JBS International. Inc. Institutional Review Board

5515 Security Lane, Suite 800 North Bethesda, MD 20852 301-495-1080

May 6, 2013

To: Bohne Silber, Ph.D.

Principal Investigator Silber & Associates

From:

Joseph Willey, Ph.D.

IRB Chair

JBS International, Inc.

Re:

JBS IRB #SB12-001

Review Approved by Expedited Review

Approval Period from November 5, 2012 through November 4, 2013

Dear Dr. Silber:

Your continuing renewal request for the protocol entitled *Information Collection on the NIDA for Teens Website on Usefulness and Knowledge to be Learned* (JBS IRB # SB12-001) 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. This updated approval letter reflects the new name for the project received May 6, 2013. It amends the previous approval to reflect the change in the protocol name.

The period of approval is 11/05/2012 through 11/04/2013. Approval of this protocol will terminate on the above date unless a progress report and renewal request is submitted, *in writing*, to the IRB. Your continuation request should be submitted to the IRB by 10/04/2013.

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.

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 240-645-4789 or jwilley@jbsinternational.com

Joseph Willey, Ph.D.

ARB Chair