## INDIANA UNIVERSITY

## OFFICE OF RESEARCH ADMINISTRATION

To: Alexander C. McCormick

Ctr. For Postsecondary Res.

From: **IUB Human Subjects Office** 

Office of Research Administration - Indiana University

Date: March 4, 2009

RE: PROTOCOL APPROVAL - EXPEDITED

> Protocol Title: Beginning College Survey of Student Engagement

08-13060 Protocol #: N/A Sponsor:

The above-referenced protocol was reviewed by the IRB. The protocol meets the requirements for expedited review pursuant to §46.110, Category 7. The protocol is approved for a period of March 3, 2009 through March 2, 2010. This approval does not replace any departmental or other approvals that may be required.

If you submitted and/or are required to provide participants with an informed consent document, study information sheet, or other documentation, a copy of the approved stamped document is enclosed and must be used.

As the principal investigator (or faculty sponsor in the case of a student protocol) of this study, you assume the following responsibilities:

- CONTINUING REVIEW: Federal regulations require that all research be reviewed at least annually. You may receive a "Continuation Renewal Reminder" approximately two months prior to the expiration date; however, it is the Principal Investigator's responsibility to obtain continued approval from the IRB before March 3, 2010. If the IRB does not grant continued approval by this date, the study will automatically expire, requiring all research activities, including enrollment of new participants, interaction and intervention with current participants, and analysis of identified data to stop.
- **AMENDMENTS:** Any proposed changes to the research study must be reported to the IRB prior to implementation. Only after approval has been granted by the IRB can these changes be implemented. An amendment form can be obtained at http://research.iu.edu/rschcomp/instruct.html.
- ADVERTISEMENTS: Only IRB-approved advertisements may be used to recruit participants for the study. If you submitted an advertisement with your study submission, an approved stamped copy is provided with the approval. To request approval of an advertisement in the future, please submit an amendment, explaining the mode of communication and information to be contained in the advertisement.
- **COMPLETION:** Prompt notification must be made to the IRB when the study is completed (i.e. there is no further subject enrollment, no further interaction or intervention with current participants, including follow-up, and no further analysis of identified data). To notify the IRB of study closure, please obtain a close-out form at http://research.iu.edu/rschcomp/instruct.html.
- LEAVING THE INSTITUTION: The IRB must be notified of the disposition of the study when the principal investigator (or faculty sponsor in the case of a student project] leaves the institution.
- VULNERABLE POPULATIONS: Please note that there are special requirements for the inclusion of vulnerable populations (i.e. children and minors, prisoners, pregnant women and human fetuses, and cognitively impaired) in research. You may not enroll or otherwise include an individual who is or becomes a member of a vulnerable population while enrolled in the research if that vulnerable population has not already been approved by the IRB for enrollment. For additional information on the requirements for including vulnerable populations in research, please refer to http://research.iu.edu/rschcomp/hmpg.html.

Note: SOPs exist covering a variety of topics that may be relevant to the conduct of your research. For more information on the relevant policies and procedures, go to http://research.iu.edu/rschcomp/hmpg.html.

You should retain a copy of this letter and any associated approved study documents (e.g. informed consent or advertisements) for your records. All documentation related to this study must be maintained in your files for audit purposes for at least three years after closure of the research; however, please note that research studies subject to HIPAA may have different requirements regarding file storage after closure. Please refer to the project title and number in future correspondence with our office. Additional information is available on our website at http://research.iu.edu/rschcomp/hmpg.html. Please contact our office if you have questions or need further assistance.

Thank you.