**Getting Started**

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|  | **About Cayuse IRB (Human Ethics)**   * Cayuse IRB is an interactive web application. * As you answer questions, new sections relevant to the research being conducted will appear. * You do not have to finish the application in one sitting - all information can be saved. |
|  | **Submission Guidance**   * Complete this application form for a new research study submission. * Each application question must be specifically and accurately answered in non-technical language. * If technical language is required - clearly define the terms/and or concepts in the application and all  study documents. * Study information must be detailed, harmonized, and consistent throughout all application sections  and study documents. * Do not copy and paste language from other documents into the application. * Respond to all application questions as if you are talking with the IRB, directly. * All items with red stars are required and must be completed to submit. * As you complete the application, save frequently. * If application questions are numbered or bulleted, include a numbered or bulleted list in your response. |

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|  | **Training and Education Canvas**   * For an in-depth understanding of the IRB submission and review process and special focus topics,  please reference the [Institutional Review Board (IRB) Training and Guidance](https://tcsedsystem.instructure.com/courses/945) course.   **CITI**   * For human subjects protection training, please reference the [Social and Behavioral Research](https://www.citiprogram.org/index.cfm?pageID=14&message=20)  course modules. |
|  | **Study Materials and Documents**  Categories of study materials required to be attached to the IRB application,**if applicable**, and when  prompted, include:   * CITI Training Score Report * Site Permission Documentation * Recruitment Materials * Screening Materials * Informed Consent Document(s) * Assent Document(s) * Study Measures, Data Collection Tools and/or Instructional Materials * Debriefing Materials * Resource or Referral Information |

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|  | **TCSPP Research Compliance**  Study procedures CANNOT begin until the IRB issues a letter of documented approval or exempt determination to begin the research, or a non-human subjects notification.    * Conducting human subjects research without documented IRB approval or notice  of exemption is noncompliance. |
|  | **Questions?**  **Help Text:**   * Information and guidance can be found by clicking the question mark at the top-right  corner of each application section.   **Resource Center:**   * Assistance and articles can be found by clicking the orange question mark at the  bottom-right corner of each application page.   **Cayuse Help Center**   * For more information about the submission process, tracking, tasks, or technical support, please refer to the [Cayuse IRB Procedures Manual](http://support.cayuse.com/). * Please note, you will need to create a separate username and password for the Cayuse Help Center, as access to this site does not use the TCSPP single sign-on (SSO) credentials.   **TCSPP IRB**   * Email: [irb@thechicagoschool.edu](mailto:irb@thechicagoschool.edu) * Website: [https://community.thechicagoschool.edu/irb](https://community.thechicagoschool.edu/irb/) |

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|  | | **Acknowledgement**  I have read the information above and am ready to begin my submission. | |
|  | Yes | |

**Study Personnel**

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|  | | **Affiliation** | |
|  | Faculty | |

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|  | | Please list your department. |
|  | Student | |

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|  | Dissertation |
|  | Other |
|  | Staff |

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|  | | Please list your department. |
|  | Adjunct Faculty | |

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|  | Please list your department. |

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|  | **Department Chair Approval Documentation**  Please upload approval from the Department Chair to conduct your research.  ATTACH  , REQUIRED |

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|  | **Study Personnel**  If you cannot find a person in the people finder, please contact the IRB Office at [irb@thechicagoschool.edu](mailto:irb@thechicagoschool.edu) |

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|  | **Principal Investigator**  Provide the name of the Principal Investigator (PI) for this study.  FIND PEOPLE  , REQUIRED |

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|  | **Qualifications**  Briefly describe your qualifications to conduct the study.   * Students: Include a brief statement about how your Chair will mentor you on this project. |

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|  | **Principal Investigator CITI Training Documentation**   * Attach your [CITI](http://www.citiprogram.org/) completion report **(not the certificate)** for the Social and Behavioral  Research modules. * A score of 80% or higher must be obtained for each module. * CITI training must have been completed in the past TWO YEARS to be valid.   ATTACH  , REQUIRED |

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|  | **Primary Contact**  Provide the name of the person completing this application.  FIND PEOPLE  , REQUIRED |
|  | **Dissertation or Thesis Chair**  Provide the name of your Chair.  FIND PEOPLE |

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|  | | **Other TCSPP Research Personnel**  Will there be TCSPP research personnel who will either have contact (in-person or virtual) with research participants or who will have access to identifiable data, at any point throughout the study? | |
|  | Yes | |

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|  | List all TSCPP research personnel.  FIND PEOPLE  , REQUIRED |

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|  | **Qualifications and Role**  Briefly describe the qualifications for **each** person to conduct the study - and - their role in the research. |

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|  | **TCSPP Research Personnel CITI Training Documentation**   * Attach the [CITI](http://www.citiprogram.org/) completion report **(not the certificate)** for the Social and Behavioral  Research modules for all TCSPP research personnel. * A score of 80% or higher must be obtained for each module. * CITI training must have been completed in the past TWO YEARS to be valid.   ATTACH  , REQUIRED |

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|  | | **Outside Research Personnel**  Will there be non-TCSPP research personnel who will either have contact (in-person or virtual)  with research participants or who will have access to identifiable data, at any point throughout the study? | |
|  | Yes | |

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|  | List all non-TSCPP research personnel who will either have contact (in-person or virtual)  with research participants or who will have access to identifiable data, at any point throughout the study?   * Briefly describe the qualifications for **each** person to conduct the study - and - their role in the research. * Listed non-TCSPP research personnel may not be covered under TCSPP's Federal Wide Assurance (FWA) and may require their own IRB approval through their affiliated institution or organization. * Please contact [irb@thechicagoschool.edu](mailto:irb@thechicagoschool.edu) to determine if the non-TSCPP research personnel are considered engaged in the research to discuss potential options. |
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|  | **Outside Research Personnel CITI Training Documentation**   * Attach the [CITI](http://www.citiprogram.org/) completion report **(not the certificate)** for the Social and Behavioral  Research modules for ALL outside research personnel. * A score of 80% or higher must be obtained for each module. * CITI training must have been completed in the past TWO YEARS to be valid.   ATTACH  , REQUIRED |

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|  | | **Conflict of Interest (COI)**  Do you or any research personnel have a potential conflict of interest for this study?   * Examples include having interests in the outcome of the research that may lead to a personal advantage or financial gain, or holding responsibilities as an investigator and as a treating therapist for the same study participant. | |
|  | Yes | |

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|  | No |

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|  | Declare and/or explain the Conflict of Interest. |
|  | Explain your procedures to minimize the Conflict of Interest to ensure risks to participants are minimized, to include how you will prevent coercion and undue influence/pressure. |

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|  | | **Funding**  Is this study funded (e.g., grant, award, internal funds)? | |
|  | Yes | |

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|  | Funding is pending |
|  | No |

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|  | **Funding Source**  List all sponsors and/or funding sources. |
|  | **Grant/Award Letter**  Attach the grant or award letter.  ATTACH |

**Human Subjects Research Determination and Design**

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|  | | Is this study any of the following?   * Journalistic activities * Oral history (without extracting and generalizing themes) * Biography * Literary criticism * Legal research * Historical scholarship * Quality Assurance or Quality Improvement for program evaluation or improvement purposes, only * Comprehensive Review and Evaluation of the Literature (CORAL) * Development of a grant proposal * Theory of Clinical Application and Conceptualization * Public policy or legislative analysis | |
|  | Yes | |

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|  | **Non-Human Subjects Research Assessment**  To assist the IRB in this evaluation, please provide the following responses using bullet points to address each required element.   * Description of the project * Describe how and why the activity is not a systematic investigation designed to develop or contribute to generalizable knowledge. * Describe how you will not involve a living individual about whom you will obtain information through intervention or interaction with the individual and use, study, or analyze the information. |
|  | **Non-Human Subjects Research Assessment Supplemental Materials**  If applicable, attach any supplemental materials that may be used for the project.  ATTACH |

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|  | | **Research Determination**  Is the activity a **systematic** investigation **designed** to develop or contribute to **generalizable** knowledge? | |
|  | Yes | |

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| The activity is research. | |
|  | No | |

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|  | | **Research with Human Subjects Determination**  Does the research involve a living individual about whom an investigator conducting research  obtains information through intervention or interaction with the individual and uses, studies, or  analyzes the information? | |
|  | Yes | |

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| This activity is research with human subjects and requires IRB review. | |
| No |  | |

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| Contact the IRB Office at [irb@thechicagoschool.edu](mailto:irb@thechicagoschool.edu) |

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|  | | **Study Design**  Is this **exclusively** a secondary data analysis study? Examples include: retrospective or prospective analysis of existing or archival data, such as medical records, student records, data collected from previous studies, audio/video recordings, etc., that were initially collected for another purpose. | |
|  | Yes | |

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|  | | Does this study **exclusively** involve interacting or intervening with participants, online and/or in-person? Examples include: administering assessments, conducting interviews, implementing a behavioral intervention, engaging in physical procedures, research using experimental procedures, employing an online survey, conducting focus group sessions, etc. | |
|  | Yes | |

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|  | | Does this study involve secondary data analysis AND interacting and intervening with participants? | |
|  | Yes | |

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|  | No | |
| Contact the IRB Office at [irb@thechicagoschool.edu](mailto:irb@thechicagoschool.edu) | |

**Use of Secondary Data**

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|  | | Are you using a pre-existing data set (archival data) for secondary **retrospective** data analysis, only?   * All data exist at the time of this application submission. | |
|  | Yes | |

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|  | | Are you conducting **prospective** data analysis?   * Ongoing access to existing and present-time, accumulating data throughout the course of the study | |
|  | Yes | |

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|  | Provide the name of the database. |

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|  | * What is the purpose of the study? * Provide a description of the data set. |

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|  | | Are the data publicly available? | |
|  | Yes | |

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|  | Describe the information you intend to collect or obtain from the dataset. |

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|  | | Are the data identifiable? | |
|  | Yes | |

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|  | Clarify if you will attempt to re-identify participants (e.g., if will you have a link to the coded information that may be used to re-identify the potential participants). |
|  | Explain your data confidentiality procedures, and include all of the following:   * How data will be transferred * How data will be stored and secured * How long data will be retained |

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|  | **Data Use Documentation**  Upload the original IRB approval letter, letter from original investigator, letter of support, and/or data use agreement from the organization granting permission to use the existing dataset. The document  should include the following information:   * All types of data to be accessed need to be explicitly detailed and listed. * How (what form) the data will be provided to you - identifiable, indirectly identifiable, coded, de-identified. If the data are coded, an explanation of how the data will be coded and if you  have access to the code for re-identification purposes. * How data will be transferred, secured, and stored for research purposes. * If consent was previously obtained from research participants to use data for future research  purposes. If yes, upload a copy of the consent document indicating this permission. * If other regulations do or do not apply to the disclosed records (e.g., FERPA, PPRA, HIPAA) and what provisions are in place to ensure compliance with these regulations.   ATTACH  , REQUIRED |

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|  | | **HIPAA**  The Health Insurance Portability and Accountability Act (HIPAA) requires additional protections for  Protected Health Information (PHI) collected from HIPAA-covered entities. HIPAA-covered entities  include health insurance plans, health clearinghouses, or entities that bill insurance for health care.  Are you prospectively collecting identifiable Protected Health Information (PHI) under a HIPAA-covered entity? | |
|  | Yes | |

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| You must include HIPAA Authorization language in your consent form. | |
| No |  | |

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|  | | **HIPAA**  The Health Insurance Portability and Accountability Act (HIPAA) requires additional protections for  Protected Health Information (PHI) collected from HIPAA-covered entities. HIPAA-covered entities  include health insurance plans, health clearinghouses, or entities that bill insurance for health care.  Are you obtaining existing Protected Health Information (PHI) from a HIPAA-covered entity? | |
|  | Yes | |

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|  | **HIPAA Authorization or Data Use Agreement**  Attach documentation of approval from the HIPAA-covered entity indicating you have permission to access the data. This may include a HIPAA Authorization form or a Data Use Agreement.  ATTACH, REQUIRED |

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|  | | **FERPA**  The Family Educational Rights and Privacy Act (FERPA) is a federal law protecting the rights of students regarding the privacy of their educational record. Collection of data from an official educational record must be FERPA-compliant.  Are you requesting access to TCSPP educational records? | |
|  | Yes | |

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|  | **TCSPP Student Record Permission Documentation**  Contact the Office of the Registrar and attach documentation of approval for use of student records.  ATTACH, REQUIRED |

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|  | | Are you requesting access to K-12 educational records? | |
|  | Yes | |

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|  | Explain the nature and content of the records to be accessed. |

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|  | How will you obtain parent permission to use the student records?   * Parental permission is only required for use of identifiable data from the educational record  of a minor. |

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|  | Explain how you plan to obtain permission from students/individuals to use their educational records  for research.   * Use of de-identified or anonymous records does not require individual permission. |

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|  | **K - 12 Student Record Permission Documentation**  Attach documentation of approval for use of student records.  ATTACH, REQUIRED |

**Research Site(s)**

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|  | | **Other Research Sites**  Does this study involve physical or virtual research sites or locations - other than TCSPP -  where research procedures will occur?   * Research procedures include recruitment, enrollment, interactions with participants, and/or  access to data. * Any social media sites, listservs, online forums, etc., not personally managed by you as a personal accountholder, must be included. | |
|  | Yes | |

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|  | List all collaborating sites and locations. You must include the site name, person of contact, and contact  information. |

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|  | Describe the site’s role in the research (e.g., recruitment, interactions with participants, access to data, etc.). |

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|  | Clarify if this study is being performed for the research site.   * If not, specify the reason for performing this study involving the site. * If applicable, explain what study procedures will occur for the site and if this study is a program evaluation or quality improvement project. |

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|  | Will data be stored at the research site?   * If yes, explain where data will be stored at the site, how data will be secured, who will have access to the data, and if the data are identifiable, coded, or de-identified. |

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|  | Will you present the results of the study to the research site(s)?   * If yes, explain how, and in what form, the site will receive the study results (e.g., identifiable, aggregate, etc.). * Providing individual results is not permitted. |

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|  | | **International Research**  Does this study involve research sites outside of the United States? | |
|  | Yes | |

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|  | Address each question, listed by number, in your response.  (1) Describe the site’s experience conducting research with study participants.  (2) Describe the site’s experience working with the population you intend to research.  (3) Specify the local regulations that govern research in the country, state, or locale.   * For more information, reference the [International Compilation of Human Research Standards](https://www.hhs.gov/ohrp/sites/default/files/2020-international-compilation-of-human-research-standards.pdf). |

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|  | **Site Permission Documentation or Letter of Support**  A letter of support to conduct research from each study site listed is required.   * **Virtual site:**A letter, email, or screenshot from the site/group administrator is required. * **Physical site:**The letter of support must be written on company letterhead, dated, include  a handwritten signature, and must include a description of the site’s involvement in the research.   If you do not have a site permission document or letter of support at the time of this initial, new study submission, attach a Word document listing**each** site and explain why the site permission documentation or letter of support is currently pending.  ATTACH  , REQUIRED |

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|  | | **Site IRB**  Does the other research site(s) have an IRB or Ethics Board? | |
|  | Yes | |

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|  | **IRB/Ethics Board Approval Letter**  If IRB/Ethics Board approval is not necessary or not available at this time, explain why and indicate if an approval letter will follow. |
|  | Attach the IRB/Ethics Board approval letter.  ATTACH |

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|  | | **Site Affiliation**  Are you or any research personnel an employee or affiliated with the listed site(s)? | |
|  | Yes | |

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|  | Address each question, listed by number, in your response.  (1) Explain your role at the site.  (2) Describe if will you be enrolling your clients or direct reporting employees?  (3) Explain the measures you have in place to mitigate or minimize these individuals from feeling  influenced or pressured (coerced) to participate in your study. |

**Purpose of the Study**

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|  | **Background**  Provide a brief summary of your study in non-technical terms. Limit this summary to no more than 300 words or 3 paragraphs. Please include the following information:   * Overall background with sources cited * Gaps in the literature * Knowledge to be gained |

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|  | **Hypothesis/Expected Results**  State the research problem(s) under investigation, hypothesis, and/or expected results. |

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|  | **Purpose**  What is the purpose of the study? |

**Participant Description**

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|  | **Sample Size**  Specify the **maximum** number of participants to be enrolled in the study.   * If you are enrolling multiple groups, provide the number of participants in each group. |

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|  | **Age Range(s)**  Specify the age range of participants to be enrolled.   * If you have more than one participant group, specify the age range or each participant group. |

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|  | **Inclusion Criteria**  Detail the relevant characteristics of individuals eligible to participate in this study.   * Use bullet points or a numbered list. |

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|  | **Exclusion Criteria**  Detail the relevant characteristics of individuals not eligible to participate in this study.   * Use bullet points or a numbered list. |

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|  | | **Study Groups**  Are participants going to be assigned to different study groups (e.g., experimental and control)? | |
|  | Yes | |

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|  | Describe the randomization/assignment procedure and how many participants will be in each group. |

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|  | | **Vulnerable and Special Populations**  Do you plan to include any of the following participant populations in your study? | |
|  | [Minors](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html) (under 18 years of age) | |

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| Complete the **Minors** section of this application and provide an assent plan in the Informed Consent section  of this application. |
| [Pregnant women](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html), human fetus and/or neonates |  |

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| Complete the **Pregnant Women, Fetuses, and Neonates** section of this application. | |
| [Prisoners](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html) or detainees (involuntarily confined) |  | |

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| Complete the **Prisoners** section of this application (Supplemental Application). | |
| Persons with a physical disability or physical health concerns |  | |

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|  | Persons with a decisional, cognitive, or mental impairment (includes individuals who are unable to  provide their own consent) | |
| Include information about if/how you plan to use a Legally Authorized Representative (LAR) for each  participant in the Informed Consent section of the application. | |
|  | Economically or educationally disadvantaged persons (includes individuals who are illiterate or have  limited literacy skills) | |

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| Adjust the language in your consent form appropriately. |
| Non-English speaking |  |

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| Translated documents must be uploaded to the submission. Provide the name and qualifications of the person who translated the study documents in the text box, below. | |
| Victims or survivors of crime or other traumatic experiences |  | |

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|  | Individuals in non-prison institutions (e.g., nursing homes, halfway houses, etc.) |
|  | Students |

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|  | None of the above |

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|  | **Rationale**  Describe the rationale for enrolling **each** participant group selected. |

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|  | **Protections and Safeguards**  For **each** group checked above, detail and describe the procedures in place to provide additional protections and safeguards to protect the rights and welfare of these participants. |

**Recruitment and Screening**

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|  | **Recruitment Process**  Describe how, when, where and by whom individuals will be recruited for study participation. |

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|  | **Recruitment Material(s)**  Reference the [Advertisements for Research](https://tcsedsystem-my.sharepoint.com/:w:/r/personal/sdixon2_thechicagoschool_edu/Documents/Cayuse%20Documents/Advertisements%20for%20Research.doc?d=w0392abc381784b5eab43480c4531e3af&csf=1&web=1&e=M0oqxs) requirements and [Sample Advertisement Flyer](https://tcsedsystem-my.sharepoint.com/:w:/r/personal/sdixon2_thechicagoschool_edu/Documents/Cayuse%20Documents/Sample%20Advertisement%20Fill.docx?d=wace4258756bd41989d5ec61dc6f4e819&csf=1&web=1&e=5fS94b)  and attach all recruitment materials.  ATTACH  , REQUIRED |

\*required

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **TCSPP Directory**  Will The Chicago School Directory Information be used to recruit participants for your study? | |
|  | Yes | |

|  |  |
| --- | --- |
| Contact Alicia Scott, IRB Director, after you have obtained documented IRB approval or notice of  exemption at [aliciascott@thechicagoschool.edu](mailto:aliciascott@thechicagoschool.edu). | |
| No |  | |

\*required

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **Screening**  Will you screen participants for study eligibility prior to enrollment (before consent is obtained)? | |
|  | Yes | |

|  |  |
| --- | --- |
|  | No |

|  |  |
| --- | --- |
|  | **Screening Process**  Describe how, when, where, and by whom individuals will be screened to determine study eligibility or ineligibility. |
|  | **Screening Material(s)**  Attach all screening materials – to include – eligibility and ineligibility notices or messages.   * Screening materials must be harmonized with the outlined study inclusion and exclusion  criteria, only. |

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|  | Explain why conducting a screening process is not applicable to the study. |

**Informed Consent**

|  |
| --- |
| **There are strict regulatory requirements regarding the format and content of consent forms.**   * **Use the**[Informed Consent template](https://tcsedsystem-my.sharepoint.com/:w:/r/personal/sdixon2_thechicagoschool_edu/Documents/Cayuse%20Documents/Consent%20Form%20Template%202020.docx?d=w45a310cb7b294852ab40262a8ef047de&csf=1&web=1&e=AaVWYY)**available on the**[TCSPP website](https://community.thechicagoschool.edu/irb/Pages/Application-Submission-Material.aspx)**as the basis for your consent form.** * **Consent forms that do not follow TCSPP IRB requirements will be returned for revision without IRB review.** |

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|  | | Will all individuals be able to legally consent for themselves?   * Select "No" if your study involves minors or persons requiring a Legally Authorized Representative (LAR). | |
|  | Yes | |

|  |  |  |
| --- | --- | --- |
| No | No | |
| Explain how you plan to involve a parent(s) in the case of minors, or a Legally Authorized Representative during the consent process in the description of the **Informed Consent Process** application section, below. | |

\*required

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| --- | --- | --- | --- |
|  | | Will informed consent be obtained for all research participants?   * Select "No" if your study involves deception. | |
|  | Yes | |

|  |  |
| --- | --- |
|  | No |

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| --- | --- |
|  | **Requirements for Waiver or Alteration of Consent**  The IRB may approve a consent procedure that does not include, or alters some or all, of the elements of informed consent. The IRB may waive the requirement to obtain consent, provided **ALL** the following criteria are met. This method could be appropriate for studies using archival data collection or studies involving deception.   * The research involves no more than minimal risk to the participants; * The research could not practicably be carried out without the requested waiver or alteration; * If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; * The waiver or alteration will not adversely affect the rights and welfare of the participants; **AND** * Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation.  Provide justification detailing why you are requesting to waive or alter informed consent and how your study fulfills the criteria for a waiver or alteration of consent. |

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|  | **Informed Consent Process**  You must provide the prospective participant sufficient information and opportunity to discuss and consider why they may, or may not, want to participate in the research. The consent process must minimize the possibility of coercion or undue influence.  Describe how, when, where and by whom consent will be obtained from individuals interested in study participation.   * Confirm participants will be able to ask questions and have their questions answered prior to obtaining consent. |

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|  | | Will individuals **physically** sign the consent form with a handwritten or “draw tool” signature?   * Select "No" if you plan to obtain online or verbal consent. | |
|  | Yes | |

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| --- | --- |
|  | No |

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|  | **Requirements for Waiver of Consent Documentation**  The IRB may waive the requirement to obtain a signed informed consent form for some or all participants, if **ANY** of the following criteria are met. This method could be appropriate for studies obtaining consent online or verbally. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants or legally authorized representatives with a written statement regarding the research.   * The only record linking the participant and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant (or legally authorized representative) will be asked whether the participant wants documentation linking the participant with the research, and the participant’s wishes will govern; * The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; **OR** * The participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.   Provide a justification for why you are requesting to waive documentation of consent and how your study fulfills the criteria for a waiver of consent documentation. |

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|  | **Informed Consent Document(s)**  Attach all consent materials in MS Word using the [Informed Consent template](https://tcsedsystem-my.sharepoint.com/:w:/r/personal/sdixon2_thechicagoschool_edu/Documents/Cayuse%20Documents/Consent%20Form%20Template%202020.docx?d=w45a310cb7b294852ab40262a8ef047de&csf=1&web=1&e=AaVWYY) – to include – verbal scripts, online consent forms, etc.  ATTACH  , REQUIRED |

**Study Procedures**

\*required

|  |  |
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|  | **Study Procedures**  Describe step-by-step, very clearly, all research procedures that will occur during your project. Be sure to include the following:   * Sequential description of all procedures to be conducted with the participants * Detail how, when, where and by whom data will be collected * The frequency and duration of all study visits and overall study participation * Whether video/audio/digital recording will occur * If compensation will be provided * Whether follow-up visits or debriefing meetings will occur   If you have two or more groups of participants, and/or multiple study visits, describe in detail the procedures for**each** group and/or visit. |
|  | **Multiple Study Groups and/or Visits**  Attach a chart, timeline, or table for multiple study groups and/or visits. |

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| --- | --- | --- | --- |
|  | | Does your study involve any experimental procedures? | |
|  | Yes | |

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| --- | --- |
|  | No |

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|  | Explain which aspects of the project are standard care, routine practice, normal educational practice, and/or any other aspect of this project that would normally occur outside of the research context. |

\*required

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|  | Explain which aspects of this project are specifically experimental to your research study. You must clearly differentiate the procedures which will occur that are unique, experimental in nature, and would not normally occur in standard care or normal/routine practice. |

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| --- | --- | --- | --- |
|  | | Will the participant be required to download an app or acquire software or programming with an end-user license agreement (EULA)? | |
|  | Yes | |

|  |  |
| --- | --- |
|  | No |

|  |
| --- |
| Indicate if the participant will be subject to an end-user license agreement (EULA) and whether EULA consent is required by for use of the digital platform, as the participants and the IRB must be aware of how those terms may affect the study participants.   * If consent to a EULA is required for this study, participants should be informed of this in the informed consent process and consent form – please also describe this to the IRB in the Study Procedures section of this application. * Any significant risks presented by use of the app (and by consent to its EULA) in the research must be identified to participants and the IRB. * Privacy risks, and the autonomy interests involved in allowing broad or unlimited future uses, commercial or academic, of personal data, and provisions for unilateral future changes to EULA terms, should be identified for the participants, and for the IRB. * In circumstances in which the digital platform must be acquired or given to the participant for the research, and the participant has not previously acquired the app for personal use, you are obligated to identify risks, because but for the study, the participant would not be exposed to the risks inherent in the app and its EULA. * To the extent that the consent form contains references to a EULA’s terms, the text should be as simplified and straightforward as possible, avoiding jargon and complex terminology not generally understood by participants. |

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|  | **Study Measures**  Provide a brief description of each measure/assessment/survey/interview guide you plan to use. |

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| --- | --- |
|  | **Study Measures, Data Collection and/or Instructional Materials**  Attach all study measures (surveys, assessments, interview guides, data collection or instructional sheets, PPT's, links to online content, etc.). |

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|  | | Will participants be exposed to deception, contrived social situations, manipulation of the participants’  attitudes, opinions, or self- esteem, psychotherapeutic procedures, or other psychological influences? | |
|  | Yes | |

|  |  |
| --- | --- |
|  | No |

\*required

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| --- | --- |
|  | Describe the procedures for follow-up and/or debriefing. |

\*required

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|  | **Debriefing Material(s)**  Attach the debriefing materials. |

**Costs and Compensation**

\*required

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| --- | --- | --- | --- |
|  | | **Costs**  Will there be any personal costs to participants that must be paid for research procedures? | |
|  | Yes | |

|  |  |
| --- | --- |
|  | No |

\*required

|  |  |
| --- | --- |
|  | Describe any costs participants must incur as a condition of enrollment in the research study.   * Do not include costs for activities that would occur outside of the research project (e.g., transportation, time, costs for programs in which involvement does not require participation in the research project, etc.). |

\*required

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| --- | --- | --- | --- |
|  | | **Compensation**  Will participants be paid or otherwise compensated for their time/participation in the research study? | |
|  | Yes | |

|  |  |
| --- | --- |
|  | No |

\*required

|  |  |
| --- | --- |
|  | Describe any compensation to be received by the study participants.   * Explain the source of the compensation and who will provide the compensation. * Detail and describe the exact amount and type of compensation, as well as, when and how  participants will receive the compensation (e.g., upon conclusion of the interview, the participant will be sent a $10 Starbucks gift card via email). * If compensation is pro-rated, explain how the proration will be determined and the amount of compensation the participant will receive per study visit. |

**Risks and Benefits**

\*required

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| --- | --- | --- | --- |
|  | | **Risks**  What are the potential risks to participation in the study? | |
|  | Loss of confidentiality | |

|  |  |
| --- | --- |
|  | Emotional distress or upset |
|  | Deception of the participant |

|  |  |
| --- | --- |
|  | Damage to reputation of employability |
|  | Administration of food |

|  |  |
| --- | --- |
|  | Materials or questions that may be regarded as sensitive or invasive |
|  | Questions about illegal behaviors |

|  |  |
| --- | --- |
|  | Questions about traumatic experiences or abuse |
|  | Systematic selection or exclusion of a specific group (age, identity, ethnicity, gender, etc.) |

|  |  |
| --- | --- |
|  | Disclosure of participants' names |
|  | Physical activity |

|  |  |
| --- | --- |
|  | Invasion of privacy |
|  | Other |

\*required

|  |  |  |
| --- | --- | --- |
|  | |  |
|  | No anticipated risks | |

\*required

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|  | For each risk checked or identified above, list the risk minimization or mitigation procedures. |

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| --- | --- | --- | --- |
|  | | Do you believe that your study involves more than "minimal risk" to participants?   * 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. | |
|  | Yes | |

|  |  |
| --- | --- |
|  | No |

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|  | **Benefits**  What are the potential direct benefits to participants? If there are no direct benefits to participants, please state so.   * Compensation is not a benefit. |

\*required

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|  | What are the potential benefits to science, society, and/or the field of study? |

**Privacy and Confidentiality**

\*required

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|  | **Privacy of the Participant**  Explain how you plan to protect participant privacy. Privacy refers to the **person** – not the data.  Include the following:   * Methods used to identify, contact, and interact/intervene with prospective participants * Setting(s) in which research procedures will occur * If applicable, the presence and appropriateness of research personnel or others |

\*required

|  |  |  |  |
| --- | --- | --- | --- |
|  | | Indicate the personally identifiable, private information which will be accessed and/or collected about the study participant during study participation. | |
|  | Name | |

|  |  |
| --- | --- |
|  | Address |
|  | Phone number |

|  |  |
| --- | --- |
|  | Email address |
|  | Social Security number |

|  |  |
| --- | --- |
|  | Medical information (diagnosis/es, test results, medical record number, etc.) |

\*required

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| --- | --- | --- |
|  | |  |
|  | Academic information (grades, assessment scores, attendance records, etc.) | |

\*required

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| --- | --- | --- |
|  | |  |
|  | Demographic information (age, gender, race/ethnicity, sexual identity, income, etc.) | |

\*required

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| --- | --- | --- |
|  | |  |
|  | Other | |

\*required

|  |  |  |
| --- | --- | --- |
|  | |  |
|  | None | |

 \*required

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| --- | --- |
|  | Provide the rationale for obtaining personally identifiable, private information from research participants. |

\*required

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| --- | --- | --- | --- |
|  | | **Confidentiality of the Data**  Initial data collected will be the following:   * This question does NOT pertain to what form the data will be in for  analysis or dissemination of the results. | |
|  | **Directly Identifiable**   * Data set contains values or variables that, on their own, identify research participants. Direct identifiers include name, social security number, video and audio recordings, student ID number, email address, home address, phone number, medical record number, IP address, etc. | |

|  |  |
| --- | --- |
|  | **Coded or Indirectly Identifiable**   * Data set does not contain any direct identifiers, the data set contains a study ID number which is linked, in a separate file, to direct identifiers – or - individual values, fields, or variables within the data set can be combined to re-identify participants. Indirect identifiers could include the collection of demographic information. |
|  | **Anonymous or De-Identified**   * There is no way for a reasonable person to identify participants, either through direct identifiers, study ID codes linked to direct identifiers, or by combining fields in a data set, where the researcher cannot readily ascertain the identity of individuals. For example, an online survey can potentially facilitate anonymous data collection. However, researchers must disable the feature allowing the collection of IP addresses, in addition to not collecting any identifying information, such as gender, age, race, worksite, etc. |

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|  |  |
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|  | How will data be obtained or acquired? |

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| --- | --- |
|  | Where will data be stored and how will data be secured? |

\*required

|  |  |
| --- | --- |
|  | What are the methods used to transfer data? |

\*required

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| --- | --- |
|  | Who will have access to the data? |

\*required

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| --- | --- |
|  | How long will the data be retained?   * Ensure data is retained per APA policy. |

\*required

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| --- | --- |
|  | What are the methods for data destruction? |

\*required

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| --- | --- |
|  | Where will signed consent forms be stored and how will they will be secured?   * Signed consent forms must be kept separate from the data. |

\*required

|  |  |
| --- | --- |
|  | **Results of the Research**  How will research results be disseminated?   * Include plans for the protection of participant privacy and how you will maintain the confidentiality of the data in publications, presentations, and other distribution methods. |