

## APPROVAL

October 25, 2022

Anna Esbensen  
 DDBP - Psychology

Dear Anna Esbensen:

The Cincinnati Children's Hospital Institutional Review Board (IRB) reviewed the following submission:

Type of Review:	Initial Study - 2022-0743
Title of Study:	Parent Survey to Develop a Measure of Maladaptive Behavior for Down Syndrome
Investigator:	Anna Esbensen
IRB ID:	<a href="#">2022-0743</a>
Review Level:	Expedited
Special Requirements:	<p>The IRB has waived the requirement to obtain DOCUMENTATION of informed consent for all adult participants.</p> <p>The IRB has waived the requirement to obtain DOCUMENTATION of parental permission for all child participants.</p> <p>The IRB has determined that documented assent is not needed for all children.</p> <p>The IRB has granted a waiver for the requirement to obtain DOCUMENTATION of authorization for the use and/or disclosure of protected health information (PHI).</p>
Risk Level:	No greater than minimal risk

The above submission and all associated documents, including the protocol and consents (if applicable), are approved by the IRB from 10/24/2022 to 10/23/2025.

Please see the documents tab for all approved documents by clicking on the submission ID link above.



Cincinnati Children's Hospital Institutional Review Board  
Federalwide Assurance #00002988  
Phone: (513) 636-8039  
3333 Burnet Avenue | MLC 7040 | Cincinnati, OH 45229

Thirty days before 10/23/2025 you are to submit a completed continuing review and required attachments to request continuing approval or closure. You can submit a continuing review by navigating to the active study and clicking "Create Modification / CR".

If continuing review approval is not granted before the expiration date of 10/23/2025, approval of this study expires on that date.

If this study meets the definition of a clinical trial, [it involves the assignment of one or more human subjects to one or more interventions (procedure, device, or drug, including use of placebo or control) to evaluate the effects of the interventions on biomedical or behavioral health outcomes], then the approved IRB consent form template must be posted by the awardee to a federal website to be disclosed. This document must be posted after the research has been closed and no later than 60 days after the last study visit of any subject. In conducting this protocol, you are required to follow all applicable regulations, institutional policies and requirements of the reviewing IRB, which can be found by navigating to the IRB Library within the ePAS-IRB system.

In conducting this research, you are required to follow all applicable regulations, policies, procedures and award terms. This includes obtaining IRB approval for any changes in the research prior to their implementation, except when such changes are being made to alleviate immediate risk of harm to research participants. You should contact the IRB office for additional information regarding these requirements.

Sincerely,  
Cincinnati Children's Hospital IRB  
Federalwide Assurance #00002988

*The Office of Research Compliance and Regulatory Affairs (ORCRA) would like your feedback on your interactions with the Cincinnati Children's Hospital Human Research Protection Program and IRB. Click the following link to complete our anonymous feedback survey: <https://survey.sogosurvey.com/r/chkrne>*

Statement regarding International Conference on Harmonization and Good clinical Practices. The Cincinnati Children's Hospital Institutional Review Board is duly constituted (fulfilling FDA requirements for diversity), has written procedures for initial and continuing review of clinical trials, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements defined in 21 CFR Parts 50, 56 and 312 Code of Federal Regulations. This institution is in compliance with the ICH GCP as adopted by FDA/DHHS.