

This document is simply a template for drafting and personal records. All submissions should be made direct within the current NIU IRB portal digital form.

**Section A: ADMINISTRATIVE INFORMATION**

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **BE SURE TO CLICK SUBMIT OUTSIDE OF THIS DOCUMENT WHEN YOU ARE READY TO SUBMIT EVERYTHING!!!** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | *DO NOT USE THE****PRINT****BUTTON AT THE TOP OF THE FORM* |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **To print, select "control" (or "command") P - then use "More Settings" in order to select "Minimum" margins** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **ID#**  **Title:**  **Main PI:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **Department** | : | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Have all researchers completed the **CITI course "Social and Behavioral Research - Basic Course"** in the past 5 years? | | **Yes  No** | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | BE SURE TO ADD ALL PERSONNEL TO THIS PROTOCOL RECORD USING THE **PERSONNEL TAB** ON THE INITIAL REVIEW SUBMISSION PAGE (all personnel need to be linked to the entire record rather than entered into this application). |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **Within the personnel page, use the drop down menus to indicate each person's role (PI for main Principal Investigator), Mentor (faculty advisor overseeing thesis or dissertation), co-Investigator (all other researchers included faculty when the project is NOT a thesis or dissertation).** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | PLEASE BE AWARE THAT ALL COMMUNICATIONS WILL BE **SENT TO NIU EMAIL ACCOUNTS** - CHECK YOUR ACCOUNT REGULARLY OR LINK IT TO A PREFERRED EMAIL ACCOUNT |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Is the main researcher on this project a student (either undergrad or grad)? **[Is a student submitting the project?]** | | **Yes  No** | |

|  |
| --- |
|  |

|  |
| --- |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Is this project grant funded - through either internal or external funds? | | **Yes  No** | |
| |  |  |  | | --- | --- | --- | |  | Select any items below that are relevant for your protocol [**Note** - item selection will open additional sections to complete including new tabs on the left] : |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | This study involves deception | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | ­­\_\_ | This study involves compensation (e.g., class credit, payment) | |

**SECTION B: PURPOSE AND PROCEDURES**

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **PURPOSE:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Describe the purpose of your study and the reason(s) this study is needed. Include any necessary background information and a description of your hypothesis or your research question. | | **CLICK HERE TO TYPE** | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | ***The following items will help the IRB reviewers understand the step-by-step procedures of your study:*** | |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **PARTICIPANTS:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **Gender/Biological Sex:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | All (from below) | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Man/Male | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Woman/Female | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | | \_\_ |  | Transman | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Transwoman | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Nonbinary/Genderqueer | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Agender | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Other | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **Age:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Will any participants be under age 18? | | Yes  No | |

|  |  |
| --- | --- |
| |  | | --- | | Estimated Ages:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **Special Populations:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | Select any special populations being targeted in this study: |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Pregnant women | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Fetuses | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Prisoners | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Homeless individuals | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Victims of physical or psychological trauma | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Those with decisional impairments/mental disabilities | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Specific racial/ethnic groups | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | People in a different country | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **Total Count:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| Target number of ALL participants in the entire study (keep in mind that this is just an estimate):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Students as Participants:**   |  |  | | --- | --- | |  | Will the participants be students in one of the researcher's classes? | | **­­ Yes  No** | |
| |  |  |  | | --- | --- | --- | |  | **RECRUITMENT:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Explain the recruitment procedures (how will participants learn about the study?). If using the snowball technique, please explain who contacts potential participants (other participants or the researcher). | | **CLICK HERE TO TYPE** | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **UPLOAD:** Using the **ADD** button next to "Document/Form" on the submission page, upload any **RECRUITMENT SCRIPTS OR FLYERS**. |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Explain the participant eligibility and exclusion criteria that will be used. | | **CLICK HERE TO TYPE** | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Will any outside institutional approval (e.g., schools, hospitals) be needed before being able to access potential participants? | | Yes  No | |

|  |
| --- |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **INFORMED CONSENT PROCESS:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **Changes to requirements:** Please be aware that the federal requirements for consent forms were updated in 2019. **You are now required to include a "key information" section** at the beginning of the consent form. In addition, all studies involving the collection of identifiable data (even if matched using a code) will **need to include a statement regarding how the data will be handled after de-identification occurs**. Please see the updated sample consent form on the IRB "Documents" page. |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Explain the consent process (verbal and/or written procedures for informing participants of the nature of the study and what they will do). | | **CLICK HERE TO TYPE** | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **UPLOAD:** Using the **ADD** button next to "Document/Form" on the submission page, upload all **CONSENT RELATED DOCUMENTS** (assent, consent, parent permission) that are appropriate for each group of subjects participating in the study. Consent forms: 18 and over; assent forms for under 18; parent permission forms for parents or legal guardians. A script may be more appropriate for a very young participant. Parent permission alone is acceptable if the research will provide direct benefit to the subject, a member of the subject's family, or other children with the same condition as the subject. |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **MATERIALS:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **UPLOAD:** Using the **ADD** button next to "Document/Form" on the submission page, upload copies of all **MATERIALS** including questionnaires, interview items, a listing of all information/data to be collected, etc. |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | It is the responsibility of the researcher to **obtain any relevant permission for copyrighted materials**. |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | If the research involves an **oral interview or focus group discussion** that could evolve as it progresses, include a list of discussion topics and any "starter" questions for each topic that can reasonably be expected to be covered. |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | If a **draft of a written questionnaire** is attached, it should be clearly labeled as such and a final version must be submitted before data collection begins. |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **DATA COLLECTION:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Describe the data collection procedures including what data will be collected, how it will be collected (include a description of any interventions to be used), the duration of participation in the study session(s), and how the session(s) will end. | | **CLICK HERE TO TYPE** | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **DEBRIEFING:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Will participants be debriefed? | | Yes  No | |

**SECTION C: RISKS AND BENEFITS**

**Risks in the current study (select all that apply):**

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Use of identifiable, private information | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Psychological stressors (e.g., social isolation, threat of embarrassment) | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Collection of personal or sensitive information (through surveys, interviews, etc.) | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Presentation of content that people may consider sensitive, offensive, or threatening | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Invasion of privacy of participant or family | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Social or economic risk | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Risk associated with exercise or physical exertion | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Legal risk | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Review of medical records | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Review of criminal records | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Review of educational records | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Employment/occupational risk | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | \_\_ | Other | |

**Risk/benefit information:**

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | What knowledge/benefit(s) to the field will be gained from the study? | | **CLICK HERE TO TYPE** | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | What direct benefits (if any) are there for the participants from the proposed research? [e.g., learning a skill, psychological insight - please note: compensation is NOT a direct benefit.] | | **CLICK HERE TO TYPE** | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Describe any potential risks (e.g., breach of confidentiality, economic loss, legal risk, physical harm, social embarrassment) to the participants posed by the proposed research. [Note: Some studies may have "no reasonably foreseeable risks.] | | **CLICK HERE TO TYPE** | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| |  |  |  |  | | --- | --- | --- | --- | |  |  | **NOTE:** Investigators are required to report all unexpected and/or adverse events to the IRB. Therefore, it is important that you list all reasonably anticipated risks because unanticipated adverse events may need to be reported by NIU to OHRP. |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Federal regulations require that researchers use procedures that minimize any risks to participants. What procedures will be used to minimize each risk listed above? | | **CLICK HERE TO TYPE** | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | How do the potential benefits of the study justify the potential risks to the participants? | | **CLICK HERE TO TYPE** | |

**Support services:**

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Will support services be required to minimize risk of harm to participants? | | Yes  No | |

|  |
| --- |
|  |

**SECTION D: INFORMED CONSENT DETAILS**

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | Select the items below that are relevant for the current study (and answer any additional items that are presented): |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | ­ | \_\_The use of audio, video, or film recording | |

|  |
| --- |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  |  | \_\_The use of consent/assent documents written in a language other than English | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  |  | \_\_The use of any HIPAA protected health information | |

|  |
| --- |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  |  | \_\_The use of any protected school records | |

|  |
| --- |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  |  | \_\_A request for a waiver of a signature on the informed consent document | |

|  |
| --- |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  |  | \_\_A request for a waiver/alteration of some other aspect of the informed consent document [This section is particularly relevant for studies involving deception.] | |

**SECTION E: CONFIDENTIALITY/ANONYMITY**

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Will identifying information be connected to the data? **Check "yes" even if connection only occurs through an identification key linking identities to a pseudonym or code that is kept separate from the data.** | | Yes  No | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Will data be collected through an on-line survey tool (e.g., Qualtrics)? | | Yes  No | |

|  |
| --- |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | How will the records (data, recordings, consent forms) be stored and for how long? | | **CLICK HERE TO TYPE** | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **Please note:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | Signed informed consent documents must be maintained for **3 years** following completion of data collection. |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Explain how the data records will be disposed of/destroyed. | | **CLICK HERE TO TYPE** | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **Please note:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | Some electronic survey items may not be accessible to people who use screen readers as a way of accommodating their visual impairments. We recommend that you follow the link below to check the accessibility of your Qualtrics survey items: https://www.qualtrics.com/support/survey-platform/survey-module/survey-tools/check-survey-accessibility/) |  | |

**INVESTIGATOR INFORMATION**

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Do any of the researchers working on the project have any potential conflicts of interest? [These may include financial or personal interest or any condition in which the investigator's judgment regarding a primary interest may be biased by a secondary interest.] | | Yes  No | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | List each investigator's qualifications to conduct any procedures to be used in this study. This item is referring to training whether in the classroom, lab, or field. | | **CLICK HERE TO TYPE** | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | PLEASE BE AWARE THAT ALL COMMUNICATIONS WILL BE **SENT TO NIU EMAIL ACCOUNTS** - CHECK YOUR ACCOUNT REGULARLY OR LINK IT TO A PREFERRED EMAIL ACCOUNT |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **MANDATORY:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | Ready to submit? |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | |  | \* Selecting "yes" indicates that I am aware that **I still need to click "submit"**after I close out of this e-form application. | | **Yes  No** | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | **READ THIS BEFORE SUBMITTING:** |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  | ***TO SUBMIT:****Click****completed****at the top of this e-form. Save and close the e-form. Upload any necessary documents using the****Add****button. Click the****SUBMIT****button in the upper right of the submission page. A window will appear - click****ACCEPTED****and then click****SUBMIT****once more.* |  | |

**Office of Research Compliance, Integrity & Safety**

**Northern Illinois University**

DeKalb, IL 60115

**PHONE:**815-753-8588

**FAX:**815-753-1631

<http://www.research.niu.edu/divresearch/compliance/safety/index.shtml>

[Northern Illinois University](http://www.niu.edu/)