#  *Request for IRB Review cover Page*

**Download and complete form electronically. Once complete, save the form as a Word document and send as an email attachment to the IRB committee at** **walkerln@delhi.edu**
Also, include any supporting documentation as attachments to the email (see bottom of p. 6). **Please use SUNY Delhi webmail. All paperwork is filed electronically.**

For IRB Use Only

**Protocol Number:**

# State University of New Yorkat Delhi

# Institutional Review Board This form was adopted with permission from the University at Albany

**Review Requested (check one): FULL** **[ ]  (COMPLETE APPLICATION)
EXPEDITED** **[ ]  (COMPLETE APPLICATION)
EXEMPT** **[ ]
(FOR EXEMPT, COMPLETE APPLICATION AND THE ‘EXEMPT REVIEW’ SECTION ON PAGE 7)**

|  |  |
| --- | --- |
| Primary Investigator Name: (Researcher requesting IRB review) |  |
| **Research Proposal Title:** |  |
| Check all of the following that apply to your research proposal: |
| [ ]  | *Research Involving* ***LESS*** *than Minimal Risk* | [ ]  | *Research Involving* ***MORE*** *than Minimal Risk* |
| [ ]  | *Prisoners* | [ ]  | Oral History Project  |
| [ ]  | *Children*  | [ ]  | *Intervention* (Physiological, psychological, etc.) |
| [ ]  | Elected or Appointed Officials | [ ]  | Biological Specimens (e.g. noninvasive saliva, urine collection) |
| [ ]  | Class Research Assignment | [ ]  | *Deception* |
| [ ]  | Secondary Data Analysis | [ ]  | *Biomedical Research (invasive procedures, e.g.venipuncture)* |
| [ ]  | Human Tissue Research | [ ]  | *International Research (any phase of the research occurs outside US)* |

|  |
| --- |
| GENERAL FUNDING INFORMATION |
| **Are you seeking funding or sponsorship for this project?** | [ ]  **Yes:**  If **YES,** is the funding:[ ]  Pending [ ]  Approved**Grant #:**  | *[ ]* **No** (If **NO**, skip to ***page 1***) |
| **Funding / Sponsorship Source(s)** Specify ***all******possible*** sources of funding including federal, state, university, foundation etc. *Please be as specific as possible.* |  |
| **Title of Funding Application or Grant\**2 COPIES*** *of the grant or funding documentation must be provided with this form.*  |  |
| **Primary Investigator/Author on Grant/Funding Application**: *(If different than PI)* |  |
| Name of SUNY Delhi Grant Administrator |  |

# *\*You are required to identify the RELEVANT SECTION (S) of the application or grant for which this submission corresponds. If the grant or*

# *application is written in highly technical terms you are required to provide a summary in layperson’s terms.*

#

#  *New Research Protocol Submission Form*

For IRB Use Only

**Protocol Number:**

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| --- |
| GENERAL PROTOCOL INFORMATION |
| Research Proposal Title |  |
| **Primary Investigator Name / Contact Information** (Provide contact information where we can reach you regarding this project.) | **PI Name**  | **Address** (*campus or business)* | **Email Address** | **Phone Number(s)** |
|  |  |  |  |  |
| PI Affiliation with SUNY Delhi (e.g. doctoral student, professor)  |  |
| **PI Department Affiliation** (e.g. History Department)  |  |
| **Faculty Advisor Name / Contact Information** (Required when PI is a student.) | **Name** | **Department & Campus Address**  | **Email Address** | **Phone Number(s)** |
|  |  |  |  |  |
| **Collaborative Research** (Specify if your research will be a collaborative effort with another institution.) |  |
| **SUNY Delhi Primary Investigator Role/Responsibility in Research** (please be as specific as possible) |  |
| Anticipated Start Date for Research  |  |
| **Expected Duration of Research** (From initial recruitment through data analysis) |  |
| **Dissemination Forum(s)** (e.g. journals, poster sessions, presentations, etc.)(omit for exempt proposals) |  |
| Has this protocol already received 2 continuations?  | [ ]  No [ ]  Yes: **Previous Protocol #:**      (If **YES**, please attach a brief summary of the completed research activities and provide a summary of the activities to be conducted in the upcoming year.)  |

**Please complete all sections in layperson’s terms. All appropriate components must be included with this request for IRB review:**

* **Application**
* **Informed Consent process and documentation (if needed)**
* **Recruitment materials**
* **Any research instruments that will be used for the study (interviews, scripts, questionnaires, advertisements). If the study is designed to develop instruments and test the instruments for validity, state this in the Research Summary and provide a copy of the materials to the IRB Committee once developed following amendment procedures.**
1. **Describe the proposed research in layperson’s terms** (The purpose and significance of the project, including a statement of hypotheses to be tested, along with an indication of the theoretical, biomedical and/or social significance of potential findings (include a minimum of two references).
2. **Describe the research methodology / procedure(s) you will use:** *(Include an explanation of all physiological, psychological and medical procedures, tests, interaction or interventions, and questionnaires that will be utilized during the conduct of the study. Include a brief description of the sample, recruitment methods/process [include dates/times], implementation/procedure of the study, and data analysis)*
3. **Does your research involve the use of existing data or datasets?** [ ]  Yes [ ]  No
* If **YES**, identify the source; specify if data is publicly available and if it will contain personal identifiers.
1. **Describe your intended participant population, where participants will be recruited and the selection or recruitment process you will use to obtain participants:**

**Identify the following information about participants:**

**Total Number of Participants:**  **Children: [ ]  Yes [ ]  No Age Range:**  **to**

 **Adults: [ ]  Yes [ ]  No Age Range:**  **to**

1. **Do you plan to offer compensation to the participants?** [ ]  Yes [ ]  No
* If **YES**, explain the type, amount and schedule by which it will be distributed (you must include provisions for payment if participant withdraws prior to completion).

1. **Identify the risk level of this study.** “Minimal Risk” means that the 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. **Check the appropriate risk level.**

|  |  |
| --- | --- |
| Less than Minimal Risk | [ ]  |
| **More than Minimal Risk**  | [ ]  |

1. **Identify the types of risk to participants in this study.**  **Check all that apply.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| [ ]  | Physical | [ ]  | Discomfort | [ ]  | Social |
| [ ]  | Psychological | [ ]  | Confidentiality | [ ]  | Economic |
| [ ]  | Privacy |  |  |  |  |
| [ ]  | Other - **Please explain:** |
|  |  |

1. **Identify the benefit to participants in this study:**
2. **Describe the process you will use to obtain informed consent from participants**:
3. **Will identifiable, private information be obtained about the participant(s)?** [ ]  Yes [ ]  No
* If **YES**, complete the following table:

|  |  |
| --- | --- |
| Describe the type of information to be obtained |       |
| **Describe how the information will be obtained** (electronically, paper, voice recording, etc.) |       |
| **Describe the confidentiality procedures to be used** |       |
| **Identify risks to participants if confidentiality is broken**  |       |

1. **Describe where study records (research data, signed consent forms, voice recordings, transcripts, etc.) will be stored, specify how long data will be maintained and how it will be destroyed.**

1. **Are you requesting any sensitive information about the participants or any other individual known to the participant?** [ ]  Yes [ ]  No
* If **YES**, check all that apply. If **NO**, please proceed to #13.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [ ]  | Sexual behavior |  | [ ]  | Drug use/abuse [ ] HIV/AIDS Status |
| [ ]  | Illegal conduct |  | [ ]  | Alcohol use/abuse |
| [ ]  |  | Any other types of information about the subject that, if it became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects financial standing or employability? If **YES**, please explain.       |

* **If you checked any of the above, specify any additional confidentiality measures you will take.**
* **Do you plan to request a Certificate of Confidentiality?** [ ]  Yes [ ]  No
* **Describe any additional services you will offer to the participants.**
1. **How will information be obtained from your participants? Check all that apply**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | Questionnaire / Survey | [ ]  | Test / Task |
| [ ]  | Interview  | [ ]  | Video Recording / Photograph |
| [ ]  | Observation | [ ]  | Audio Recording |
| [ ]  | Focus Group | [ ]  | Internet / email  |
| [ ]  | Other – **Please explain:** | [ ]  | Review of Personal Files (e.g. school, medical records, etc.) |
|  |       |

1. **Do you plan to use deception in your research?**  [ ]  Yes [ ]  No
* If **YES**, justify the need for use of deception and explain how the participants will be debriefed about the true intent of the research.

1. **Do you plan to include any of the following populations as participants? In other words, do you plan to investigate any of these populations as a group? Check all that apply.**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | Children/Minors (ages 0-17) | [ ]  | Pregnant Women |
| [ ]  | Individuals with diminished mental/physical capacity | [ ]  | Individuals with FERPA Accommodated Learning Needs |
| [ ]  | Economically/Educationally Disadvantaged  | [ ]  | Individuals who are institutionalized |
| [ ]  | Students in your classroom | [ ]  | Prisoners |
| [ ]  | Other - If **YES**, please explain.  |

* **If you checked any of the above, explain the safeguards you will use to protect the participant’s rights and welfare.**
1. **Will this research project involve organizations other than SUNY Delhi?** (*Such as organizations or institutions involved in any of the following activities: participant interaction or recruitment, viewing, obtaining or storing identifiable private information, coordinating research centers, study participant providers, data analysis or storage, etc.)*  [ ]  Yes [ ]  No
* If **YES**, identify the organization(s)/institution(s) in the following table, specify the role(s) of the organization in the research project and provide a signed letter of approval/permission from each organization, school or institution. ***Attach additional pages if necessary.***

|  |  |  |  |  |
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| **Organization Name** | **Role in Research Proposal\*** | **Site Address / Contact Person** | **Signed Approval Letter Attached** | **Approval Letter Requested** |
|       |       |       | [ ]   | [ ]  |
|       |       |       | [ ]   | [ ]  |
|       |       |       | [ ]   | [ ]  |
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**\*E.g. use of organization’s facility or resources, collaborator (actively engaged in research project), data analysis, data storage, etc.**

1. All personnel associated with this project are required to complete human subjects training, which is offered online via CITI Program training for Delhi employees at the CITI website below (where you will need to enter our institution as “SUNY – College of Tech. at Delhi”:

<https://www.citiprogram.org/index.cfm?pageID=154&icat=0&clear=1&_ga=2.121828418.835385401.1534943724-450106434.1534943724>

Please refer to the SUNY Delhi IRB Policies and Procedures Manual for current training requirements. Contact the IRB Chair, Lindsay Walker, at walkerln@delhi.edu or 607.746.4143 for more information.

Study personnel include the ***faculty advisor, principal investigator and all individual(s) who will interact*** with the study participants, collaborate on study design, analyze or record data or view any personal identifying information about the participants, ***including those individuals that are not affiliated*** with SUNY Delhi. ***In addition, all co-investigators listed on a funding application or grant must be included as study personnel and complete required training.***

Identify all study personnel that *ARE affiliated* with SUNY Delhi

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| **Study Personnel Names** | **Individual Responsibility / Role in Study** | **Training Completion Date**  | **Training Certificate Attached\*** |
|       |       |       | [ ]  |
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**\* Provide the IRB with documentation of training when initial training is completed or renewed. Once documentation is on file, it is not necessary to provide additional copies with each new project/protocol submission.**

Identify all study personnel that *are NOT affiliated* with SUNY Delhi
(Unaffiliated Investigator Agreement(s) may be required.)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study Personnel Names** | **Individual Responsibility / Role in Study** | **Specify Institution(s)/Organization(s) Where Individual is Affiliated / Employed**  | **CITI Training Completion Date**  | **Training Certificate Attached\*** |
|       |       |       |       | [ ]  |
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|       |       |        |       | [ ]  |
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**\*Provide the IRB with documentation of training when initial training is completed or renewed. Once documentation is on file, it is not necessary to provide additional copies with each new project/protocol submission.**

**PRINCIPAL INVESTIGATOR ASSURANCE: By signing this form you are acknowledging that:**

* You have completed the SUNY Delhi required training as specified in the Investigator Handbook.
* You must conduct the research in compliance with SUNY Delhi Policies, federal, state and local laws, Declaration of Helsinki and the Belmont Report.
* You will not begin this research project until you have received final written approval from the SUNY Delhi’s Institutional Review Board.
* You must report all intended changes in previously approved research prior to implementation.
* If you have obtained funding for this research, you will submit all changes in research that have been made to the sponsor’s funding application within 30 calendar days to the IRB.
* You will report all adverse events within 5 calendar days of the occurrence to the IRB.
* You will provide an annual update if your research extends beyond the final approval period.
* If you are a student principal investigator, you are responsible for obtaining review and approval for this research proposal from your faculty advisor.

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| **Print Principal Investigator Name** | **Principal Investigator Signature**  | **Date** |

 **SUPERVISOR ASSURANCE: By signing this form you are acknowledging that:**

* You have reviewed the research proposal.
* You support implementation of the research proposal.
* The investigator(s) have the appropriate academic and clinical and credentials and experience to conduct this study.

\*\*\*If a signature is not included, provide documentation (email acceptable) in the form of a pdf from the department supervisor where research will be conducted noting the above information. Please submit this pdf with all the required documentation for the proposal review.

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| **Print Supervisor Name** | **Supervisor Signature**  | **Date** |

 **FACULTY ADVISOR ASSURANCE (if applicable): By signing this form you are acknowledging that:**

* You have completed the SUNY Delhi required training as specified in the current SUNY Delhi IRB Policies and Procedures Manual.
* You have reviewed and approved this research proposal and certify that the student principal investigator is under your direct supervision.
* You will oversee the conduct of the research for compliance with SUNY Delhi Policies, federal, state and local laws, Declaration of Helsinki and the Belmont Report and will promptly report any deviations to the IRB.

\*\*\*If a signature is not included, provide documentation (email acceptable) in the form of a pdf, noting the above information. Please submit this pdf with all the required documentation for the proposal review.

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| **Faculty Advisor Name** | **Faculty Advisor Signature**  | **Date** |

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| **PLEASE INDICATE THE ITEMS INCLUDED WITH THIS FORM (Be sure to include all materials appropriate for your study.** |
| Informed Consent(s)  | [ ]  | Script(s) | [ ]  | Existing Data Set Approval(s) | [ ]  |
| Institution Permission / Approval Letter(s) | [ ]  | Interview Questions | [ ]  | Internet / Email correspondance | [ ]  |
| Request for Alteration of Required Elements of Informed Consent | [ ]  | Test(s) | [ ]  | Recruiting Materials (fliers, scripts, etc.) | [ ]  |
| Questionnaires/Surveys | [ ]  | Debriefing Information | [ ]  | Child Assent(s) | [ ]  |
| Secondary Participant Consent | [ ]  | Training Certificate(s) | [ ]  | Funding/Grant Proposal(s) | [ ]  |
| Unaffiliated Investigator Agreement(s) | [ ]  | IRB Approval from CollaboratingInstitution(s) | [ ]  | Local Contact/Expert for International Studies | [ ]  |
|  |  |  |

FOR EXEMPT REVIEW REQUESTS, PLEASE COMPLETE THIS SECTION.

Please check the appropriate Exempt Category:

\_\_ (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. This applies only to Normal educational research in regular educational settings.

\_\_ (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation. This exemption does not apply to children or prisoners.

\_\_ (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. This applies only to elected officials, not officials appointed via a regular hiring process.

\_\_ (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifier linked to the subjects. All data must exist when the application is submitted.

\_\_ (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternative to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. This applies only to research and demonstration projects under the Federal Social Security Act. This does NOT apply to state or local public service projects that are not pursuant to the Social Security Act.

\_\_ (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Revised 8/7/19