



November 27, 2019

To: Raphael Gaeta, Ph.D.
Principal Investigator
JBS International, Inc.

From: Amanda Gmyrek, Ph.D.
IRB Chair
JBS International, Inc.

Re: JBS IRB #New Editions 19-001
Approved by Expedited Review
Approval Period from November 27, 2019 through November 26, 2020

Dear Dr. Gaeta:

Your protocol *Adult Protective Services (APS) Client Outcomes Study* (JBS IRB # New Editions 19-001) 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 initial period of approval is **11/27/2019** through **11/26/2020**. Approval of this protocol will terminate on the above date unless a progress report and renewal request are submitted, ***in writing***, to the IRB. Your continuation request should be submitted to the IRB by **10/26/2020**.

The IRB Chair will send you an email reminder prior to the end of the protocol; however, it is your responsibility to assure that project activities are not conducted past the approval termination date. The continuation request must be submitted to the IRB via expedited review. **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 renewal request is not necessary.** A closure report is 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.
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.

Value of thought. Value of solution.

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 me at 240-645-4848 or agmyrek@jbsinternational.com.

Expedited Review Approved By:

A handwritten signature in black ink, appearing to read "Amanda Gmyrek", with a long horizontal flourish extending to the right.

Amanda Gmyrek, Ph.D.
IRB Chair