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| **INSTRUCTIONS**:* This form is intended to help you determine if your proposed project meets the federal definition of research involving human subjects (see [**Appendix A**](#AppendixA)) and requires oversight from the Office of Research Integrity or the IRB.

***Note****: See* [***Appendix B***](#AppendixB)*for examples of projects that are NOT considered human subjects research. See* [***Appendix C***](#AppendixC) *for examples of projects that ARE considered human subjects research.* * Submit your completed form to irb@une.edu for review ***before*** you initiate your project.

***Note****: The Office of Research Integrity cannot make retrospective determinations when the project has already started or has been completed.* * The Office of Research Integrity will provide you with a written determination. This determination can be used to provide to sponsors, collaborators, journal editors, and others who need verification from an impartial source that the proposed activities do not require IRB approval.
* Contact the Office of Research Integrity at irb@une.edu for any questions you may have with regard to this form.
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| --- | --- |
| Submission Date: | Enter text |
| Project Title: | Enter text |

| 1. **APPLICANT & FACULTY ADVISOR INFORMATION**
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| --- |
| **Applicant’s Name**:Enter text | **You are**:[ ]  Faculty[ ]  Staff[ ]  Student[ ]  Resident | **UNE Center or College**: | Enter text |
| **E-Mail**: | Enter text | **UNE Dept. or Program of Study**: | Enter text |
| **Phone #**: | Enter text |
|  |
| **Faculty Advisor Name1**:Enter text | **E-Mail**:Enter text | **Phone #**:Enter text |
| **1** | A Faculty Advisor is required when the Applicant is a student. |

| 1. PROJECT DESCRIPTION
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| 1. Have you either started or completed the proposed project? [ ]  No [ ]  Yes *(see note below)*

*If ‘Yes’, do NOT proceed with submitting this form. The Office of Research Integrity cannot issue a retrospective determination when the project has already started or has been completed.* |
| 1. Provide a brief description of the proposed project:

Enter text |
| 1. Describe the goals/objectives of the proposed project:

Enter text |
| 1. Describe the location and setting where the activities will take place:

Enter text |
| 1. Describe the study population that the activity includes:

Enter text |
| 1. Describe all data collection activities involved with the proposed project:

Enter text |
| 1. Is the proposed project currently funded or will it be funded? [ ]  No [ ]  Yes *(complete the section below)*

[ ]  Federal *(specify below)*[ ]  State of Maine *(specify below)*[ ]  UNE Internal Award[ ]  Other/Private *(specify below)*Enter text |

| 1. RESEARCH
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| --- |
| 1. Is the proposed project a *systematic investigation*, including research development, testing, and evaluation?

[ ]  Yes[ ]  No*A systematic investigation is a predetermined system, method, or plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. It includes the collection of information and/or biospecimens (e.g., blood, saliva), and quantitative or qualitative analysis.*Enter text |
| 1. Is the proposed project designed to develop or contribute to *generalizable knowledge*?

[ ]  Yes[ ]  No*Activities designed (with intent) to develop or contribute to generalizable knowledge are those designed to draw broad conclusions, inform policy, or generalize outcomes beyond the specific group/population, program, entity, or institution being studied.*Enter text |
| 1. Are the data collected solely for a program, department, or other administrative purpose?

[ ]  Yes[ ]  NoEnter text |
| 1. Is the proposed project designed to assess, analyze, critique, or update current processes in an institutional setting (involving data-guided systematic activities) to improve a program?

[ ]  Yes *(answer the questions below)*[ ]  No1. Will the activity involve *randomization* into different intervention groups? [ ] Yes [ ]  No

*Randomization is the process of assigning subjects by chance to groups that receive different treatments/interventions. In the simplest trial design, the investigational group receives the new treatment and the control group receives standard therapy.* 1. The proposed project is primarily designed to: *(check all that apply)*

[ ]  Improve a practice or process to ensure it conforms to expected norms.[ ]  Evaluate a specific program only to provide information for and about that program.[ ]  Be applied to populations beyond the specific study population.Enter text |
| 1. Is there an intention to *disseminate* the results of the proposed project via publication or presentation outside of UNE?

[ ]  Yes[ ]  No*The intention to disseminate results via publication/presentation outside of UNE is not a determining factor for whether an activity is human subjects research. Results do not have to be published or presented to qualify the activity as research.*Enter text |

| 1. HUMAN SUBJECTS
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| 1. Does the proposed project involve *interaction* or *intervention* with living individuals?

[ ]  Yes[ ]  No*Interaction includes communication or interpersonal contact between the investigator and the subject. This includes indirect or remote interaction such as a survey.**Intervention includes both physical procedures (e.g., blood draw) and manipulations of the subject (e.g., altering perception, cognition, emotion) or the subject’s environment (e.g., altering lighting or noise conditions) that are performed for research purposes.*Enter text |
| 1. Is the data or biospecimens (e.g., blood, saliva) obtained or used for the proposed project about/from living individuals?

[ ]  Yes[ ]  NoEnter text |
| 1. Will the proposed project obtain, use, study, analyze, or generate *identifiable private information* or *identifiable biospecimens* (e.g., blood, saliva)?

[ ]  Yes[ ]  No*Collection of identifiable information/biospecimens for which the identity of the subject is or may be readily ascertained by someone on the project team or associated with the information or biospecimens.* *Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonable expect will not be made public (e.g., a medical or education record).*Enter text |
| 1. Will the data or biospecimens (e.g., blood, saliva) for the proposed project be obtained entirely from *publicly available* sources?

[ ]  Yes *(answer the questions below)*[ ]  No*Publicly available refers to data and/or biospecimens that are accessible to anyone in the general public, without the need for special qualifications, permissions, or privileges. Examples include data/biospecimens available for public purchase, searchable online, or available at a library.**Note: This does NOT include reviewing or analyzing information from social media.*1. What is the source(s) of the publicly available information or biospecimen(s)?

Enter text1. Is the data set completely *de-identified*? [ ]  Yes [ ]  No

*De-Identified means the complete removal of all identifiers (e.g., HIPAA identifiers and any other personally identifying information) from the data set so that the remaining information cannot identify an individual and there is no reasonable basis to believe the information could be used to identify an individual. Note: Analysis of video, image, or digital recordings is considered identifiable.*1. Will the proposed project involve merging any data sets in such a way that individuals might be identified, or enhance the public data set with identifiable or potentially identifiable data? [ ]  Yes [ ]  No

Enter text |
| 1. Will the proposed project use *coded* data and/or biospecimens (e.g., blood, saliva) from living individuals?

[ ]  Yes *(answer the questions below)*[ ]  No*Coded means identifiable information, such as name or social security number has been replaced by a code (e.g., a subject ID, number, letter, or combination thereof) AND there is a key or master list to link between the code and identifiable information.* 1. Describe the type of data and/or biospecimens to be collected or obtained for the proposed project. If it will include protected health information, please specify the identifiers.

Enter text1. Will the provider of the data and/or biospecimens remove the code before sending the data/biospecimens to the investigator? [ ]  Yes [ ]  No
2. Will the holder of the key/master list and the investigator enter into an agreement prohibiting the release of the key/master list to the investigator under any circumstances? [ ]  Yes [ ]  No [ ]  N/A
3. Does the policy of the repository or data management center prohibit the release of the key/master list to the investigator under any circumstance? [ ]  Yes [ ]  No [ ]  N/A
4. Are there other legal requirements prohibiting the release of the key/master list to the investigator?

[ ]  Yes [ ]  No [ ]  N/AEnter text |

| 1. **APPLICANT ATTESTATION** *(A typed signature is NOT acceptable!)*
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| --- |
| By signing below, I attest that the information provided in this submission is true and accurate.

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|  |  |  |
| Applicant Signature |  | Date |

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**Appendix A**

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| **Is my project human subjects research?** For a project to be deemed human subjects research, it must meet the federal definition for ***both*** ‘research’ and ‘human subject’ per [45 CFR 46.102](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102).

|  |  |
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| Research | Human Subject |
| A *systematic investigation1*, including research development, testing and evaluation, designed to develop or contribute to *generalizable knowledge2*.  | A living individual about whom an investigator (whether faculty, student, or staff) conducting research: * Obtains data or biospecimens through ***intervention3*** or ***interaction4*** with an individual and uses, studies, or analyzes the data or biospecimens; *and/or*
* Obtains, uses, studies, analyzes, or generates ***Identifiable private information or identifiable biospecimens5***.
 |

1. *A predetermined system, method, or plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. It includes the collection of information and/or biospecimens, and quantitative or qualitative analysis.*
2. *Activities designed to draw broad conclusions, inform policy, or generalize outcomes beyond the specific group/population, entity, or institution being studied.*
3. *Includes both physical procedures (e.g., blood draws) and manipulations of the subject (e.g., altering perception, cognition, emotion) or the subject’s environment (e.g., altering lighting or noise conditions) that are performed for research purposes.*
4. *Includes communication or interpersonal contact between investigator and subjects.*
5. *Identifiable private information or biospecimens (e.g. blood, saliva) for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information or biospecimens.*
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**Appendix B**

| Examples of Projects that are NOT Human Subjects Research |
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| 1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, focus directly on the specific individuals about whom the information is collected.

*Note*: The objective of the project should NOT be the development of generalizable knowledge. If the project involves using the information for purposes of drawing general conclusions about the overall group, then the project may require oversight from the UNE Office of Research Integrity or the IRB. Please submit a ‘*Research Determination Request Form*’ to irb@une.edu for review.  |
| 1. Public health surveillance activities, including the collection and testing of information or biospecimens, are conducted, supported, requested, ordered, required, or authorized by a public health authority.
* Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products).
* Such activities include those associated with providing timely situational awareness and priority setting during an event or crisis that threatens public health (including natural or man-made disasters).
 |
| 1. Collection and analysis of information, biospecimens (e.g., blood, saliva), or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
 |
| 1. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
 |
| 1. Data collection for internal departmental, program, school, or other university administrative purposes (e.g., teaching evaluations and customer service surveys).
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| 1. Service surveys issued or completed by University personnel for the intent and purpose of improving services and programs of the University or for developing new services or programs for students, employees, or alumni do not require review by the UNE Office of Research Integrity or the IRB; however, they should be designed in such a way that privacy of the subjects is protected, the confidentiality of individual responses is maintained, and survey participation is voluntary. This would include surveys by professional societies or University consortia.

*Note*: If an opportunity arises at a future date to contribute previously collected identifiable or coded survey data to a new project that will produce generalizable knowledge, the project may require oversight from the UNE Office of Research Integrity or the IRB before the existing data could be used in the new project. Please submit a ‘*Research Determination Request Form*’ to irb@une.edu for review. |
| 1. Information-gathering interviews in which questions focus on things, products, or policies rather than people or their thoughts, their opinions, or their thoughts regarding themselves (e.g., canvassing librarians about inter-library loan policies or rising journal costs).
 |
| 1. Course-related activities designed specifically for educational or teaching purposes, in which data is collected from and about human subjects as part of a class exercise or assignment but are not intended for use outside of the classroom (e.g., instruction on research methods and techniques).

*Note 1*: Faculty teaching a course (as defined above) that requires students to collect data via interaction (e.g., interview, survey) with individuals outside the course are required to submit an ‘*Application for Student Classroom Project Exclusion*’ to irb@une.edu for review 2 weeks prior to the course starting. *Note 2:* Course work conducted as part of a master’s thesis, capstone project, dissertation, or honor’s program may require oversight from the UNE Office of Research Integrity or the IRB. Please submit a ‘*Research Determination Request Form*’ to irb@une.edu for review. |
| 1. Independent contracts for procedures carried out for an external agency (e.g., personnel studies, cost-benefit analyses, customer satisfaction studies, biological sample processing for a fee and not authorship or other credit, public park usage, IT usage, and software development).
 |
| 1. Research involving cadavers, autopsy material, or biospecimens (e.g., blood, saliva) from now-deceased individuals.

*Note 1*: Some research in this category, however, such as genetic studies providing private or medical information about *living* relatives, may require oversight from the UNE Office of Research Integrity or the IRB. Please submit a ‘*Research Determination Request Form*’ to irb@une.edu for review.*Note 2*: Research involving the use of identifiable biospecimens from *living* individuals may require oversight from the UNE Office of Research Integrity or the IRB. Please submit a ‘*Research Determination Request Form*’ to irb@une.edu for review. |
| 1. Innovative therapies, except when they involve "research" as defined by OHRP (The Office for Human Research Protections). An innovative clinical practice is an intervention designed solely to enhance the well-being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventive treatment, or therapy to particular individuals. As long as the intent remains focused on patient well-being and does not evolve into systematic assessment with results, conclusions, and dissemination, the activity is not deemed research.
 |
| 1. Quality improvement projects are generally not considered research unless there is a clear intent to contribute to generalizable knowledge and use the data derived from the project to improve or alter the quality of care or the efficiency of institutional practice.

*Note 1*: If the data is re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, oversight from the UNE Office of Research Integrity or the IRB may be required. Please submit a ‘*Research Determination Request Form*’ to irb@une.edu for review.*Note 2*: If you are unsure whether or not a proposed quality improvement project should be classified as human subjects research, please submit a ‘*Research Determination Request Form*’ to irb@une.edu for review. *Note 3*: Planning to publish an account of a quality improvement project does not mean that it meets the definition of research or requires oversight from the UNE Office of Research Integrity or the IRB. Individuals publish results to share their knowledge about non-research topics as well. Alternatively, a quality improvement project may involve human subjects research even if there is no intent to publish the results.  |
| 1. Medical case studies (also known as case reports) involving three or fewer patients are not considered research at UNE; however, case studies that meet the aforementioned criteria do require registration via the ‘*Application for Case Study Registration*’ available on the UNE IRB [website](https://www.une.edu/research/integrity/irb).
 |
| 1. Use of publicly available de-identified data sets (e.g., census data and labor statistics) do not require oversight from the UNE Office of Research Integrity or the IRB. The use of the data set must comply with the following two conditions:
* The research will NOT involve merging any of the data sets in such a way that individuals might be identified.
* The researcher will NOT enhance the public data set with identifiable, or potentially identifiable data.

*Note*: This does NOT include reviewing or analyzing information from social media. |
| 1. Coded private information or biological specimens (e.g., blood, saliva) that were not collected for a currently proposed project do not need review from the UNE Office of Research Integrity or the IRB as long as the investigator cannot link the data/specimens back to individual subjects. Coded means that:
* Identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, and/or combination thereof (i.e., the code); and
* A key to deciphering the code exists, enabling linkage of the identifying information to the private information or specimens.

*Note*: If the data/specimen provider has access to the identity of the subjects (e.g., subjects’ names, and addresses), the investigator must enter into an agreement with the data/specimen provider that states that under no circumstances will the identity of the subjects be released to the investigator. |

**Appendix C**

| Examples of Projects that ARE Human Subjects Research¥ |
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| 1. Projects that collect and analyze data from/about living individuals and contribute to generalizable knowledge. Examples include:
* Interviews
* Surveys/questionnaires
* Focus groups
* Educational research
* Benign behavioral interventions
* Use of identifiable data or biospecimens
* Retrospective chart reviews
* Observational research
* Biomedical research
* Clinical trials involving drugs and medical devices
 |
| 1. Projects using private information that can be readily associated with living individuals (or the identity may be ascertained), even if the information was not collected specifically for the project in question.
 |
| 1. Projects that use bodily materials (e.g., cells, blood, urine, tissues, organs, hair, nail clippings) from living individuals even if one did not collect these materials for the project.

*Note*: These projects may be considered exempt or not human subjects research if the materials/data are coded, and the investigator does not have access to the coding systems. Guidance on research involving coded private information or biological specimens is available on the web at: (<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>).  |
| 1. Projects that produce generalizable knowledge about categories or classes of living subjects from individually identifiable information.
 |
| 1. Projects that use living human beings to evaluate environmental alterations, for example, weatherization options or habitat modifications to their living or working space or test chamber.
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**¥**  *This assumes the activity is a systematic investigation and there is an intent to generalize findings beyond UNE.*

**Acknowledgements & Sources**:

1. The Office for Human Research Protections (OHRP). [What is Human Subjects Research?](https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/lesson-2-what-is-human-subjects-research/index.html)
2. [Activities Deemed Not to Be Research: Public Health Surveillance 2018 Requirements](https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-activities-deemed-not-be-research-public-health-surveillance/index.html)
3. [What is Research and What it isn’t? And Who is Human Subject Anyway? – Explaining the Common Rule in Plain Language](https://www.hhs.gov/sites/default/files/ohrp-what-is-research-and-what-it-is-not.pdf)
4. The University of Iowa. [Do I need IRB Review? Is This Human Subjects Research? A Guide for Investigators](https://www.google.com/search?q=the+university+of+iowa+Do+I+need+IRB+Review%3F+Is+This+Human+Subjects+Research%3F+A+Guide+for+Investigators&rlz=1C5GCEM_enUS1039US1039&oq=the+university+of+iowa+Do+I+need+IRB+Review%3F+Is+This+Human+Subjects+Research%3F+A+Guide+for+Investigators&aqs=chrome..69i57.4841j0j4&sourceid=chrome&ie=UTF-8#:~:text=https%3A//hso.research.uiowa.edu/sites,research.uiowa.edu%20%E2%80%BA%20files%20%E2%80%BA%20forms)
5. Northern Arizona University – Human Research Protection Program
6. [45CFR46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)
7. [21CFR50](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50)