### **Section 1: Project Information**

**1.1 Project Title:**

Enter the title of your project- The title should be descriptive and concise and align with the project's questions, hypothesis (if applicable), goals and objectives.

**1.2 Investigator(s):**

* **Principal Investigator (PI):** Your name, title (i.e. graduate student, undergrad student, faculty, staff, etc), department, and contact information. Student researchers must provide the contact information of their research advisor/sponsor.
* **Co-Investigator(s):** List names, departments, and contact information of other researchers involved.
* **Complete CITI training:** Submit your completed CITI training

**1.3 Collaborating**

* Are you collaborating with any external entities? If no, skip, if yes, go through the remaining information under 1.3
* Research may not begin at the new sites until the required approvals and assurances are complete.
* Research at collaborating institutions-domestic and international- requires review by the IRB at NEIU
* Each institution that is conducting human subjects research and is considered “engaged in the research” (per federal definition), must have its own IRB or Independent Ethics Committee approval before research can begin there
* Approval is needed regardless of the funding source.

**NEIU investigators who work with other institutions must fulfill requirements that may vary depending on the following factors:**

* Provide the name of all collaborating investigators and their institutions
* The role the collaborating organization plays;
* The type of regulatory infrastructure in place – namely whether the institution has a governing Institutional Review Board (IRB) or Independent Ethics Committee (IEC);
* The source of funding for the research.

**Collaborating with Institutions: (How about a flowchart? Here is an [example](https://research-compliance.umich.edu/sites/default/files/resource-download/iaa_flowchart.pdf))**

* **Institutions with a FWA:**
	+ This is an agreement with the institution(s) that hold FWA with the Office of Human Research Protections (OHRP) of the U.S. Department of Health and Human Services (HHS)- must have an FWA number
	+ This agreement is used when NEIU or the external institution will be the relying institution that oversees the safety of the human subjects in research and overall compliance
	+ The IRB Authorization Agreement (IAA) must be completed and signed by each of the Institutional Officials
* **Institutions without FWA:**
	+ This agreement type is typically used for non-federally sponsored research projects involving multiple collaborators who are affiliated with the organization (i.e. alumni, professor emerita, etc.)
	+ A Collaborating Institutional Agreement (CIA) form is completed and signed by the NEIU Institutional Official and a representative who has the authority to make commitments on behalf of their institution
* **Individual Investigators:**
	+ NEIU faculty who collaborate with individuals who are not affiliated with NEIU or an FWA institution, must complete the Individual Investigator Agreement (IIA) form.
	+ The IIA outlines the responsibilities of the Individual investigator for the protection of human subjects
	+ The IIA must be signed by: external Individual Investigator, NEIU PI, and NEIU Institutional Official

**1.4 Project Dates:**

* **Start Date:** The date you intend to begin data collection.
* **End Date:** The date you plan to complete the study.

**1.5 Funding Source:**

* Specify if your project is funded and by whom. If not funded, indicate "N/A."

### **Section 2: Study Design**

**2.1 Purpose and Rationale for conducting the Study:**

* **Research Objectives**: Clearly state what you aim to discover, prove, or analyze through your research.
* **Research Questions:** Specify the research questions that guide the study.
* **Hypothesis**: If your research is hypothesis-driven, clearly state what it is.
* **Gap in Existing Knowledge**: Describe what gaps in existing research your study aims to fill. Explain how your research questions have not been adequately addressed in current literature.
* **Significance:** Explain why the study is important. Discuss the potential for it to improve understanding of a certain topic, contribute to theory, inform policy, or have practical applications.
* **Relevance:** Discuss how your study relates to existing theories, practices, or research in your field. Make a case for why this study is needed now.
* **Population Benefit**: If applicable, describe how the study benefits the community or population group you're studying, or society as a whole.
* **Feasibility:** Briefly discuss why the research can be successfully conducted given available resources, timeframe, and expertise.
* **Ethical Consideration**: While ethical issues will be discussed in greater depth elsewhere in the application, briefly mention any high-level ethical considerations related to the purpose and rationale of your study.
* **Innovative Aspects:** Are there any innovative aspects of your study, such as new methodologies, that contribute to its rationale.

**2.2 Methodology:**

* **Participants:**

When completing the "Population of the Study" section in an IRB (Institutional Review Board) application, you should provide detailed information that allows the review board to assess the ethical considerations and potential risks involved in your research. Below are specific elements you might consider including:

* + General Description:
		- Target Population: Clearly identify the general group of people that your research will focus on, e.g., adolescents, adults over 65, healthcare professionals, etc.
		- Sample Size: Indicate how many participants you intend to recruit for the study.
	+ Characteristics:
		- Demographics: Describe the demographic makeup of your population, including age, gender, ethnicity, educational level, and other relevant factors.
		- Special Conditions: If the study involves individuals with special conditions such as illnesses, mental health issues, or particular social circumstances, these should be described.
	+ Recruitment:
		- Recruitment Methods: Explain how you intend to recruit participants. Will you use advertisements, social media, referrals, or direct contact?
		- Inclusion Criteria: Detail the characteristics that a participant must have to be included in the study.
		- Exclusion Criteria: Likewise, list any characteristics or conditions that would disqualify someone from participating.
	+ Vulnerable Populations:
		- Identification: Clearly identify if your study involves vulnerable populations such as children, pregnant women, or prisoners.
		- Additional Safeguards: Describe the additional safeguards you will put in place to protect these populations.
	+ Compensation:
		- Incentives: Describe any incentives, financial or otherwise, that participants will receive.
		- Reimbursements: Will participants be reimbursed for any costs they incur (e.g., travel, parking)?
* **Data Collection Methods:** Will you use surveys, interviews, observations, etc.?
* **Data Analysis:** Explain the statistical methods you will use to answer the study questions, and how you plan to analyze the data. Will you use statistical software, coding, etc.? Does the chosen method accurately analyze the data to answer the study question(s) and/or aim(s)?

**2.3 Inclusion/Exclusion Criteria:**

* List all the criteria that participants must meet to be eligible for the study or reasons they may be excluded. Explain why.

**2.4 Risks and Benefits:**

* Describe potential risks to participants and how you plan to mitigate them.
* Explain any benefits to participants, community, profession, and society at large.

**2.5 Consent Process:**

* Describe the process of obtaining informed consent from this population. Especially if there are any language or cultural barriers that may affect comprehension and how the barriers will be addressed.
* Outline the process by which you will obtain informed consent from participants.

### **Section 3: Confidentiality and Data Security**

**3.1 Data Storage:**

* Explain where data will be stored (secure server, encrypted device, etc.) and for how long.
	+ **Storage Medium**: Describe where the data will be stored (e.g., secure server, encrypted hard drive, cloud storage) and the type of encryption used if applicable.
	+ **Physical Storage**: If any data will be stored in a physical format, explain how and where this will occur and what security measures will be in place (e.g., locked filing cabinets).
	+ **Backup Procedures**: Outline backup procedures, including frequency and method.
	+ **Duration:** Specify how long the data will be stored.
	+ **Anonymization:** Describe any steps taken to anonymize or de-identify the data, and at what point this will happen (if applicable).
	+ **Compliance**: Note any compliance with data protection and privacy laws (e.g., GDPR, HIPAA).

**3.2 Data Access:**

* Specify who will have access to the data and under what conditions.
	+ **Access Levels:** Indicate who will have access to the data and for what specific purposes. Will different team members have different levels of access?
	+ **Authentication**: Describe authentication procedures for accessing the data (e.g., multi-factor authentication, secure login credentials).
	+ **Monitoring:** Explain how data access will be monitored or audited to ensure only authorized access.
	+ **Data Sharing**: If the data will be shared with external parties, such as other researchers or organizations, describe how this will be done securely, and what agreements will be in place.
	+ **Data Transfer:** Describe the methods used to securely transfer data between locations or team members if applicable.

**3.3 Data Destruction Timeline:**

* Indicate when the data will be destroyed or anonymized after the study is complete.
	+ Deletion Procedure: Describe the process and timeline for securely deleting or destroying the data once it is no longer needed.
	+ Certificate of Destruction: Indicate whether a certificate of destruction will be obtained as proof of secure deletion if applicable.
	+ Archival Plans: If the data will be archived for future research, describe the conditions under which this will happen and the long-term plans for securing the data.
	+ Software Tools: List any software tools that will be used in the data destruction process to ensure its thoroughness and permanence.

### **Section 4: Attachments Checklist**

* **Informed Consent Forms- All versions (if applicable)**
* **All scripts or forms used to obtain consent**
* **Data Collection Instruments:** Include copies of surveys, questionnaires, or interview guides.
* **IRB Training Certificates:** Attach proof of ethical training, like CITI certificates, for all investigators
* **All training or intervention materials**
* **All recruitment flyers, scripts, emails, etc.**

## **IRB Protocol Application Checklist**

* **Project Information**: Filled in all sections under Project Information.
* **Study Design**: Detailed Purpose, Methodology, Inclusion/Exclusion Criteria, Risks, and Benefits.
* **Confidentiality and Data Security**: Specified data storage and access protocols.
* **Attachments**: Included all necessary attachments, such as informed consent forms, and training certificates.
* **Review**: Ensured the application and attachments are complete and accurate.

Completing each section and following the checklist should help ensure a comprehensive and well-organized application. If you have any questions or need additional guidance, don't hesitate to seek help from faculty advisors or IRB staff.