**Bellarmine University**

**Waiver of HIPAA Authorization Form**

The HIPAA Privacy Rule requires that certain criteria be met to grant a waiver of individual authorization for research uses of Protected Health Information (PHI; individually identifiable health information held by a health care provider or health plan covered by HIPAA).

Please complete this form and submit it with your IRB application package.

1. Does the use or disclosure of PHI involve no more than a minimal risk to the privacy of individuals based on at least the presence of the following:
	1. An adequate plan to protect the identifiers from improper use and disclosure.
	2. An adequate plan to destroy 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 as otherwise required by law.
	3. Adequate written assurances that the protected health information will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of PHI would be permitted.

 [ ]  **YES** [ ]  **NO**

2. Describe the plan to protect the identifiers (e.g., names, addresses, telephone numbers, social security numbers, medical record numbers, photos, or any of the 18 identifiers listed in the regulations) from improper use and disclosure?

1. Describe the plan to destroy the identifiers at the earliest opportunity, or provide justification for retaining the identifiers?

1. Will a waiver adversely affect the privacy rights of the individual?

[ ]  **YES [ ]  NO**

1. Could the research be practicably conducted without the waiver?

[ ]  **YES [ ]  NO**

If “no” justify below:

1. Could the research practicably be conducted without access to, use or disclosure of the PHI identified below?

[ ]  **YES [ ]  NO**

1. Please include a detailed list of the PHI to be collected and the source(s) of the PHI.
2. Who will have access to this PHI?
3. The HIPAA regulation requires reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. Explain why the PHI obtained for this study is/are the minimum information needed to meet the research objectives.
4. By signing this form, I assure that the PHI will not be reused or disclosed to any other person or entity, except as required by law or for authorized oversight of the research project.

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

Investigator’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator’s Signature and Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_