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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](mailto: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. **DECEDENT PROJECT INFORMATION** | |
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| 1. **Name of the covered entity (e.g., medical institution) where the PHI originates:**   Enter text | 1. **The proposed research project involves the access to, use, or disclosure of PHI belonging to:**   Only deceased individuals  Both living and deceased individuals |
| 1. **Explain why the access to, use, or disclosure of PHI belonging to deceased individuals is necessary for this research project:**   Enter text | 1. **Identify in detail the PHI to be accessed, recorded, or used for this research project:**   Enter text |

| 1. **PRINCIPAL INVESTIGATOR ATTESTATION** |
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| As Principal Investigator of this research project, I confirm the following:   * The use or disclosure is sought solely for research on the PHI of deceased individuals. * Only the **minimum amount of PHI necessary** will be reviewed or collected to accomplish the intended purpose of this project. * At the request of the covered entity (as identified in Section A of this form), documentation of the death of any individuals whose PHI will be used or disclosed for this research project will be provided. * The use or disclosure of PHI belonging to deceased individuals is necessary for the purposes of conducting this research project. * If the PHI to be reviewed as part of this research project is not held by UNE, a signed copy of this form will be forwarded to the privacy officer or other appropriate individual associated with the non-UNE covered entity for notification purposes. * To comply with HIPAA record retention requirements, the final signed version of this form will be retained for at least six (6) years from the date of creation.  |  |  |  | | --- | --- | --- | |  |  |  | | Signature of Principal Investigator |  | Date | |

**Appendix A**

| Frequently Asked Questions |
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| 1. What is the ‘Privacy Rule’?   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.  The Privacy Rule protects PHI about a decedent (e.g., a deceased individual) for 50 years following the date of death of the individual. Decedent research can be done with a notice to the covered entity 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 | |
| 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 that involves the use of PHI from deceased individuals, 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 decedent research?   Decedent research involves the access to, use, or disclosure of PHI belonging to deceased individuals for research purposes when the entire project or a distinct part of the project is directed at decedents.  Note: A retrospective chart review project that only involves the incidental collection of PHI on deceased individuals would NOT be considered decedent research. |
| 1. When does decedent research require IRB approval or exemption?   Research involving the access to, use, or disclosure of PHI belonging to deceased individuals requires IRB approval or exemption when the project involves BOTH living and deceased individuals.  Research projects that involve access to, use, or disclosure of PHI belonging ONLY to deceased individuals do NOT require IRB approval or exemption. |
| 1. What circumstances trigger the need for this attestation form to be submitted?   If your research project involves the access to, use, or disclosure of PHI from deceased individuals only, submit the completed form to the IRB mailbox at [irb@une.edu](file:///\\netapp\groups\ResearchCompliance\Document%20Control\Drafts%20in%20Process\irb@une.edu). The Office of Research Integrity will review and acknowledge receipt of your attestation form via e-mail. Typically, no further action is required of you unless the Office of Research Integrity requests additional information.  If your research project involves access to, use, or disclosure of PHI from BOTH deceased and living individuals, IRB approval or exemption is required. Do NOT submit this form as a stand-alone document. This attestation form should be submitted as supplemental documentation to accompany your exempt or non-exempt research project submission for review. |
| 1. What if the PHI is held by a non-UNE covered entity?   If the PHI to be reviewed as part of the decedent research is not held by UNE, a signed copy of this attestation form should also be forwarded to the privacy officer or other appropriate individual associated with the non-UNE covered entity for notification purposes. |