**IRB Renewal Form**

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| **Application Information** |

1. **IRB Protocol Number:** Click or tap here to enter text.
2. **Project Title:** Click or tap here to enter text.
3. **Level of Initial Review:** Choose an item.
4. **Initial date of approval:**  Click or tap here to enter text.
5. **Pending expiration date:** Click or tap here to enter text.
6. **Project end date:** Click or tap here to enter text.

The project end date should be the estimated date when data collection, intervention or interaction with subjects, and identifiable private information and any other identifiers or keys linking the data to the participants have been stripped and destroyed. IRB approval can be granted for up to five years for exempt research, two years for expedited projects, and one year for projects with full board review.

1. **School:** Choose an item.
2. **Investigator Information:**

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| --- | --- |
| **Principal Investigator’s Name** | **Status** |
| Click or tap here to enter text. | Choose an item. |

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| **Co-Investigator’s Name(s)** (If Applicable) | **Status** |
| Click or tap here to enter text. | Choose an item. |
| Click or tap here to enter text. | Choose an item. |

Add new lines as needed to disclose ALL CURRENT Co-Is.

1. **External IRB Approval:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes | No | N/A |
| Has this study been previously approved by another IRB?If yes, upload IRB approval.  |[ ] [ ] [ ]
| Does/did this study require renewal by another IRB?If this study was previously approved by another IRB, please explain below why continuing review was or was not necessary (i.e., ongoing study at both institutions, closed study at other institution because affiliation terminated, etc.) |[ ] [ ] [ ]
| Explanation: Click or tap here to enter text. |

1. **Conflict of Interest**

|  |  |  |
| --- | --- | --- |
| Do you or any investigators participating in this study have a financial interest or other conflict of interest related to this project? | Yes [ ]  | No [ ]  |

1. **Funding Source:**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Was the initial project funded/sponsored? If yes, answer the following two questions.  |[ ] [ ]
| 1. Is the funding ongoing/has ended? If yes, provide the following.
 |[ ] [ ]
| 1. Internal Grant Name: Click or tap here to enter text.
2. External Grant Agency Name: Click or tap here to enter text.
3. External Grant Number: Click or tap here to enter text.
4. Upload Award Letter if not done so already.
 |
| 1. Is the application for funding is pending/will be submitted? If yes, provide the following.
 |[ ] [ ]
| 1. Internal Grant Name: Click or tap here to enter text.
2. External Grant Agency Name: Click or tap here to enter text.
3. External Grant Number: Click or tap here to enter text.
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1. **Scholarship of Engagement**

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| Is your research considered scholarship of engagement? Scholarship of engagement involves a collaborative interaction with the community, and it is beneficial to you as the researcher and to the community members and/or organizations with whom you are collaborating in any of the following ways: for the exchange, exploration, and application of knowledge, information, and resources. | Yes[ ]  | No[ ]  |

1. **What is the current status of your study?** Please **check one** that applies.

|  |  |
| --- | --- |
| Not started, planning on enrollment within the next year. | [ ]  |
| New subject enrollment still in progress | [ ]  |
| Enrollment closed, but subjects are still involved in data collection procedures. | [ ]  |
| Subject involvement is complete, analyzing the data with identifiable information. | [ ]  |
| Subject involvement is complete, analyzing the data with no identifiable information. Identifiers have been removed or were not collected.If you select this option, please **STOP** and submit a **FINAL REPORT FORM** instead. Data analysis needs continuing review ONLY if the data includes identifiable information. If the only research activity remaining is data analysis with no identifiable information, your study is considered closed. | [ ]  |
| Other (Explain): Click or tap here to enter text. | [ ]  |

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| **General Study Information** |  |

1. **Statement of Progress**

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| In the textbox below provide a brief summary of the study progress to date. Summary should be less than 500 characters. |
| Click or tap here to enter text. |

1. **Unanticipated Challenges**

Have there been unanticipated challenges for this study? Provide a brief summary of issues present for researchers that the IRB should be aware of.

1. **Current Consent Forms**

Attach a copy of current consent form(s) to your submission if subject recruitment is still active. Include assent, consent, verbal scripts, etc.

1. **Knowledge of Increased Risk**

|  |  |  |
| --- | --- | --- |
| To your knowledge, since the last approval date, has there been any new information, either through the study itself or through outside sources (e.g. literature, journal articles, conferences, etc.) that may indicate an increased risk to subjects in this study, including social, physiological, or physical harm)?If you answered **YES**, explain below.  | Yes [ ]  | No [ ]  |
| Explanation: Click or tap here to enter text. |

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| **Participants**  |

1. **Vulnerable Populations**

|  |  |  |
| --- | --- | --- |
| Does this study include vulnerable populations defined by federal regulations?*Populations listed below are defined as vulnerable per federal regulations.* | Yes [ ]  | No [ ]  |
| Indicate if you target any of the following populations in your study. Targeting includes recruitment of the population as persons of interest rather than including them as happenstance of broader recruitment strategy. **Mark all that apply.**[ ]  Pregnant persons, human fetuses, or neonates[ ]  Prisoners[ ]  Children / Persons under the age of 18[ ]  Individuals with impaired decision-making capacity[ ]  Economically or educationally disadvantaged persons |

1. **Participant Recruitment and Subject Attrition/Withdrawal**

|  |  |
| --- | --- |
| Indicate the number of participants you initially aimed to include in this study: | Click or tap here to enter text. |
| Please indicate the total number of participants involved in this study to date: | Click or tap here to enter text. |
| If this goal has not been attained, please explain: Click or tap here to enter text. |
| How many additional/new participants do you plan to recruit from this point onward? | Click or tap here to enter text. |
| Indicate the number of participant withdrawals that have taken place over the course of this study: | Click or tap here to enter text. |
| Provide a summary of the reasons for withdrawal if known.: Click or tap here to enter text. |

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| **Study Modifications** |

1. **Study Amendments**

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| Are there any proposed changes/amendments that need to be reviewed and approved at this time?Select the statement below that most accurately represents this study’s status in regards to modifications. Modifications include, but are not limited to, changes in investigators or research team members, purpose/scope of the research, recruitment procedures, compensation, subject population, data collection procedures, consent process/forms, and/or surveys or other data forms. |
| **Select one option below.** [ ]  No modifications have been made to this study; there are no modifications needed at this time. [ ]  Modifications were reviewed and approved at a previous date and there are no new modifications. Date modifications were last approved: Click or tap here to enter text.[ ]  There are modifications that need approval. If there are modifications that need approval, STOP this form and submit a change in research form with an uploaded narrative of changes and why they are necessary prior to the final submission of the study renewal. At this point, we are not able to simultaneously approve renewals and changes. You must complete one at a time. |

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| **Adverse/Unanticipated Events & Complaints** |

1. **Adverse/Unanticipated Event**

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| --- | --- | --- |
| Have there been any adverse or unanticipated events? If your answer is YES, please answer the following questions. | Yes [ ]  | No [ ]  |
| 1. Was an incident report submitted? If YES, specify the date here: Click or tap here to enter text.
 | Yes [ ]  | No [ ]  | N/A [ ]  |
| 1. Provide a summary, including the outcome of the event: Click or tap here to enter text.
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1. **Complaints**

|  |  |  |
| --- | --- | --- |
| Have you received any complaints regarding your research? If YES, please provide a summary of any complaints about the research from subjects or others since the last IRB review below. | Yes [ ]  | No [ ]  |
| Explanation: Click or tap here to enter text. |

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| **Data Storage** |

1. **Data Security**

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| Where are project files stored? Indicate specific locations and specify two sets of lock and key. Data must be kept for at least three years. |
| Click or tap here to enter text. |

1. **Identifiable Data**

|  |  |  |
| --- | --- | --- |
| Do you have any identifiable data stored?If YES, explain how confidentiality will be maintained below.  | Yes [ ]  | No [ ]  |
| Explanation: Click or tap here to enter text. |

1. **Secondary Use of Data**

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| --- | --- | --- |
| Do you plan to share the data with other researchers?If YES, detail who you will share the data with for secondary research below. Be sure disclosure of such a plan is included in the consent document. | Yes [ ]  | No [ ]  |
| Details: Click or tap here to enter text. |
| Is there a possibility that the raw data be shared in a repository for any researcher to use and/or replicate? | Yes [ ]  | No [ ]  |
| Will the data include identifiers?If YES, please list any direct or indirect identifiers that will be in the shared data set below.  | Yes [ ]  | No [ ]  |
| Identifiers: Click or tap here to enter text. |

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| **Additional Comments** |

1. **Information to Consider**

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| Is there any additional information that needs to be considered? If you answered **YES**, please provide details below.  | Yes [ ]  | No [ ]  |
| Explanation: Click or tap here to enter text. |

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| **Principal Investigator’s Pledge** |

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| I affirm the accuracy of this application, and I accept the responsibility for the conduct of this research, the supervision of human subjects, and maintenance of informed consent documentation as required by the Institutional Review Board. | Yes[ ]  | No[ ]  |
| I will promptly report any unexpected or otherwise significant adverse effects encountered during this study. |[ ] [ ]
| I certify that the project identified above will be carried out as approved by the IRB and will neither be modified nor carried out beyond the period approved without express review and approval by the IRB. |[ ] [ ]

**Upload a copy of this form to the IRB Portal.**

**Ensure additional documentation is uploaded with your renewal submission, such as:**

* **Current CITI training certificates for all research personnel is REQUIRED.**
* **If study is approved by another IRB, upload approval notification.**
* **If study is currently funded/sponsored or if funding has ended, upload award letter.**