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| **INSTRUCTIONS**:* Before completing this form, please review the **Frequently Asked Questions** outlined in **Appendix A**.
* Contact the Office of Research Integrity at irb@une.edu for any questions you may have with regard to this form.
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| Version Date: | Enter the date this form was originally completed or subsequently revised |
| Principal Investigator: | Enter text |
| Project Title: | Enter text |

| 1. **GENERAL PROJECT INFORMATION**
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| 1. **Requested waiver type:**

[ ] Full waiver of HIPAA authorization *(e.g., retrospective chart review)*[ ]  Partial waiver of HIPAA authorization for screening/recruitment purposes only | 1. **Identify the source(s) of the PHI:**

*(check all that apply)*[ ]  Clinical database[ ]  Hospital or clinic medical records[ ]  Other *(specify below)*Enter text |
| 1. **What activities will this project include?**

*(check all that apply)*[ ] Access to, or viewing of PHI[ ]  Receiving or recording health information[ ]  Receiving or recording identifiers[ ]  Use of a master list or linking key (to be stored separately from coded study data) to record identifiers (e.g., patient name, MRN) and assign participants a unique study ID number  | 1. **Identify in detail the health information to be accessed, recorded, or used for this project:**

Enter text |
| 1. **Will any of the 18 HIPAA identifiers be accessed, recorded, or used for this project?** *(check all that apply)*
 |
| [ ]  Name[ ]  Address (all geographic subdivisions smaller than state, including street address, city, county, and zip code)[ ]  All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)[ ]  Telephone numbers[ ]  Fax numbers | [ ]  E-mail addresses[ ]  Social security numbers[ ]  Medical record numbers (MRNs)[ ]  Health plan beneficiary numbers[ ]  Account numbers[ ]  Certificate or license numbers[ ]  Vehicle identifiers and serial numbers including license plate numbers[ ]  Device identifiers and serial numbers | [ ]  Web URLs[ ]  Internet protocol (IP) address[ ]  Biometric identifiers, including fingerprints and voiceprints[ ]  Photographic images – including full facial photographs and other comparable images[ ]  Any other unique identifying number, characteristic, or code that could identify an individual |

| 1. **PLAN FOR PROTECTING THE PHI TO BE ACCESSED, RECORDED, OR USED FOR THE PROJECT**
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| 1. **Where will the PHI be stored, and how will it be protected from improper use and disclosure?** *(indicate ‘N/A’ if PHI will not be received or recorded)*

Enter text | 1. **Who will have access to the PHI?** *(list all entities that are able to access the project’s PHI such as the Office of Research Integrity, IRB, study sponsor, or others given authority by law)*

Enter text |
| 1. **When is the earliest opportunity identifiers can be destroyed?** *(indicate ‘N/A’ if identifiers will not be received or recorded)*

Enter text**Justify why this is the earliest opportunity when identifiers can be destroyed:** Enter text | 1. **How will the identifiers collected for this project be destroyed?** *(indicate ‘N/A’ if identifiers will not be received or recorded)*

Enter text |

| 1. **JUSTIFICATION FOR REQUESTED WAIVER OF HIPAA AUTHORIZATION**
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| 1. **Explain why the research could not practicably be conducted without the requested waiver:**

Enter text | 1. **Explain why the research could not practicably be conducted without access to and use of the PHI:**

Enter text |

| 1. **PRINCIPAL INVESTIGATOR ASSURANCE**
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| As Principal Investigator of this research project, I acknowledge the following: * The information provided in this request for a waiver of HIPAA authorization is complete and correct.
* Only the **minimum amount of PHI necessary** will be reviewed or collected to accomplish the intended purpose of this project.
* The use or disclosure of PHI for this project involves no more than a minimal risk to the privacy of individuals.
* Necessary review by the IRB will be sought if changes made in the research protocol may result in the research no longer meeting the waiver criteria.
* The PHI obtained as part of this project will not be reused or disclosed to any other person or entity, except as required by law.
* To comply with HIPAA record retention requirements, the final signed version of this form will be retained for at least six (6) years after the project receives IRB approval or exemption.

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| Signature of Principal Investigator |  | Date |

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**Appendix A**

| Frequently Asked Questions |
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| 1. What is HIPAA?

The Health Insurance Portability and Accountability Act (HIPAA), also known as ‘The Privacy Rule’, sets standards and regulations to protect patients from inappropriate disclosures of their protected health information (PHI) that could cause harm to their insurability, employability, and/or their privacy.The Privacy Rule permits a covered entity to use and disclose PHI for treatment, payment, and healthcare operation purposes without the explicit permission of the individual to whom the PHI relates. Use or disclosure of PHI for research, in contrast, requires a separate regulatory pathway. The Privacy Rule permits PHI to be used or disclosed for research purposes pursuant to an individual’s authorization or pursuant to other research-specific pathways such as a waiver of HIPAA authorization when certain conditions are met. |
| 1. What is protected health information (PHI)?

PHI is individually identifiable health information held by a covered entity. PHI is any information in the medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment. |
| 1. What are the 18 HIPAA identifiers?

HIPAA defines 18 specific identifiers that create PHI when directly or indirectly linked to health information:

|  |  |
| --- | --- |
| 1. Name
2. Address (all geographic subdivisions smaller than a state, including street address, city, county, and zip code)
3. All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and 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
4. Telephone numbers
5. Fax numbers
6. E-mail addresses
7. Social security numbers
8. Medical record numbers
 | 1. Health plan beneficiary numbers
2. Account numbers
3. Certificate/License numbers
4. Vehicle identifiers and serial numbers including license plate numbers
5. Device identifiers and serial numbers
6. Web universal resource locators (URLs)
7. Internet protocol (IP) address
8. Biometric identifiers, including fingerprints and voiceprints
9. Photographic images – including full facial photographs and other comparable images
10. Any other unique identifying number, characteristic, or code that could identify an individual
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|  1. What is the HIPAA minimum necessary standard?

The minimum necessary standard is a requirement that covered entities take all reasonable steps to see to it that PHI is only accessed to the minimum amount necessary to complete the task at hand. When planning a research proposal/protocol, researchers should carefully think through the data that will be needed, and collect the minimum necessary to conduct the research. In many cases, identifiers are collected when it is not necessary and does not add value to the research data. Limit the use of the 18 HIPAA identifiers to only what is absolutely needed to conduct the research. |
|  1. What is a waiver of HIPAA authorization?

A waiver is a request to forgo the HIPAA authorization requirement based on the fact that the disclosure of the PHI involves minimal risk to the participant and the research cannot practicably be done without access to or use of PHI.A waiver of authorization may be granted in situations where an individual’s authorization to access their PHI will not be obtained. The IRB may waive authorization for an entire study (e.g., a full waiver of HIPAA authorization) or just for screening/recruitment purposes (e.g., a partial waiver of HIPAA authorization). Examples of research projects that may qualify for a waiver of HIPAA authorization include:* Reviews of medical records for data collection (e.g., retrospective chart review projects)
* Access to databases that have PHI in them
* Projects that access clinical databases, hospital medical records, or other similar databases to identify potential research participants for screening or recruitment purposes
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|  1. What is a master list and coded study data?

A master list is a document that is stored securely and separately from the study data, and is used to record direct identifiers (e.g., name, MRN) and assign a unique study ID number to each research participant.When the master list is in existence, the data is deemed ‘coded’ and does not contain any direct identifiers. Study data is not deemed ‘de-identified’ until the master list has been destroyed (because the existence of the master list allows an opportunity for the research participants to be re-identified).Best practice dictates that the master list be destroyed at the earliest opportunity during the research project (e.g., after data abstraction has been completed for all research participants). Example Master List:

|  |  |  |
| --- | --- | --- |
| **Study ID** | **Name** | **MRN** |
| 1 | John Bloom | 12-34-51 |
| 2 | Daisy Moore | 22-74-17 |
| 3 | Philip Green | 16-98-03 |
| 4 | Stanley Smith | 23-65-18 |

Example Coded Data Set:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study ID** | **Sex** | **Age** | **Triglyceride (mg/dL)** | **HDL(mg/dL)** | **LDL(mg/dL)** |
| 1 | Male | 29 | 130 | 62 | 125 |
| 2 | Female | 51 | 155 | 52 | 157 |
| 3 | Male | 44 | 141 | 80 | 119 |
| 4 | Male | >90 | 221 | 41 | 172 |

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