**Initial Submission for New Studies – Special Populations: Minors and Prisoners**

**Minors**

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| The directive of the IRB is to protect the rights and welfare of human research participants. The special vulnerability of children makes the consideration involving them as research participants particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations [(Title 45 CFR 46 Subpart D)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html) are in place for reviewing research involving children. As such, the IRB is required to consider the risks and discomfort in relation to the benefits to the child and/or to society as a whole. To assist the IRB in this consideration please address the following questions. |

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|  | **Qualifications**Briefly describe any previous experience you may have working with this participant population. |

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|  | **Study Population**Indicate whether the study involves children with a health condition and/or if the study involves healthy children. |

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|  | Specify the age-range of minor participants. |
|  | 0 - 6 years of age |

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|  | 7 - 17 years of age |

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|  | **Risk/Benefit**Describe the potential and/or perceived risks and direct benefits to the children participating in the research. If there are no direct benefits to the children, state so, and describe the benefits to society. |

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|  | The Office of Human Research Protections (OHRP) defines minimal risk as the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than that ordinarily experienced in daily life or during the performance of routine physical or psychological examinations. In considering this definition, please check the appropriate box to describe the risk level for this study. |
|  | No greater than minimal risk |

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|  | Greater than minimal risk but presents the prospect of direct benefit to the participant |
|  | Greater than minimal risk with no prospect of direct benefit but likely to yield knowledge about the participant’s disorder or condition |

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|  | **Parental Consent or Permission**Will written parental consent be obtained for this study? |
|  | Yes |

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| Complete the Informed Consent section of this application to provide information about parental consent. |
| No |  |

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|  | Please clarify if consent will be obtained by one or both parents.* If your study is minimal risk, only the consent of one parent is required.
* If the risk to the participant is more than minimal, without the prospect of direct benefit to the

participant, the consent of both parents is required unless one parent is deceased, unknown or reasonably unavailable. |
|  | One parent |

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|  | Both parents |

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|  | Provide justification and explain why you will not obtain written parental consent. * Select the Requirements for Waiver of Consent Documentation in the Informed Consent section

of this application. |

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|  | **Assent of the Child**The assent process should be appropriate to the child's chronological age, developmental ability, and reading level. If you have a large age range, you may need two or more different assent processes and scripts/forms. * Written assent: can be used for children of a higher maturity, age, and/or psychological state

(typically between the ages of 12 - 17 years old)* Verbal assent: can be used for those of a lower maturity, age, and/or psychological state

(typically between the ages of 7 - 11 years old)* Waiver of assent may be appropriate for children based on the age and capability of the child

(typically between the ages of 0 - 6 years old or other underlying factors/conditions).Will you obtain assent from the minor participants? |
|  | Yes |

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| Reference the child [assent template](https://tcsedsystem-my.sharepoint.com/%3Aw%3A/r/personal/sdixon2_thechicagoschool_edu/_layouts/15/Doc.aspx?sourcedoc=%7B02F4FF0E-8A7E-45E3-B512-5AB71DECF6AA%7D&file=Sample%20Assent%20Form%20Template-1.doc&action=edit&mobileredirect=true&wdOrigin=TEAMS-ELECTRON.p2p_ns.undefined) . |
|  | How will assent be obtained? |

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|  | Verbal or Online |
|  | Written |

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|  | Describe how, where, when, and by whom assent will be obtained. |

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|  | Describe how it will be determined that the child has agreed to participate. |

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|  | Describe the developmentally appropriate criteria that will be used to determine if a child wishes to discontinue their participation. |

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|  | **Waiver or Alteration of Assent**The IRB requires child assent unless it can be appropriately waived, or if the child is not capable of providing assent. Select the circumstance, below, so the IRB may determine that waiver of children’s assent is appropriate. |
|  | The capability of some or all of the children is so limited that they cannot reasonably be consulted. |

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|  | The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research. |
|  | The child is capable of providing assent and the research meets the same regulatory criteria as those required for waiver or alteration of informed consent in research involving adults. |

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|  | **Waiver or Alteration of Consent**The IRB may approve an assent procedure that does not include, or alters some or all, of the elements of informed consent. The IRB may waive the requirement to obtain assent, provided **ALL** the following criteria are met. * 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. |

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|  | Provide justification and explain why you will not obtain assent from the minor participants. |

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|  | Describe the developmentally appropriate criteria that will be used to determine if a child wishes to discontinue their participation. |

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|  | **Assent Document(s)**Attach all assent documents (e.g., scripts, forms, etc.).ATTACH, REQUIRED |

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|  | **Consent for Participants who turn 18**Describe how you plan to obtain consent from participants who turn 18 during the course of the study, if applicable. |

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|  | **Wards of the State**Will this study involve children who are Wards of the State?* Wards of the state are minors for whom the state is the legal guardian.
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|  | Children who are wards of the state or any other agency, institution, or entity may be included in research that is greater than minimal risk without prospect of direct benefit to the child, but like to yield generalizable knowledge about the child's disorder, only if the research is: |
|  | Related to the participants' status as wards |

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|  | Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards |
|  | None of the above |

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| You cannot enroll Wards of the State. |

**Prisoners**

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|  | **Research with Prisoners**The directive of the IRB is to protect the rights and welfare of human research subjects. Prisoners may be limited in their ability to make a truly voluntary decision regarding participation in a research study due to their incarceration. Therefore, the IRB must determine appropriate safeguards are in place to protect the rights of prisoners involved in research studies. To assist the IRB in this determination please address the following questions.For the purposes of research, a prisoner is defined as “any individual involuntarily confined or detained in a penal institution. This term encompasses individuals sentenced to such an institution under a criminal or civil statute as well as individuals detained in other facilities by virtue of statues or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. |

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|  | The participants in this study include: |
|  | Individuals involuntarily confined or detained in a penal institution (e.g., prison, jail, or juvenile offender facility). |

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|  | Individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution (e.g., court-ordered substance abuse treatment). |
|  | Individuals detained pending arraignment, trial, or sentencing |

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|  | Other individuals involuntarily detained under a criminal or civil statute |

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|  | Research may involve prisoners if the research represents one of the following categories. Indicate which of the following categories apply to this study.Check all that apply: |
|  | The research involves studying the possible causes, effects, and processes of incarceration, and of criminal behavior. |

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|  | The research studies prisons as institutional structures or prisoners as incarcerated persons. |
|  | The research studies conditions particularly affecting prisoners as a class. |

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|  | The research studies practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. |
|  | None of the above |

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| You **may not** enroll prisoners as research participants. |

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|  | Any advantages granted to the prisoner through participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, cannot be of such magnitude that their ability to weigh the risks of the research against the value of such advantages is impaired due to the limited choice environment.* Describe any possible advantages that a prisoner research participant might experience through their participation in this research.
* Indicate whether the advantage(s) granted to the prisoner may impair their ability to weigh the risks of the research against the value of the advantage(s).

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|  | The procedure for the selection of participants within the prison must be fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. When the research involves control participants, the participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project unless justification for following other procedures is provided and approved the IRB.* Explain how individuals will be selected within the prison to participate in this research and describe how the procedure for selection of subjects within the prison is fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.

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|  | When research involves prisoners, risks involved in the research must be commensurate with risks that would be accepted by non-prisoner volunteers.* Describe the risks and how they are commensurate with risks that would be accepted by non-prisoner volunteers.

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|  | * Provide study specific details on how it will be ensured that the parole board will not take into account a prisoner’s participation in research in making decisions regarding parole.
* Indicate how each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.
* Include a statement in the consent form to inform the participants that their decision to participate will not affect their parole.

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|  | Review your documents and confirm, by clicking on each item, that the following is included in your submission: |
|  | The consent form has a statement to inform the prisoner that their decision to participate will have no effect on the charges pending against them, their prison sentence, parole, or their release from custody. |

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|  | The information is presented in language which is understandable to the participant population. |
|  | Permission from the facility and the appropriate authorities has been obtained. |