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| **INSTRUCTIONS**:   1. Before completing this form, please review the **Frequently Asked Questions** outlined in **Appendix A**. 2. Complete the **Notification Form Checklist** located in **Appendix B** to determine what documents aside from this form are required as part of the notification process. 3. Submit your completed form along with any required supplemental documentation to [irb@une.edu](mailto:irb@une.edu) for review.   Contact the Office of Research Integrity at [irb@une.edu](mailto:irb@une.edu) for any questions you may have with regard to this. |

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| Notification Date: | Enter text |
| Study Title: | Enter text |

| 1. **APPLICANT & EXTERNAL IRB INFORMATION** | | | | | | | | |
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| **Applicant’s Name**:  Enter text | | | | **You are**:  Faculty  Staff  Student  Resident | **Estimated Start Date1**: | | | Enter text |
| **Estimated End Date1**: | | | Enter text |
| **E-Mail**: | | Enter text | | **UNE Center or College**: | | | Enter text |
| **Phone #**: | | Enter text | | **UNE Dept. or Program**: | | | Enter text |
|  | | | | | | | | |
| **Principal Investigator’s Name**:  Enter text | | | **E-Mail**:  Enter text | | | | **Phone #**:  Enter text | |
|  | | | | | | | | |
| **Name of the external IRB**:  Enter text | | | | | | **Site(s) where the research will take place**:  Enter text | | |
| **1** | Record the estimated start/end date of the Applicant’s involvement with the study in the respective fields. | | | | | | | |

| 1. **GENERAL STUDY INFORMATION** | | |
| --- | --- | --- |
| 1. **Type of funding**:*(check all that apply)*   Federal *(specify below)*  State *(specify below)*  Other/Private *(specify below)*  Not Funded  Enter text | 1. **Type of research**:*(check all that apply)*   Biomedical  Educational  Social/Behavioral  Other *(specify below)*  Enter text | 1. **Will the research involve any vulnerable populations?** *(e.g., children, prisoners, pregnant women, adults with impaired decision-making capacity, etc.)*   No  Yes *(specify below)*  Enter text |

| 1. **GENERAL STUDY INFORMATION** | |
| --- | --- |
| 1. **What is the purpose of the research study?** *Briefly describe the research study and its aims/goals/objectives using plain language that a nonscientist would understand.*   Enter text | 1. **Have you been (or will you be) formally added to the study team in accordance with the external IRB’s written policies and procedures?**   Yes  No *(explain below)*  Enter text |

| 1. **APPLICANT’S ROLE IN THE RESEARCH STUDY** | | | |
| --- | --- | --- | --- |
| 1. **What research activities will you be engaged in?** *(check all that apply)* | | | |
| Consenting participants  Interaction**2** or intervention**3** with participants  Data collection  Biospecimen collection | | Analysis of de-identified**4** data or biospecimens  Analysis of identifiable or coded**5** data/biospecimens  Participant screening/recruitment | Review of participants’ medical records  Administration of medical tests or procedures  Other *(specify below)* |
| Enter text | | | |
| 1. **Based on the information provided above, describe what you will be asked to do as part of this research study.** *Please be as specific as possible in defining your role(s) and responsibilities.*   Enter text | | | |
|
| **2** | *Includes both physical procedures by which information or biospecimens are gathered (e.g., blood draws) and manipulations of the participant or the participant’s environment that are performed for research purposes.* | | |
| **3** | *Includes communication or interpersonal contact between investigator and participant. This includes indirect or remote interaction such as via a survey.* | | |
| **4** | *All personally identifiable information has been removed. Recorded information cannot readily identify the participant directly, or indirectly through coding systems (e.g., master list or linking key). When a coding system is used, data and/or biospecimens are not considered to be de-identified until the master list or linking key is destroyed.* | | |
| **5** | *Any personally identifiable information has been replaced by a unique code (e.g., a number, letter, and/or symbol) that is linked to a master list or key that is stored securely and separately from the study data. The master list or key contains identifying information about participants and is used to decipher the coded study data.* | | |

**Appendix A**

| Frequently Asked Questions |
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| 1. What is an external IRB?   Any institution or commercial entity (other than the UNE Office of Research Integrity or the UNE IRB) that reviews and issues IRB approval or exemption for a research study involving human participants. |
| 1. What circumstances trigger the need for this notification form to be submitted?   Any UNE-affiliated faculty, staff, or student must submit this notification form if they are (or will be) engaging in research activities for a study that was approved or exempted by an external IRB.  Note 1: If you engaged in research activities for a study approved or exempted by an external IRB prior to becoming affiliated with UNE, you do NOT need to submit a notification form for review provided that your participation in the research has ended.  Note 2: If the external IRB issued a determination letter specifying the project is not human subjects research (NHSR) *or* the principal investigator self-determined the project does not constitute human subjects research requiring IRB review (e.g., research involving the use/analysis of a publicly available de-identified data set, quality improvement (QI) or quality assurance (QA) project), you do NOT need to submit a notification form for review. |
| 1. When should I submit this notification form?   Ideally, the notification form should be submitted as soon as you engage in research activities for the study. Do not submit the notification form until you have obtained a copy of all required supplemental documentation as outlined in Appendix B.  If you assume additional (new) responsibilities within the research study after submitting this form, please submit a revised notification form. |
| 1. Why do I need to submit a notification form if the study was approved or exempted by an external IRB?   In an effort to promote the responsible conduct of research and manage risk across the institution, UNE has an incentive to monitor research activities being conducted by UNE-affiliated faculty, staff, and students for studies that have been approved or exempted by an external IRB.  This notification form also provides an opportunity for the Office of Research Integrity to confirm that the notification form applicant has completed appropriate human research protection training (e.g., CITI training). |
| 1. What human research protection training is required?   The external IRB may require you to complete the human research protection training mandated by their institution (e.g., CITI training or other suitable training method). When this occurs, you do NOT need to complete UNE-specific CITI training.  If the external IRB does not require you to complete the human research protection training mandated by their institution, you MUST complete UNE-specific CITI training.  *(See table below for details)*   |  |  | | --- | --- | | **UNE-Specific CITI Training Course** | **Take when the research study…** | | Social & Behavioral Research Investigators | Involves the collection of data via focus groups, interviews, surveys, educational or psychometric tests, or observation of non-public behavior | | Data or Specimens Research | Involves existing data (e.g., retrospective chart review) or use of biospecimens | | Biomedical Research Investigators | Involves the collection of biomedical data, or biometric or physical data from participants (e.g., blood or saliva, blood pressure, weight, timing movements, or measuring performance on physical task) | | Conflict of Interest | Is funded or sponsored by a federal Public Health Service (PHS) agency |   Note: UNE CITI training is valid for four (4) years from the date of course completion. Unless informed otherwise, only one training course is required. |
| 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. |

**Appendix B: Notification Form Checklist**

| Required Supplemental Documentation *(Do Not Send Any Zip Files!)* | | Yes |
| --- | --- | --- |
| 1 | **Original** approval or exemption letter from the external IRB |  |
| 2 | Copy of your current human research protection training certificate(s) as required by the external IRB or UNE institutional policy *(see* ***Appendix A: FAQ #5*** *for details)* |  |

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| **Applicant Remarks:** |
| Enter text |