**Alteration or Waiver of HIPAA Authorization**

GVSU IRB may approve a waiver of the requirements for HIPAA Authorization to use and/or disclose protected health Information. This decision is based on the research meeting the criteria in 45 CFR 164.512. This criteria for alteration or waiver, in whole or in part, must satisfy the following criteria as stated in 45 CFR 164.512:

1. The use or disclosure of protected health information involves no more than a minimal risk1 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 research2,3 justification for retaining the identifiers or such retention is otherwise required by law; and
	3. adequate written assurances that the protected health information (PHI)4 will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
2. The research could not practicably be conducted without the waiver or alteration; and
3. The research could not practicably be conducted without access to and use of the protected health information.

Each of the three requirements above along with the subparts should be explained and justified within an IRB Application. Examples of how to justify these requirements may be very similar or to the rationale for Informed Consent. Below are examples for justification of the requirements.

# The use or disclosure of protected health information involves no more than a minimal risk1 to the privacy of individuals, based on, at least, the presence of the following elements:

# **Minimal Risk Response Example**: This retrospective study represents no more than minimal risk to subjects and will not adversely affect their rights and welfare. Due to the impracticality of contacting those individuals no longer in follow-up at the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ we are requesting waiver of HIPAA authorization. No patients will be contacted as part of this study. All patient identifiers will be removed once the data from the patient medical records is collected.

# an adequate plan to protect the identifiers from improper use and disclosure.

# **Example**: Data will be stored on password-protected computer with the data stored \_\_\_\_\_\_\_\_\_\_\_\_\_\_. Subjects will be de-identified via the use of a separate document correlating subjects’ medical record numbers with a study ID assigned for the sole purpose of this study. At the end of data collection, that key will be destroyed. Access will be limited to individuals listed on the IRB key personnel list. Files will not be shared with non-study personnel or those not delegated by the PI.

# 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

# **Example**: At the end of data collection, the key to patient identifiers will be destroyed/deleted by a study team member assigned by the PI who is listed on the IRB application.

# 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 project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

# **Example**: By electronically signing this submission in IRBmanager, the PI provides this written assurance.

1. The research could not practicably be conducted without the waiver or alteration; and

**Example**: Patient identifiers are needed to identify eligible patients for this study. This retrospective study represents no more than minimal risk to subjects andwill not adversely affect their rights and welfare. Due to the impracticality of contacting individuals no longer in follow-up at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ we are requesting waiver of HIPAA authorization.

1. The research could not practicably be conducted without access to and use of the protected health information.

# **Example**:Patients will be identified for this study by diagnosis and procedure codes, and relevant data collected by accessing \_\_\_\_\_\_ in the \_\_\_\_\_\_\_\_\_\_ database. There are no direct risks or benefits to patients recruited to this study. There will be no study interventions and no contact with the subjects. Patients’ identities will not be identifiable in publications resulting from this investigation.

When requesting an Alteration or Waiver of HIPAA, list the specific protected health information to be collected and its source (s). You may also want to attach the data collection tool identifying all the information you will be extracting from the medical record to the IRB application.

**Example:** No subjects will be recruited for this study. However, they will be identified by their \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (e.g.: diagnosis and procedure codes). The PI will record the \_\_\_\_\_\_\_\_\_\_\_\_\_ diagnosis and procedure codes, radiology and pathology findings, and relevant data values (e.g.: temperature, height, weight, CBC, Lipid Profile, Chemistry Values, and Urinalysis). Data collection will be between the dates of \_\_\_\_\_\_\_\_\_\_\_\_\_\_ and \_\_\_\_\_\_\_\_\_\_. No identifying information such as names, addresses, medical record number or other personal information3 will be recorded.

Footnotes:

1. “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the daily life or during the performance of routine physical or psychological examinations or tests”**45 CFR 46.102(i)**

2. Research is defined as a “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” If there is any element of research in an activity, that activity should undergo IRB review under **HHS Regulations (46.102)**

3. For a list of data sources that are considered PHI: <https://www.hipaajournal.com/what-is-considered-protected-health-information-under-hipaa/>

4. GVSU IRB Guidance on deidentification of research data: <https://www.gvsu.edu/irb/research-on-data-28.htm>

References:

1. <https://az.research.umich.edu/medschool/guidance/waiver-or-alteration-hipaa-authorization>
2. <https://dukeeyecenter.duke.edu/node/5987>
3. <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#standard>