and use of identifiable medical record information for the purpose of this research study will be limited to an investigator(s) who is (are) also involved directly in the care of the respective patients. The medical record information that will be accessed, recorded and used by this (these) investigator(s) will be limited to that information which is related to the investigator's (investigators') area of medical practice. Since this (these) investigator(s) would already have knowledge of and access to such identifiable medical record information for his/her (their) patient care responsibilities, granting of this waiver will not adversely affect the privacy of the involved patients or the confidentiality of their medical record information.*

3. Criterion: “The research could not practicably be carried out without the waiver.”

*Justification: It is not possible to conduct this research study without access to and the use of the patients' medical record information. In accordance with the Federal Policy regulations governing human subject protections, the process of accessing identifiable medical record information for the purpose of identifying eligible patients for this research study so as to permit the subsequent obtaining of their informed consent, itself, requires the prior informed consent of the involved patients. The patients, whose protected health information will be accessed under this waiver request, have not previously provided informed consent for this research activity. Thus, obtaining the informed consent of these patients for the collection and use of their identifiable medical record information for the purpose of this research study is impractical. In the absence of obtaining the informed consent of the patients for the use of their identifiable medical record information for research, the IRB and UPMC recommend the involvement of an honest broker system/ process to perform an independent (i.e., independent of the research investigators) collection of the requisite medical record information and its subsequent de-identification prior to providing the information to the research investigators. Such involvement of an independent honest broker system/process is cumbersome and adds expense to the study, but is typically necessary so as to avoid a violation of the patients' privacy and medical record confidentiality by the research investigators. However, consistent with this waiver request, the research investigator(s) who will access and use the patients' identifiable medical record information is (are) also involved directly in the care of the patients, thus obviating the privacy and confidentiality concerns.*

*In summary, this research study could not practically be conducted without a waiver of the HIPAA authorization requirement.*

4. Criterion: “Whenever appropriate, the subjects will be provided with additional pertinent information after participation.”

*Should the analysis of the medical record information collected for the purpose of this research study reveal a situation that may impact on the health of a patient, the investigator(s), who is (are) also involved in the care of the respective patient, will promptly notify the patient and offer the availability of care.*

To be considered for such a waiver, the principal investigator must, in the recruitment section of the corresponding IRB research protocol (submitted in accordance with the requirements for expedited IRB review), request a waiver of HIPAA authorization/informed consent for access to and the recording of identifiable medical record information; to include the respective HIPAA and Federal Policy waiver criteria and model justifications addressed above.