USC University of Southern California | Children's Hospital Los Angeles | Los Angeles General Medical Center | iStar

Feb 20, 2025, 03:26pm

To: Jessica Schwartzman, PhD
DEVELOPMENTAL-BEHAVIORAL PEDIATRICS - CHLA

From: Children's Hospital Los Angeles Institutional Review Board

Re: CHLA-24-00360
Reward responsivity and depression in autistic youth with intellectual disability: A pilot study (RDA-ID Pilot)

NOTICE OF IRB APPROVAL

Valid from: 2/19/2025 **Expires: 2/18/2026**

IRB APPROVAL CONDITION: Recruitment/enrollment may not begin until a copy of the Certificate of Confidentiality for this research is submitted to the IRB via amendment. The consent and assent documents for this research will not be released for use until this time.

Document(s) Reviewed:

- iStar Application (version date 2/6/2025)
- Protocol (version date 1/13/2025)
- Consent/Permission/Assent Form (version date 2/6/2025)
- Simplified Assent Form (version date 1/9/2025)

The above-named study was reviewed by the CHLA IRB at a convened meeting on 2/19/2025**.** The study has been approved.

It has been determined that the research involves no greater than minimal risk.

It has been determined that children may be included in the research. The IRB determined and documented that the research meets the requirements of 45 CFR 46.404.

When enrolling a minor into this research, the permission of at least one parent/legal guardian is required.

The written assent of all children is necessary for participating in the research. In all cases, the IRB expects that investigators will provide children with developmentally appropriate information about research participation.

Because minor subjects may turn 18 years old while participating in the research and may not be capable of providing consent for themselves for their continuing participation in the research, the IRB determined and documented that adults lacking consent capacity may be included in the research with the consent of their legally authorized representative (LAR). The subjects should be informed about the research to the extent compatible with the subject's understanding. Assent should be obtained from those subjects who are capable.

This study has been granted an alteration of informed consent/assent/permission per 45 CFR 46.116(f) for the purposes of deception.

CHLA Research HIPAA authorization is required for this research as subject's protected health information is being accessed, used, or disclosed for purposes of this research. Approved CHLA Research HIPAA templates are available at www.chla.org/research/hspp. Any changes to the approved template language, such as those requested by study sponsors, must be approved by the IRB prior to use. HIPAA authorization should be obtained from the adult subject (or the surrogate

for adults not capable of providing authorization) or from the parent (for minor subjects). When subjects turn 18 and continue on the research, HIPAA authorization must be obtained from those subjects.

For the purposes of retaining screening data, this study has been granted a waiver of HIPAA authorization (45 CFR Part 160 and Subparts A and E of Part 164) per the Privacy Rule for the following reasons:

- description of the PHI for use or access is included in the protocol summary and is necessary for the research;
- use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals;
- there is an adequate plan to protect the identifiers from improper use and disclosure;
- there is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law;
- there are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted;
- the research could **NOT** practicably be conducted without the waiver or alteration; and
- the research could **NOT** practicably be conducted without access to and use of the protected health information.

The Experimental Subject's Bill of Rights must be signed and dated at the beginning of the consent conference to enroll a subject into this research. The Experimental Subject's Bill of Rights may be found here: www.chla.org/research/hspp. The Experimental Subject's Bill of Rights should be signed by the adult subject (or the surrogate for adults not capable of providing consent) or the parent (for minor subjects).

IRB approval for this study will expire on the expiration date noted above. In order to continue the research beyond the expiration date, a Continuing Review application must be received by the HSPP office at least 8 weeks before the expiration date, and continuation of the study must be approved by the IRB. The iStar application should be closed once the research has been completed.

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