**Concordia University Texas Institutional Review Board
2021-2022 CTX IRB Application Modification Template**

*Please use the table below to inform the CTX IRB of any modifications to an exempt or approved research study. Details of proposed modifications should be listed below by application section; indicate “NONE” for sections without proposed modifications. Completed forms should be saved using the format “2020-29-Smith\_Modification\_Jan1.doc” and submitted by email to* *irb@concordia.edu* for review and response from the CTX IRB.

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| --- | --- | --- | --- | --- | --- |
| **CTX IRB Identifier (e.g., 2019-29-Smith)** |  | **Principal Investigator** |  |  | ***Date*** |

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| --- | --- |
| **APPLICATION SECTION** | **PROPOSED MODIFICATION(S)** |
| 1. **Title**
 |  |
| 1. **Principal Investigator (PI)**
 |  |
| 1. **Purpose**
 |  |
| 1. **Specific Aims of Proposed Research**
 |  |
| 1. **Background/Significance of Proposed Research**
 |  |
| 1. **Research Site(s)**
 |  |
| 1. **Conflict of Interest**
 |  |
| 1. **Study Team**
 |  |
| 1. **Study Design and Procedures**
 |  |
| 1. **Participant Recruitment Method(s)**
 |  |
| 1. **Consent Process for Participants**
 |  |
| 1. **Participants and Target Population**
 |  |
| 1. **Inclusion and Exclusion Criteria**
 |  |
| 1. **Accessibility**
 |  |
| 1. **Informed Consent Documentation**
 |  |
| 1. **HIPAA Privacy Protections**
 |  |
| 1. **FERPA Protections**
 |  |
| 1. **Vulnerable Populations**
 |  |
| 1. **Risks**
 |  |
| 1. **COVID-19 Safeguards**
 |  |
| 1. **Benefits**
 |  |
| 1. **Participant Privacy**
 |  |
| 1. **Data Confidentiality**
 |  |
| 1. **Data or Statistical Analysis Plan**
 |  |
| 1. **Compensation for Research Participation**
 |  |
| 1. **Sharing Study Results**
 |  |
| 1. **External IRB Approval**
 |  |
| 1. **Unanticipated Events**
 |  |
| **Supporting Documentation – Informed Consent(s)** |  |
| **Supporting Documentation – Research Material(s)** |  |