UC Irvine Institutional Review Board

Appendix D

VULNERABLE POPULATIONS: CHILDREN

Please read the applicable [HRP webpage](http://www.research.uci.edu/compliance/human-research-protections/researchers/vulnerable-subject-populations.html) for information about the involvement of children in research studies and clinical investigations.

**SECTION 1: Select the category that best describes your proposed research.**

**Please check the box(es) that best describe your proposed research. Answer the corresponding questions and then complete Sections 2 – 4 and Section 5, if applicable.**

When reviewing these categories, consider whether the research poses greater than minimal risk to subjects (i.e., full committee review). Expedited research usually falls within Category 1; Full committee research usually falls within Category 2 or 3.

**☒ CATEGORY 1 (§46.404)** - This proposed research poses no greater than minimal risk to children.

*(Note: for research that qualifies for Expedited level of review)*.

1. Indicate why the proposed research poses no greater than minimal risk to children.

Participants will be expected to complete a collection of one-sentence translation tasks. LINE IDs will be collected and used for compensation, and they will be destroyed two weeks after the data collection process is finished.

**☐ CATEGORY 2 (§46.405)** - This proposed research poses greater than minimal risk to children and includes an intervention or procedure that **DOES hold out the prospect of a direct benefit** for the individual child **or** a monitoring procedure that is likely to contribute to the child’s well-being*.*

1. Explain why the risk is justified by the anticipated benefit to the child.

1. Explain why the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

**☐ CATEGORY 3 (§46.406) -** This proposed research poses greater than minimal riskto children and is presented by an intervention or procedure that **DOES NOT hold out the prospect of direct benefit** for the individual subject, **or** by a monitoring procedure which is not likely to contribute to the well-being of the subject but is likely to yield generalizable knowledge about the subject's disorder or condition.

1. Justify why the risk represents a minor increase over minimal risk.

1. Explain why the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.

1. Identify the subjects' disorder or condition.

1. Explain why the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition, which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.

**☐ CATEGORY 4 (§46.407) -** This proposed research does not meet the requirements of §46.404, §46.405, or §46.406. NOTE: If funded by DHHS, Secretary approval (through OHRP) is also required for this category of research.

1. Explain why the proposed research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

**NOTE:** If there is more than one group of children being enrolled in the research (e.g., patients, healthy controls) and the groups fall into different risk/benefits categories, describe the groups below listing the applicable category for each group.

**Section 2: Parental Permission**

**Select one statement that best describes how you will obtain parental permission. Answer the corresponding questions.**

**☐** I will obtain the permission of each parent or guardian, unless parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. *[required for Categories 3 & 4 above]*

☒ I will obtain the permission of one parent or guardian.

☐ I am requesting that parental permission be waived because all of the following are true:

* The research involves no more than minimal risk to the subjects.
* The waiver or alteration will not adversely affect the rights and welfare of the subjects.
* The research could not practicably be carried out without the waiver or alteration.
* Whenever appropriate, the parents or guardians will be provided with additional pertinent information after participation.

**IF A WAIVER HAS NOT ALREADY BEEN REQUESTED, GO BACK TO THE "PROCEDURES" SECTION, CHECK "WAIVER OF INFORMED CONSENT (NO CONSENT)" AND COMPLETE APPENDIX O - SECTIONS 1-3.**

☐ I am requesting that parental permission be waived because all of the following are true:

* The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects. (e.g., neglected or abused children).
* An appropriate alternative mechanism for protecting the children who will participate as subjects in the research will be in place.
* The waiver is not inconsistent with Federal, State or local law.

1. Explain how/why the research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects.

1. Describe the alternative appropriate mechanism for protecting the children who will participate as subjects in the research. The choice of an appropriate mechanism should consider the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

☐ I am requesting that parental permission be waived because all of the following are true:

* The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.
* The research could not practicably be carried out without the waiver or alteration.

**IF A WAIVER HAS NOT ALREADY BEEN REQUESTED, GO BACK TO THE "PROCEDURES" SECTION, CHECK "WAIVER OF INFORMED CONSENT (NO CONSENT)" AND COMPLETE APPENDIX O - SECTIONS 1, 2 AND 4.**

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine one of the following: (select one)

☐ Public benefit or service programs

☐ Procedures for obtaining benefits or services under the programs

☐ Possible changes in or alternatives to those programs or procedures

☐ Possible changes in methods or levels of payment for benefits or services under the programs

1. Justify your selection above in question (a).
2. Explain why if parental permission were required, the research could not practicably be carried out.

**Section 3: Assent**

**Select which best describes how you will be obtaining assent and answer the corresponding questions.**

☒ I will obtain assent from all children.

☐ I will obtain assent from some children.

Explain which children will not be asked for assent.

☐ I will not obtain assent from any of the children because the capability of these children is so limited that they cannot reasonably be consulted.

Explain the limitations of the children’s ability to assent based on their ages, maturity, and psychological state.

☐ I will not obtain assent from any of the children because the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.

Explain how/why the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.

☐ Assent will be waived because all of the following are true:

* The research involves no more than minimal risk to the subjects.
* The waiver or alteration will not adversely affect the rights and welfare of the subjects.
* The research could not practicably be carried out without the waiver or alteration.
* Whenever appropriate, the children will be provided with additional pertinent information after participation.
  1. Justify that the research involves no more than minimal risk to the subjects.

* 1. Explain how/why the waiver or alteration will not adversely affect the rights and welfare of the subjects.

* 1. Explain why if assent were required, the research could not practicably be carried out.

* 1. Explain how/why, whenever appropriate, the children will be provided with additional pertinent information after participation *(e.g., Study involves deception/incomplete disclosure. Subjects are debriefed about the true purpose of the study after participation. Researcher develops a debriefing letter or script- requires IRB approval).*

☐ Not appropriate to provide children with additional pertinent information after participation.

Explanation:

☐ Assent will be waived because all of the following are true:

* The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.
* The research could not practicably be carried out without the waiver or alteration.

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine one of the following: (select one)

☐ Public benefit or service programs

☐ Procedures for obtaining benefits or services under the programs

☐ Possible changes in or alternatives to those programs or procedures

☐ Possible changes in methods or levels of payment for benefits or services under the programs

1. Explain why if parental permission were required, the research could not practicably be carried out.

**Section 4: Enrollment of People Under 18 Who Can Consent for Themselves**

California law establishes several groups of people under 18 years of age who are legally able to consent to treatment or procedures involved in research. Under federal regulations [§ 46.402 and § 50.3], these people do not meet the definition of “children” and therefore are able to consent for themselves as if they were adults. See [**Requirements for Use of Children as Subjects, When Parental Permission is not needed**](http://www.research.uci.edu/ora/hrpp/vulnerablesubjectpopulations.htm#NoParent)for a more complete explanation.

Will people under the age of 18 who are permitted under California law to consent for themselves be enrolled in this study?

☐ Yes

☒ No

If yes, describe the people under 18, able to consent for themselves, to be enrolled in the study:

**Section 5: Children who are Wards of the State (45 CFR 46.409; 21 CFR 50.56)**

Federal regulations do not have special requirements for enrollment of wards in research approved under §46.404 or §47.405 (FDA §50.51 or §50.52); see explanations of categories in Section 1.

However, children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 (FDA §50.53 or §50.54) only if such research is:

* Related to their status as wards; ***OR***
* Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

The inclusion of children who are wards requires the following conditions be met:

* Appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. NOTE: One individual may serve as advocate for more than one child.
* The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research.
* The advocate must not be associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.
  + 1. Do you intend to enroll wards of the state or any other agency, institution, or entity?

☐ Yes

☒ No

* + 1. Does the study fall under §46.406 or §46.407 (FDA §50.53 or §50.54)?

☐ Yes

☒ No *[If No, skip remaining questions]*

#### If yes, explain why it is appropriate to enroll wards in this study.

#### d. Describe your plans for appointing advocates and explain what their duties will be.