Notification Form: Participation in a Research Study Approved or Exempted by an External IRB

NOTIFICATION INSTRUCTIONS:

1. Before completing this notification 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 notification form along with any required supplemental documentation to irb@une.edu for review.

Contact the Office of Research Integrity at irb@une.edu for any questions you may have with regard to this notification process.

Notification Date:	Enter text
Study Title:	Enter text

A. APPLICANT & EXTERNAL IRB INFORMATION

Applicant's Name: Enter text		**You are**: ☐ Faculty ☐ Staff ☐ Student ☐ Resident	**Estimated Start Date**[1]:	Enter text
			Estimated End Date[1]:	Enter text
E-Mail:	Enter text		**UNE Center or College**:	Enter text
Phone #:	Enter text		**UNE Program of Study**:	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.

B. 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	**2. Type of research**: *(check all that apply)* ☐ Biomedical ☐ Educational ☐ Social/Behavioral ☐ Other *(specify below)* Enter text	**3. 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

B. GENERAL STUDY INFORMATION

4. What is the purpose of the research study?
Provide a few sentences in layman's terms describing the research study and its intended outcome.

Enter text

5. 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

C. APPLICANT'S ROLE IN THE RESEARCH STUDY

1. What research activities will you be engaged in? *(check all that apply)*

☐ Consenting participants
☐ Interaction or intervention with participants
☐ Data collection
☐ Biospecimen collection
☐ Analysis of de-identified[2] data or biospecimens
☐ Analysis of identifiable or coded[3] data/biospecimens
☐ Participant screening/recruitment
☐ Review of participants' medical records
☐ Administration of medical tests or procedures
☐ Other *(specify below)*

Enter text

2. 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] 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.

[3] 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 separately from the study data. The master list or key is used to decipher the coded study data.

Appendix A

Notification Form Frequently Asked Questions

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.

2. 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.

3. When should I submit this notification form?

This notification form should be submitted after 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.

4. 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 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 is up-to-date with any required CITI training courses.

5. What CITI training do I need to take?

The external IRB may require you to complete the CITI training course(s) mandated by their institution. When this occurs, you do NOT need to complete additional UNE-specific CITI training.

If the external IRB does not require you to complete the CITI training course(s) mandated by their institution, you MUST complete UNE-specific CITI training as outlined below:

- If you are collecting data through focus groups, interviews, educational or psychometric tests, or observation of non-public behavior, take the CITI 'Social & Behavioral Investigators' course.
- If you are using only existing data (e.g., a retrospective chart review study), take the CITI 'Data or Specimens Research' course.
- If you plan to collect 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), take the CITI 'Biomedical Research Investigators' course.
- If the research project is funded or sponsored by a federal Public Health Service (PHS) agency, you will need to complete the CITI 'Conflict of Interest' course.

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.

Notification Form Frequently Asked Questions

6. 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	No
1	**Original** approval or exemption letter from the external IRB	☐	☐
2	**Current** IRB-approved protocol or research summary	☐	☐
3	Copy of your current CITI training completion certificate(s) as required by the external IRB or UNE institutional policy *(see **Appendix A** for details)*	☐	☐

Applicant Remarks:
Enter text

Appendix C: For Office Use Only

Determination	Comments
☐ Acknowledged ☐ Additional Information Required **Date**: Click to enter a date	Enter text