Human Research Protections (HRP) strives to ensure that people with disabilities have access to all services and content. If you experience any accessibility-related issues with this form or any aspect of the ZOT IRB application process, email OR-Web-Support@uci.edu for assistance.

 INSTRUCTIONS

This information is necessary for the IRB to determine if the criteria for approval at [45 CFR 46 Subpart D](https://www.ecfr.gov/current/title-45/part-46/subpart-D), and [21 CFR 50 Subpart D](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50/subpart-D) (as applicable) are satisfied for [children](https://www.ecfr.gov/current/title-45/part-46#p-46.402(a)). For more information, visit: [Vulnerable Populations](https://research.uci.edu/human-research-protections/subject-enrollment/vulnerable-populations/).

Answer all questions succinctly using non-technical language as much as possible.

* If a question is a numbered list, respond with a corresponding numbered list.
* If a question is not applicable to the research, state “N/A”.
* If a question is not answered, the IRB does not know if the question was overlooked. This will result in unnecessary “back and forth” for clarification.

 1. STUDY INFORMATION

**Short Title:** Specify the short study title.

|  |
| --- |
| Click or tap here to enter text. |

 2. Parental Permission & Assent Process

[**45 CFR 46.408**](https://www.ecfr.gov/current/title-45/section-46.408) **&** [**21 CFR 50.55**](https://www.ecfr.gov/current/title-21/section-50.55)**: Requirements for permission by parents or guardians and for assent by children.**

**Parental Permission:** Select all that apply and address the required action, as applicable.

|  | **Parental Permission Obtained** | **Required Action** |
| --- | --- | --- |
|[ ]  Parental permission obtained for all research procedures/groups. | 1. Specify whether parental permission will be obtained from one parent or both parents.
 |
|[ ]  Parental permission obtained for some of the research procedures/groups. | 1. Specify when parental permission will be obtained.
2. Specify whether parental permission will be obtained from one parent or both parents.
3. Attach to ZOT IRB: [Appendix - Waivers of Consent, Signed Consent, or HIPAA Authorization](https://research.uci.edu/wp-content/uploads/Appendix-Waivers-of-Consent-Signed-Consent-or-HIPAA-Authorization.docx).
 |
|[ ]  Parental permission not obtained. | Attach to ZOT IRB: [Appendix - Waivers of Consent, Signed Consent, or HIPAA Authorization](https://research.uci.edu/wp-content/uploads/Appendix-Waivers-of-Consent-Signed-Consent-or-HIPAA-Authorization.docx). |

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| Click or tap here to enter text. |

**Child Assent:** Select all that apply and address the required action, as applicable.

|  | **Child Assent Obtained**  | **Required Action** |
| --- | --- | --- |
|[ ]  Assent obtained for all research procedures/groups. | Describe how assent will be documented. Address whether children are functionally illiterate or are not fluent in English. |
|[ ]  Assent obtained for some of the research procedures/groups. | 1. Specify when child assent will be obtained.
2. Describe how assent will be documented. Address whether children are functionally illiterate or are not fluent in English.
3. Describe the procedures for which assent will not be documented.
 |
|[ ]  Assent not obtained.  | Describe the procedures for which assent will not be documented (e.g., child capacity is limited and cannot be reasonable consulted). |

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| Click or tap here to enter text. |

**Permission & Assent Processes:** Provide a step-by-step description of the processes for obtaining parent permission and child/adolescent assent.

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| Click or tap here to enter text. |

**Objection or Resistance:** Describe how a child’s objection or resistance to participation (including non-verbal indications) will be identified during the research, and what the response will be.

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| Click or tap here to enter text. |

**Re-Assent:** When children are enrolled at a young age and continue for many years, it is best practice to re-obtain assent (or to obtain it for the first time, if it was not obtained at the beginning of their participation). Describe the plans (if any) to re-obtain assent from children or provide a justification for not re-obtaining assent.

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| Click or tap here to enter text. |

 3. CONSENT PROCESS

**Age of Consent:**

1. Describe the plans (if any) to obtain consent for children when they reach the legal age of consent.
	1. If adult consent will be obtained from them, describe what will happen regarding now-adult participants who cannot be contacted.
	2. If consent will not be obtained or will not be possible, explain why.

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| Click or tap here to enter text. |

**Children who Can Consent:** Explain whether this study will enroll people under the age of 18 who are able to legally consent to treatment or procedures involved in research and if so, provide the legal citation (i.e. state regulation).

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| Click or tap here to enter text. |

 4. WARDS

[ ]  *This section is not applicable, end of form.*

[**45 CFR 46.409**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-D/section-46.409) **&** [**21 CFR 50.56**](https://www.ecfr.gov/current/title-21/section-50.56)**: Children who are wards of the state or any other agency, institution, or entity.**

**Children who are Wards:**

1. Specify if any of the children enrolled in the research be wards of the State or any other agency, institution, or entity.
2. Explain why it is appropriate to enroll wards in this study.
3. An advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards. Describe who (by name) will be the advocate(s). The description must address the following points:
	1. Background and experience
	2. Willingness to act in the best interests of the child for the duration of the research
	3. Independence of the research, research team, and any guardian organization

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| Click or tap here to enter text. |

**Assurance:** Provide assurance that the following is true.

[ ]  Study team will identify and comply with the applicable requirements for conducting research involving wards within the state where research is conducted.

**California Locations:** If the study will take place in California, select which agency oversees the wards who participate in the research. Select all that apply.

|  |  |
| --- | --- |
| [ ]  | California Division of Juvenile Justice (DJJ) |
| [ ]  | State of California Dependency Court |

**Department of Juvenile Justice (DJJ):**

1. The California Penal Code requires that the Director of the DJJ issue approval prior to the initiation of the research. *Attach to ZOT IRB: Documentation of the required approval.*
2. Biomedical research may only be conducted with DJJ wards if it is codified in the California State Statute and approved by the Director of the Department, Secretary of the Youth and Correctional Agency, and the Governor's Office. *Attach to ZOT IRB: Documentation of the required approvals.* Behavioral research conducted with DJJ wards is limited to the following. Select all that apply.

|  |  |
| --- | --- |
| [ ]  | Research is minimal risk and of no more than mere inconvenience to the participants |
| [ ]  | Research focuses on possible causes, effects, and processes of incarceration |
| [ ]  | Research focuses on prisons as institutional structures |
| [ ]  | Research focuses on prisoners as incarcerated persons |