



July 23, 2024

To: Amanda Gmyrek, Ph.D.
Principal Investigator
JBS International, Inc.

From: Katelyn Franke, Ph.D.
IRB Co-Chair
JBS International, Inc.

Maia Hyary, Ph.D.
IRB Co-Chair
JBS International, Inc.

Re: JBS IRB # AG19-001
Approved by Expedited Review

Dear Dr. Gmyrek:

Your protocol *Health Resources and Services Administration (HRSA) Evaluation of the Maternal and Child Health Bureau (MCHB) Pediatric Mental Health Care Access (PMHCA) and Screening and Treatment for Maternal Mental Health and Substance Use Disorders (MMHSUD) Programs Project* (JBS IRB # AG19-001) has been approved by expedited review by the Institutional Review Board. This study fulfills the criteria for expedited review under 45 CFR 46.110, category #7.

The IRB has determined that Continuing Review is not required. As the Principal Investigator, you have the ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB. You must abide by the following principles when conducting your research:

1. Perform the project by qualified personnel according to the approved protocol.
2. Do not implement changes in the approved protocol or consent form without prior IRB approval (except in a life-threatening emergency, if necessary, to safeguard the well-being of human subjects). This includes changes to the research design or procedures that could introduce new or increased risks to human subjects and thereby change the nature of the research. A modification form can be found here.
3. Promptly report any adverse reactions or unanticipated reactions within five working days of occurrence. All fatal or life-threatening events or events requiring hospitalization must be reported to the IRB in writing within 48 hours after discovery.

If you are not planning to collect data from human participants and have completed basic data analyses (and risk to subjects does not change), a Project Closure Form is required. The

investigator(s) identified above are required to retain an IRB protocol file, including a record of IRB-related activity, data summaries and consent forms. This file is to be made available for review for internal procedural (audit) monitoring.

If you have any questions, please contact kfranke@jbsinternational.com and mhyary@jbsinternational.com

Expedited Review Approved By:

Katelyn Franke, Ph.D.
IRB Co-Chair

Maia Hyary, Ph.D.
IRB Co-Chair