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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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| Notification Date: | Enter text |
| Project Title: | Enter text |

| 1. **CONTACT INFORMATION** | | | | | | | |
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| **Principal Investigator Name**:  Enter text | | | | **You are**:  Faculty  Staff  Student  Resident | **UNE Center or College**: | | Enter text |
| **E-Mail**: | | Enter text | | **UNE Program  of Study**: | | Enter text |
| **Phone #**: | | Enter text | |
|  | | | | | | | |
| **Faculty Advisor or Mentor Name1**:  Enter text | | | **E-Mail**:  Enter text | | | **Phone #**:  Enter text | |
|  | | | | | | | |
| **Name and location of the covered entity (e.g., medical institution) where PHI to be reviewed originates**:  Enter text | | | | | | | |
| **1** | A Faculty Advisor or Mentor is required when the Principal Investigator is a student. | | | | | | |

| 1. **PREPRATORY TO RESEARCH ACTIVITIES** | | | |
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| 1. **Is this notification associated with an existing project approved or exempted by the UNE IRB?**   No  Yes *(specify the previously assigned IRB # below)*  Enter text | | 1. **Will PHI be reviewed for the purpose of developing a new research proposal or protocol?**   Yes  No *(explain below)*  Enter text | |
| 1. **Will PHI be reviewed for the purpose of ascertaining participant eligibility for a research project?**   Yes  No | | 1. **Identify in detail the health information to be reviewed for this preparatory to research activity**:   Enter text | |
| 1. **Specify the identifiers that will be reviewed for this preparatory to research activity?** *(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. **PRINCIPAL INVESTIGATOR ATTESTATION** |
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| As Principal Investigator of this research project, I confirm the following:   * The PHI is necessary for the purposes of this preparatory to research activity. * Only the minimum amount of PHI necessary will be reviewed for this preparatory to research activity. * The PHI will not leave the covered entity identified in Section A of this form. * PHI or other identifiable private information will not be written down or recorded prior to obtaining IRB approval or exemption, and the research participant has signed a HIPAA authorization and/or consent form where necessary. * If the PHI to be reviewed as part of this preparatory to research activity 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. * The information accessed as part of this preparatory to research activity will not be used for any other purpose, including presentation or publication. * 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.  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 notice of review preparatory to research 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.  The notice of review of PHI preparatory to research is subject to the minimum necessary requirement of the Privacy Rule. |
| 1. What activities are deemed ‘preparatory to research’?   Reviewing patient medical records to design a research study, determine study feasibility, or to assess participant eligibility for a research study are considered ‘preparatory to research’ activities under the Privacy Rule.  To access PHI, the use or disclosure must be solely to prepare a research protocol or for similar purposes preparatory to research. Researchers conducting a review may not record or write down any PHI or other identifiable private information, nor use PHI or identifiable private information to contact prospective participants until IRB approval or exemption has been granted. |
| 1. What circumstances trigger the need for this notification form to be submitted, and to whom?   Any UNE-affiliated faculty, staff, or student must submit this notification form to the UNE IRB mailbox at [irb@une.edu](mailto:irb@une.edu) before reviewing PHI in order to conduct activities preparatory to research.  If the PHI to be reviewed as part of the preparatory to research activity is not held by UNE, a signed copy of the notification form should also be forwarded to the privacy officer or other appropriate individual associated with the non-UNE covered entity for notification purposes. |
| 1. What happens after I submit this notification form?   The Office of Research Integrity will review and acknowledge receipt of your notification form via e-mail. Typically, no further action is required of you unless the Office of Research Integrity requests additional information. |
| 1. Do I need to submit this notification form again if I submit my project for IRB approval or exemption?   No. You do not need to provide a copy of this completed notification form when you submit an ‘Application for Exempt Research Projects’ or an ‘Application for Non-Exempt Research Projects’ for review. |