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Description automatically generated

**HUMAN SUBJECTS RESEARCH PROPOSAL MODIFICATION FORM**

|  |  |  |
| --- | --- | --- |
| Office Use Only | Date Received: | Select the date |
| Reviewer(s): |  |
| IRB Approval No: |  |

**Use t**his form to request modifications to an already approved Institutional Review Board IRB protocol.

**Instructions:** Please complete all sections of this form and submit it to the IRB office for review and approval. Incomplete forms may be delayed or returned.

|  |
| --- |
| **SECTION 1: PROJECT AND RESEARCHERS’ DETAILS** |

**1.1 Project title:**

|  |
| --- |
| Enter Project title here |

**1.2 Project timeframe:**

|  |  |  |  |
| --- | --- | --- | --- |
| **IRB Approval Number:** |  | **IRB Approval Date:** | Select a date. |

**1.3 Primary Faculty/ Staff Applicant:**

If any other researchers, either employed by D'Youville University or from external institutions, will be involved in this project, please list their names in section 1.5

|  |  |  |  |
| --- | --- | --- | --- |
| Applicant Name: |  | Employee ID: |  |
| Applicant Title: | Choose an item. |  |  |
| School: | Choose an item. | Phone: |  |
| Department: |  | | |
| Email: |  | | |
| Research experience relevant to the project: |  | | |
| Role in the research: |  | | |

**1.4 Student Projects:**

If the project is to be undertaken by a research student as part of their studies, please complete **Section 1. 5.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No: | Name | Student ID | Email | Phone: |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |

**1.5 Other Researchers/Supervisor(s)/Research Director:**

List all other researchers or supervisors in the box below:

|  |  |
| --- | --- |
| **Names:** | **Department:** |
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| **SECTION 2: MODIFICATION REVIEW APPLICATION** |

**2.1 Briefly describe the proposed modifications to the research protocol.**

**Enter your response here**

**2.2 Be clear and concise, outlining the specific changes you are requesting.**

**Enter your response here**

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| **SECTION 3: CATEGORIZATION OF MODIFICATIONS** |

**3.1 Indicate whether the proposed modifications are considered minor or major based on the IRB criteria** (Please see Note1 below).

**Enter your response here**

**3.2 Briefly explain your reasoning for this categorization.**

**Enter your response here**

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| **SECTION 4: IMPACT OF MODIFICATIONS** |

**4.1 Explain how the proposed modifications will impact the following aspects of the research:**

**Enter your response here**

**4.1.1 Risks and benefits to participants**

**Enter your response here**

**4.1.2 Specific aims or design of the study**

**Enter your response here**

**4.1.3 Recruitment procedures**

**Enter your response here**

**4.1.4 Data collection procedures**

**Enter your response here**

**4.1.5 Informed consent process**

**Enter your response here**

**4.1.6 Data security and confidentiality**

**Enter your response here**

**4.1.7 Budget or timeline (if applicable)**

**Enter your response here**

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| **SECTION 5: JUSTIFICATION FOR MODIFICATION** |

**5.1 Explain the rationale behind the proposed modifications.**

**Enter your response here**

**5.2 Why are these changes necessary for your research?**

**Enter your response here**

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| **SECTION 6: REVISED DOCUMENTS (IF APPLICABLE)** |

**6.1 If any documents within the IRB protocol require revision due to the proposed modifications, describe them below and submit the revised versions along with this form. This might include the consent form, recruitment materials, or study procedures documents.**

**Enter your response here**

|  |
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| **SECTION 7: ADDITIONAL INFORMATION** |

**7.1 Use this section to provide any additional information relevant to your modification request**

**Enter your response here**

|  |
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| **SECTION 8: DECLARATION BY THE RESEARCHER(S)** |

**8.1 Declaration by the Researcher(s):**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **I/we, the researcher(s):**   * **have read the DYU Institutional Review Board (IRB) Manual for the Researchers, and I will adhere to the policies and procedures explained therein.** * **have reviewed and understood the ethical principles outlined in the Belmont Report.** * **have prepared this research protocol in accordance with these ethical principles and guidelines.** * **will conduct this research with scientific integrity and ensure the safety and well-being of all participants.** * **will obtain informed consent from all participants before their involvement in the research.** * **will maintain the confidentiality of all participant data.** * **will disclose any potential conflicts of interest that may arise during the project.** * **will report any serious adverse events to the IRB promptly.** * **will comply with all applicable regulations and guidelines governing human subject research**   **All persons named in Section 1 are required to sign below:** | | | | | |
| Research Director's Signature: |  | Name: |  | Date: | Select a date |
| Researcher’s signature: |  | Name: |  | Date: | Select a date |
| Researcher’s signature: |  | Name: |  | Date: | Select a date |
| Researcher’s signature: |  | Name: |  | Date: | Select a date |
| Researcher’s signature: |  | Name: |  | Date: | Select a date . |
| Researcher’s signature: |  | Name: |  | Date: | Select a date |
| Researcher’s signature: |  | Name: |  | Date: | Select a date |

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| **SECTION 9: CHECKLIST** |

**The following documents are attached to this application:**

Clearly label all attached documents with relevant names (including student/staff ID).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Yes** | **No** | **N/A\*** | **Item** | **Attachment Label** |
|  |  |  | CITI or NIH certificate of completion |  |
|  |  |  | Consent Form |  |
|  |  |  | Site permission approval letter |  |
|  |  |  | Procedure/protocol for interviews or focus groups including topics, questions |  |
|  |  |  | Data collection instrument (e.g., Questionnaire, Interview guide) |  |
|  |  |  | Adverse events procedure |  |
|  |  |  | Other recruitment documentation including advertisements, flyers, recruitment letters, emails of introduction, copy of Facebook event pages and social media event sites. |  |
|  |  |  | Research with people outside the US: Evidence of permissions, approvals from overseas authorities etc. |  |
|  |  |  | Administration of Drugs Form |  |
|  |  |  | Annual Report on Project Status (if extending project) |  |
|  |  |  | Any supporting documentation |  |

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| **SECTION 10: HOW TO SUBMIT THIS APPLICATION** |

Submit your proposal and all checked documents from Section 9 to the DYU IRB via email: [irbhelp@dyc.edu](mailto:irbhelp@dyc.edu).

Notes1

**Minor Modifications**

* Involve adjustments to research activities that have minimal impact on the risk-benefit assessment of the study and don't significantly alter the study's aims or design.

Examples include changes to research staff, adding or removing research activities not central to the main protocol, modifications to recruitment materials, adjustments in enrollment numbers, refinements to inclusion/exclusion criteria, alterations to study procedures or activity duration, updates to safety measures or participant protections, adjustments to data security or confidentiality practices, changes to participant compensation or payment schedules (with justification), improvements to the clarity of statements or corrections to typos (as long as the meaning remains unchanged), or adding/removing study sites.

**Major Modifications**

* Involve significant changes to research activities that substantially impact the risk-benefit assessment or involve major alterations to the study's aims or design.

Examples include significant broadening or narrowing of inclusion/exclusion criteria that affect risks and benefits, changes in dosage or administration route of an administered drug, substantial extensions to the duration of exposure to the study activity, inclusion of a new study device not previously approved, removal of safety-related procedures or tests, site-specific requirements impacting the original study, additions to the informed consent disclosure to address new risks, addition of an investigator with a conflict of interest, or any changes deemed by the IRB reviewer as not meeting the criteria for minor modifications.

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| **Reviewer Use only** |
| **Overall Comments and Recommendations** |
| ***Please provide your written feedback and recommendations for improvement on each section of the protocol.*** |
|  |

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| --- | --- |
| **Disposition: Check the appropriate disposition** | |
|  | Full Approval (no changes required) |
|  | Approval with recommendation: Proceed with Suggestions (minor improvements recommended) |
|  | Approval with Conditions: (There are severe and many concerns) |
|  | Disapproval (major revisions required) |
|  | Approval ID (Administrator use only): |
|  |  |