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| --- |
| **APPLICATION INSTRUCTIONS**:1. Determine if your proposed research project conforms to one or more of the 6 allowable exemption categories recognized at UNE by completing the **Exemption Eligibility Checklist** provided in [Appendix A](#AppendixA) of this application.
2. If your research project meets exemption criteria, complete the **Exemption Submission Checklist** located in [Appendix B](#AppendixB) to determine what documents aside from this form are required as part of your application.
3. Submit your completed application 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 your proposed research project or the exemption application process.  |

|  |  |
| --- | --- |
| Version Date: | Enter date when form is first completed or date when form is last updated  |
| Title of Project: | Enter text |

| 1. **PRINCIPAL INVESTIGATOR & RESEARCH TEAM**
 |
| --- |
| **Principal Investigator Name**:Enter text | **You are**:[ ]  Faculty[ ]  Staff[ ]  Student[ ]  Resident | **Estimated Start Date**: | Enter text |
| **Estimated End Date1**: | Enter text |
| **E-Mail**: | Enter text | **UNE Center or College**: | Enter text |
| **Phone #**: | Enter text | **UNE Program of Study**: | Enter text |
|  |
| **Faculty Advisor Name**:Enter text | **E-Mail**:Enter text | **Phone #**:Enter text |
|  |
| **Please list and describe the role(s) and the institutional affiliation for all key personnel on this research project.*** *For example: Bill Jones is affiliated with UNE and will be responsible for recruitment, data collection, and analysis.*
* *Key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the research project.*

*Examples include participant screening, recruitment, and consenting activities, data collection via intervention or interaction with participants, or obtaining/using/analyzing personally identifiable information or biospecimens pertaining to a research participant.****Note****: The Principal Investigator and Faculty Advisor(s) must be listed as key personnel in this section.* Enter text |
| **1** | Record the date when you expect to stop (1) obtaining data through interaction or intervention with participants; ***and/or*** (2) collecting, using, or analyzing personally identifiable information about participants.  |

| 1. **GENERAL PROJECT INFORMATION**
 |
| --- |
| 1. **Type of Funding**:

[ ]  Federal *(specify below)*[ ]  State of Maine *(specify below)*[ ]  UNE Internal Award[ ]  Other/Private *(specify below)*[ ]  Not FundedEnter text | 1. **It the research being conducted for any of these reasons?**

[ ] Doctoral dissertation[ ]  Residency program[ ]  Master’s thesis[ ]  Undergraduate project[ ]  N/A | 1. **Will this project offer compensation for participation?**

[ ]  Yes[ ]  No*If yes, provide details in the Participant Information Sheet and relevant recruitment materials.* |
| 1. **Will the research involve any of these activities?** *(check all that apply)*
 |
| [ ]  Use of recruitment materials *(e.g., flyers, e-mails, letters, etc.)*[ ]  Focus groups[ ]  Interviews[ ]  Surveys/Questionnaires | [ ]  Audio or video recording[ ]  Use of educational tests[ ]  Public observation[ ]  Benign behavioral interventions[ ]  Use of pre-existing data or specimens | [ ]  Deception *(if participant prospectively agrees)*[ ]  Retrospective chart review[ ]  Review of medical records for screening/recruitment only |

| 1. **PARTICIPANT POPULATION**
 |
| --- |
| 1. **What population(s) will be recruited and specifically targeted for this research?** *(check all that apply)*
 |
| [ ]  Normal/healthy adults[ ]  UNE employees[ ]  UNE students[ ]  Children | [ ]  Prisoners[ ]  Pregnant woman, fetuses, neonates[ ]  Adults with impaired decision‑making capacity | [ ]  Persons with limited English proficiency[ ]  Other *(specify below)*Enter text |
| 1. **What is the anticipated total number of participants to be enrolled or records to be reviewed for this project?**

Enter text | 1. **Participant age range** *(check all that apply)*
 |
| [ ]  0-6 years[ ]  7-11 years | [ ]  12-17 years[ ]  18-89 years | [ ]  90+ years |

| 1. **DATA & CONFIDENTIALITY** (see section ‘F. GLOSSARY OF TERMS’ for definitions of the terms *italicized* in blue below)
 |
| --- |
| 1. **Will you collect *personally identifiable information* about participants during the study?** *(this includes the screening/recruitment process as well)*

[ ]  Yes [ ]  No | 1. **Will you use a *master list* or *key* to link *personally identifiable information* about the participant to *coded* study data?** [ ]  Yes [ ]  No
 |
| 1. **Will you share identifiers or the *master list/key* with anyone outside the research team?** [ ] Yes [ ]  No
 | 1. **Do you plan to use the data obtained from this project in future research?** [ ] Yes [ ]  No
 |
| 1. **Will you be collecting any potentially *sensitive information* about participants for this research** (as defined in Section F of this application)**?**

[ ] Yes [ ]  No | 1. **Will educational records protected under FERPA be accessed, used, or disclosed?** *[FERPA applies to research involving a student’s school record(s)]*

[ ] Yes**2** [ ]  No |
| 1. **Will *protected health information* (PHI) be accessed, used, or disclosed for this research project?** [ ]  Yes [ ]  No

If yes, answer the following questions below:1. Is all of the PHI held by a UNE designated health care component (click [here](https://www.une.edu/research/integrity/hipaa) for details)?

[ ]  Yes [ ]  No *(specify below the name of the covered entity (e.g., clinic/hospital) where the PHI originates)*Enter text1. Will you be accessing PHI to conduct a retrospective chart review? [ ]  Yes [ ]  No

Will you be accessing PHI for screening/recruitment purposes? [ ]  Yes [ ]  NoIf yes, please submit a ‘**Request for a Waiver of HIPAA Authorization for Research Purposes**’ form for review with this application.1. Will a distinct or significant part of the project require access to PHI from deceased individuals? [ ]  Yes [ ]  No

If yes, please submit a ‘**Research Involving PHI of Deceased Individuals Attestation Form’** for review with this application.***Note****: A retrospective chart review project that only involves the incidental collection of PHI on deceased individuals would NOT be considered decedent research and the ‘No’ checkbox should be selected.*  |
| **2** | When FERPA applies, an ancillary review by the UNE Registrar’s Office is required and will be facilitated by the Office of Research Integrity on your behalf. Please be aware that this process may result in extended review times. |

| 1. **RESEARCH SETTING & SITES**
 |
| --- |
| 1. **Will any research activities take place at a non-UNE site?** [ ]  Yes [ ]  No [ ]  N/A *(explain below)*

Enter textIf yes, has the non-UNE site granted permission for the research to be conducted?[ ]  Yes [ ]  No | 1. **Is this a multisite research project being conducted at more than one institution?** [ ]  Yes [ ]  No

If yes, list the participating institutions below, and specify who is the lead/coordinating site.Enter text |
| 1. **Does the research involve any key personnel or collaborators who are NOT affiliated with UNE?** [ ]  Yes [ ]  No

If yes, see below.Before external personnel or collaborators can participate in a research project determined to be exempt by the UNE IRB, they must do the following:* If the external personnel are affiliated with an organization (e.g., university, hospital) with its own IRB, they must ask their own IRB to review their involvement in the project.
* If the external personnel are affiliated with an organization that does not have its own IRB, a letter of support from that organization may be needed.
* If the external personnel are not affiliated with any organization (e.g., an independent consultant), no additional documentation is typically required.
 |

| 1. **GLOSSARY OF TERMS**
 |
| --- |
| **Personally Identifiable Information (PII)*** A general term that is used to describe any form of information that could be used to identify an individual, including any personal information that is linked or linkable to a specified individual. This term is not related to HIPAA.
* Examples of PII include name, social security number, e-mail or mailing address, phone number, date and place of birth, mother’s maiden name, digital images, IP addresses, social media posts and other digital forms of data.
* Protected health information (PHI) is considered to be a subset of PII.
 | **Coded Data / Master List / Key*** Any personally identifiable information appearing within the study data has been replaced by a unique code (e.g., a participant ID number or pseudonym) alongside with a master list or key to decipher that code.
* The master list or key is stored separately and securely from the coded study data as a measure to protect the confidentiality of data.
* Best practice dictates that the master list or key be destroyed at the earliest opportunity within the conduct of the research project.
* Study data is NOT deemed to be de-identified until the master list or key has been destroyed.
* Please refer to the ‘**Guidance for Using a Master List in a Research Project**’ document for additional details (click [here](https://www.une.edu/research/integrity/irb)).
 |
| **‘****Sensitive Information’ includes:*** Genetic information
* Information that relates to (**a**) sexual attitudes, preferences or practices (**b**) the use of alcohol, drugs or other addictive products, or (**c**) illegal conduct.
* Information that if released, could reasonably damage an individual’s financial standing, employability, educational advancement, or reputation within the community.
* Information that would normally be recorded in a patient’s medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination.
* Information that pertains to an individual’s psychological well-being or mental health.
 | **Protected Health Information (PHI)*** A subset or smaller grouping of PII.
* PHI is individually identifiable health information that is held by a covered entity.
* PHI is any information in a medical record 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.
* PHI = Health Information that contains or is directly/indirectly linked to any of the 18 HIPAA identifiers (see below).
* Examples of research that involves PHI include: (**a**) studies that involve the review of existing health records, such as a retrospective chart review or other studies that involve the abstraction of data from the subject’s health record for research purposes; and (**b**) studies that create new medical information because a health care service is being performed as part of research (e.g., diagnosis of a health condition that creates PHI that will be entered into the medical record).
* Health information by itself that is not linked to and/or does not contain any of the 18 HIPAA identifiers (see below) is NOT considered to be PHI. This would be considered de‑identified health information.
* **Note**: HIPAA does not typically apply to self-reported health information provided by a participant (e.g., via an interview/survey), and the investigator does not review or alter the participant’s health record or make treatment decisions as part of the research.
 |
| **18 HIPAA Identifiers** |
| * Name
* Elements of dates including birth date, admission date, date of death, and all ages 90 years or older
* Fax numbers
* Social security number
* Health plan beneficiary numbers
* Certificate or license numbers
* Device identifiers and serial numbers
* Internet protocol (IP) address numbers
* Full face photographic images and comparable images
 | * Geographic information smaller than state
* Telephone numbers
* Electronic mail address
* Medical record numbers (MRN)
* Account numbers
* Vehicle identifiers and serial numbers including license plate numbers
* Web universal resource locators (URLs)
* Any other unique identifying number, characteristic, or code
 |

**Appendix A: Exemption Eligibility Checklist**

|  |  |
| --- | --- |
| **STEP 1** | * Answer the following questions.
* If all responses are ‘Yes’, proceed to **STEP 2** below.
* If you answered ‘No’ to any question, STOP HERE. Your proposed research is NOT eligible for exempt review. Please submit an ‘**Application for Non-Exempt Research Projects**’ (click [here](https://www.une.edu/research/integrity/irb)).
 |

|  |  |
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| The proposed research project is minimal risk and **is not** FDA-regulated. *Minimal risk is defined as a probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.* | [ ]  Yes [ ]  No |
| The proposed research **does not** involve prisoners. *If the research is aimed at involving a broader subject population that only incidentally includes prisoners, this is allowable under exempt review.*  | [ ]  Yes [ ]  No |
| The proposed research **is not** classified.*For example, access to sensitive information is not restricted by law or regulation, and/or formal security clearance is not required.* | [ ]  Yes [ ]  No |

|  |  |
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| **STEP 2** | * Only projects that fit into one or more eligible exemption categories as outlined in the table below may be considered for exempt review. In the far-right column, denote all categories that apply.
* If none of the outlined categories apply, your proposed research is NOT eligible for exempt review. Please submit an ‘**Application for Non-Exempt Research Projects**’ (click [here](https://www.une.edu/research/integrity/irb)).
 |

| **Category** | **Exemption Category Description** | **Conditions / Allowances / Limitations** | **Eligible for Exemption?** |
| --- | --- | --- | --- |
| **1** | Research conducted in established or commonly accepted educational settings that involves normal educational practices | Not likely to adversely impact student’s opportunities to learn or assessment of educators*This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.*  | [ ]  Yes [ ]  No |
| **2** | Research only includes educational tests, surveys, interviews, public observations if at least **ONE** of the following criteria is met: | * Data collection only
* May involve visual or auditory recording
* May NOT include intervention
 | [ ]  Yes [ ]  No |
| 1. Recorded information cannot readily identify the subject (directly or indirectly/linked); ***OR***

*[Data collected anonymously]* | * **Surveys & interviews**: No Children
* Educational tests or observation of public behavior: Can only include children when investigators do not participate in activities being observed
 |
| 1. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); ***OR***

*[Does NOT involve the collection of sensitive information about subjects]* | * **Surveys & interviews**: No Children
* Educational tests or observation of public behavior: Can only include children when investigators do not participate in activities being observed
 |
| 1. Information is recorded with identifiers & IRB conducts Limited Review

*[Collection of identifiers & sensitive information]* | No Children*The researcher must ensure that appropriate protections are put into place so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.* |
| **3** | Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees and **ONE** of the following criteria is met:  | * No Children
* May NOT include medical interventions (including physiological data collection methods such as EEG, wearable devices, blood pressure monitors, etc.)
* Prospective agreement required
* Deception is allowable ONLY if subject prospectively agrees

**Benign behavioral intervention MUST be**:* Brief in duration
* Painless / harmless
* Not physically invasive
* Not likely to have a significant adverse lasting impact on subjects
* Unlikely that subjects will find interventions offensive or embarrassing

*Examples include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.* | [ ]  Yes [ ]  No |
| 1. Recorded information cannot readily identify the subject (directly or indirectly/linked); ***OR***

*[Data collected anonymously]* |
| 1. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); ***OR***

*[Does NOT involve the collection of sensitive information about subjects]* |
| 1. Information is recorded with identifiers & IRB conducts Limited Review

*[Collection of identifiers & sensitive information]**The researcher must ensure that appropriate protections are put into place so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.* |
| **4** | Secondary research for which consent is not required. Use of identifiable private information or identifiable biospecimens that have been or will be collected for some other ‘primary’ or ‘initial’ activity if **ONE** of the following criteria is met: | * No primary collection from subjects for the research
* Allows both retrospective and prospective secondary use
 | [ ]  Yes [ ]  No |
| 1. Identifiable private information or identifiable biospecimen is publicly available; ***OR***
 | Must be publicly available |
| 1. Information recorded so subject cannot readily be identified (directly or indirectly/linked). Investigator does not contact subjects and will not re-identify the subjects; ***OR***
 |  |
| 1. Collection and analysis involving investigators use of identifiable health information when use is regulated by HIPAA ‘health care operations’ or ‘research’ or ‘public health activities and purposes’; ***OR***
 | * HIPAA still applies
* Protections include HIPAA authorization from participants, or partial/full waiver of HIPAA authorization

*This category includes retrospective chart review projects involving collection of PHI* |
| 1. Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities
 | If research generates identifiable private information it is subject to specified federal privacy laws |
| **5** | Research and demonstration projects supported by a federal agency/department AND designated to study public benefit or service programs | Must be posted on a federal website | [ ]  Yes [ ]  No |
| **6** | Taste and food quality evaluation and consumer acceptance studies |  | [ ]  Yes [ ]  No |

**Appendix B: Exemption Submission Checklist**

| REQUIRED SUPPLEMENTAL DOCUMENTATION *(as applicable to your project type)* | Yes | No | N/A |
| --- | --- | --- | --- |
| 1 | Current CV or resume of the Principal Investigator |[ ] [ ]   |
| 2 | Copy of current CITI training completion certificates for all UNE-affiliated key personnel as outlined within **Section A** of this application* *All UNE-affiliated key personnel are required to take the applicable UNE-specific CITI training course(s) outlined below.*

***Note****: The Office of Research Integrity does NOT accept CITI training certificates completed at other institutions when key personnel are affiliated with UNE.* * *CITI training completion certificates are NOT required for non-UNE affiliated personnel or collaborators. If the external personnel or collaborators are affiliated with an organization with its own IRB, they will need to ensure they meet the human subjects training requirements of their own institution.*

***Note****: If the external personnel or collaborators are not affiliated with an organization with its own IRB, they may take the applicable UNE-Specific CITI training course(s) outlined below.*

|  |  |
| --- | --- |
| **UNE-Specific CITI Training Courses** | **Take when the research project…** |
| 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 |
| Conflict of Interest | Is funded or sponsored by a federal Public Health Service (PHS) agency |

 |[x] [ ]   |
| 3 | Create a **Research Proposal Summary** using the headings listed below:

|  |  |
| --- | --- |
| 1. Introduction
2. Specific Aims
3. Methods of Data Collection & Analysis
4. Description of Participant Population, Research Setting, & Recruitment Procedures
 | 1. Participant Information Sheet
2. Provisions for Participant Privacy & Data Confidentiality
3. Statement of Potential Research Risks to Participants
4. Statement of Potential Research Benefit to Participants
 |

* *The summary should be concise (2-4 pages maximum).*
* *Visit the UNE IRB website (click* [*here*](https://www.une.edu/research/integrity/irb)*) to access available guidance for creating a research proposal for your exempt project.*

***Note****: Please ensure that your research proposal summary addresses the key considerations and best practices outlined within the relevant guidance document.* |[ ] [ ]   |
| 4 | Signed copy of the ‘**Principal Investigator Certification**’form (click [here](https://www.une.edu/research/integrity/irb))* *If the PI is a student, the document must also be signed by the respective Faculty Advisor*
 |[ ] [ ]   |
| 5 | Participant Information Sheet* *A modifiable Participant Information Sheet template can be found on the UNE IRB website (click* [*here*](https://www.une.edu/research/integrity/irb)*)*
 |[ ] [ ] [ ]
| 6 | Letter(s) of Support/Permission:* *Required from any non-UNE site where research is being conducted; or when applicable, documentation of IRB approval or exemption from the external site(s)*
* *Required when PHI originates from a non-UNE covered entity and the project involves access to, use, or disclosure of PHI for research purposes*

***Note****: The letter of support from the non-UNE covered entity must attest that they are aware of the proposed project and support the access to, use, or disclosure of PHI to the study team for research* |[ ] [ ] [ ]
| 7 | Data Collection Tools (as applicable):* *Master list or linking key template*
* *Interview scripts/guides*
* *Questionnaires*
* *Surveys*
* *Diaries*
* *Data collection form template*
* *Educational tests (applicable to exempt category 2 research projects)*
 |[ ] [ ] [ ]
| 8 | Participant Recruitment Materials (as applicable):* *Flyers*
* *Notices*
* *Letters*
* *E-Mails*
* *Verbal scripts*
* *Advertisements (e.g., newspaper, radio, tv, social medial, etc.)*
 |[ ] [ ] [ ]
| 9 | For projects that involve access to, use, or disclosure of PHI, provide any applicable supplemental HIPAA forms for review as outlined within **Section D** of this application:* ‘**Request for a Waiver of HIPAA Authorization for Research Purposes**’ form
* ‘**Research Involving PHI of Deceased Individuals Attestation Form**’
 |[ ] [ ] [ ]
| 10 | Whenever possible, submit separate **Microsoft Word** files for the following study documents:* *Exempt Application*
* *Research Proposal Summary*
* *Participant Information Sheet*
* *Data Collection Tools (see item 7 above)*
* *Participant Recruitment Materials (see item 8 above)*

**Note**: At the end of the review process, the Office of Research Integrity will provide the Principal Investigator with clean, version-controlled copies of all approved study documents for use in the project.  |[ ] [ ]   |

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