INDIANA UNIVERSITY

OFFICE OF RESEARCH ADMINISTRATION

To: Alexander C. McCormick
Education

From: IUB Human Subjects Office
Office of Research Administration – Indiana University

Date: October 5, 2009

RE: **EXPEDITED APPROVAL – PROTOCOL RENEWAL**
Protocol Title: National Survey of Student Engagement (NSSE)
Protocol #: 06-11006 (0709000079)
Sponsor: N/A

The above-referenced protocol was reviewed by the IRB. The protocol is approved as **ONGOING – OPEN TO ENROLLMENT** for a period of **SEPT 29, 2009** through **SEPT 28, 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(s) 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:

1. **CONTINUING REVIEW:** Federal regulations require that all research be reviewed at least annually. You may receive a 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*** the expiration date. 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.

2. **AMENDMENTS:** Any proposed changes to the research must be approved by the IRB prior to implementation. To request approval, please complete an Amendment form and submit it, along with any revised study documents, to iub_hsc@indiana.edu. Only after approval has been granted by the IRB can these changes be implemented.

3. **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.

4. **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://researchadmin.iu.edu/HumanSubjects/IUB/hs_forms.html.

5. **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.

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://www.iupui.edu/~respoly/human-sop/human-sop-index.htm.

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://researchadmin.iu.edu/HumanSubjects/IUB/hs_home.html. Please contact our office if you have questions or need further assistance.

Thank you.

INDIANA UNIVERSITY BLOOMINGTON INSTITUTIONAL REVIEW BOARD (IRB) REVIEW

CONTINUING REVIEW

STATUS: ONGOING – OPEN TO ENROLLMENT

IRB Study No. 06-11006

SECTION I: INVESTIGATOR INFORMATION

Principal Investigator: McCormick, Alexander C.. **Department:** Education/ELPS
(Last, First, Middle Initial)
Building/Room No.: Eigenmann Hall, Suite 419 Phone: 6-5824 E-Mail: amcc@indiana.edu

Faculty Sponsor: _____ **Department:** _____
(Last, First, Middle Initial)
Building/Room No.: _____ Phone: _____ E-Mail: _____

Project Title: **National Survey of Student Engagement (NSSE)**

Sponsor/Funding Agency: _____

SECTION II: CURRENT STUDY STATUS

☒ **ONGOING – OPEN TO ENROLLMENT**
Date study was initiated: February 15, 1999
Projected date of completion: On-going.

(Select one below)
☒ Enrollment of new participants or review of records/specimens continues
☐ No participants have been enrolled to date (Skip Sections III and IV)

☐ **Please check here if the study is currently suspended (temporarily) and indicate the reason(s) for the suspension:**

_____

SECTION III: SUBJECT SUMMARY

☐ Check here if your study utilizes records or specimens versus interaction with human subjects. When the form asks for the number of subjects, document the number of records/specimens that have been reviewed or collected.

1. SUBJECT SUMMARY TABLE

		On-Site
Since last IRB review	Total number of subjects **CONSENTED**	**369,940**
	Total number of subjects who **FAILED SCREENING** (e.g. found ineligible to participate)	**0**
	Total number of subjects who have **WITHDRAWN** from the study	**0**
Since beginning of study	Total number of subjects **CONSENTED**	**2,404,546**
	Total number of subjects who **FAILED SCREENING** (e.g. found ineligible to participate)	**0**
	Total number of subjects who have **WITHDRAWN** from the study	**0**
Number of **ACTIVE** subjects		**0**
Number of subjects who have **COMPLETED** the study		**0**

If necessary, please provide further explanation regarding the subject summary: **We interpret "Active Subjects" to be those currently involved in data collection; the survey is only open for students to complete it between January and June of each**

year. Because we continue to conduct analysis on all survey participants, we do not consider them to have completed the study.

2. **WITHDRAWAL.**

If any subjects have withdrawn from the study since the last IRB review, please state the reasons:_____

3. **JUSTIFICATION FOR STUDY CONTINUATION**

Have subjects accrued in the study since the last IRB review?

☒ Yes

☐ No, justify study continuation:_____

4. **Vulnerable Populations**. Are any of the subjects who have consented or enrolled in the study members of a vulnerable population **which have not previously been approved for enrollment by the IRB**? This includes children, pregnant women and human fetuses, prisoners, cognitively impaired individuals, and students.

☒ No

☐ Yes. Please indicate which population(s) have consented or enrolled:

☐ Children ☐ Pregnant Women and Human Fetuses

☐ Prisoners ☐ Economically/Educationally Disadvantaged

☐ Cognitively Impaired ☐ Students

Please note that you must submit an amendment to the IRB to request the inclusion of these subjects.

5. **For studies employing waivers of assent**:

a. State the number of assent waivers that were employed since the last IRB review: _____

b. Explain the circumstances surrounding each assent waiver employed: _____

SECTION IV: ETHNIC/RACIAL REPORTING REQUIRED FOR FEDERALLY-SPONSORED STUDIES

SUBJECT ACCRUAL

	Sex/Gender			Total
Ethnic Category	**Females**	**Males**	**Unknown or Not Reported**	
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals Not Reporting Ethnicity)				
Ethnic Category Total of All Subjects*				
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories Total of All Subjects*				

If ETHNIC and RACIAL category totals are not equal, please explain: _____

Have there been any unexpected problems recruiting participants, especially subjects in a particular category (including children and women)?

☐ No.

☐ Yes. Please explain: _____

CONTINUING REVIEW

STATUS: ONGOING – OPEN TO ENROLLMENT

SECTION V: SUMMARY OF EVENTS

V.A. **Since the last IRB review**, did any unanticipated problems, including adverse events, protocol deviations, or subject complaints, or noncompliance occur that required prompt reporting to the IRB?

☒ No.

☐ Yes. Were these events reported previously to the IRB, if applicable?

☐ No. Please explain why these events were not previously reported: _____

☐ Yes. Please attach a **summary** of these events.

V.B. **Since the last IRB review**, did any unanticipated problems, including adverse events, protocol deviations, or subject complaints, or noncompliance occur that did **not** require prompt reporting to the IRB?

☒ No.

☐ Yes. Please attach a **summary** of these events..

V.C. Is there a Data Safety Monitoring Board for this study?

☒ No.

☐ Yes. Provide the most recent monitoring report if it has not already been provided to the IRB or explain why one cannot be provided: _____

V.D. Based on the above information, do you feel the validity of the data is affected?

☒ No.

☐ Yes. Explain:

V.E. Based on the above information, do you feel there is an increase in risk to subjects or others or in the frequency or severity of adverse events, protocol deviations, problems, complaints, etc. since the last IRB review?

☒ No.

☐ Yes. Explain: _____

SECTION VI: SUMMARY

VI.A. Describe the progress of the research, including any preliminary observations and information about study results or trends: Findings from the past year include: student use of technology related to learning; the involvement of first-year students and seniors in certain high impact educational practices; and the relationship of high school involvement to expected persistence in college.

If no progress description is provided, please explain why: _____

VI.B. Have subjects experienced any **direct** benefit(s) from their participation in the study?

☒ No.

☐ Yes.

Please explain: _____

VI.C. Has any recent literature related to this research study been published or presented since the last IRB review?

☐ No.

☒ Yes. Please attach a copy or explain why one cannot be provided: _____

VI.D. Have there been any audits from federal agencies conducted since the last IRB review that identified unanticipated problems involving risks to subjects or others or noncompliance?

☒ No.

☐ Yes. Attach the report(s).

VI.E. Do you believe the balance of risks and benefits presented to the subjects has changed based on all of the information provided on this form and any attachments?

☒ No.

☐ Yes. Explain:_____

SECTION VII: REQUIRED ATTACHMENTS

All of the following documents must be included with your continuing review submission. Please check the appropriate boxes as they apply to your study.

☒ Continuing review form*
☒ Summary safeguard statement (SSS) (must be document version date of 06/05 or later)
☐ Recruitment checklist, if your study is subject to HIPAA and your study documentation includes a recruitment checklist
☒ Informed consent document(s), unless the IRB previously approved a waiver of consent
# of consent documents: 6 (contained in Appendix A)
☐ Check here if a waiver of assent was approved by the IRB
☐ Assent document(s), if your study is enrolling children or cognitively impaired individuals and the IRB previously approved an assent document
# of assent documents: _____
☐ Check here if a waiver of assent was approved by the IRB
☐ Authorization(s), if your study is subject to HIPAA and the IRB previously approved an authorization
# of authorizations: _____
☐ Check here if a waiver of authorization was approved by the IRB
☐ Advertisement(s), if the IRB previously approved an advertisement(s) for the study
# of advertisements:
☐ Protocol
☒ Other, description: Instructions for survey implementation (contained in Appendix A)

Include the following documents, as applicable:

☒ Publications, if you answered **YES** to VI.C. above
☐ Audit reports, if you answered **YES** to VI.D above
☐ Summaries, if you indicated in Section V that summaries are attached
☐ DSMB report, if the study includes a DSMB and you are submitting the most recent DSMB report
☐ Interim findings, if there are any to report
☐ Multi-center trial reports, if there are any available

NOTES:
- No changes to previously approved study documents are allowed at the time of continuing review unless requested by the IRB.
- Incomplete submissions will result in a processing delay, which could result in study expiration.

Your submission of this form certifies that this study has been and will continue to be conducted in full compliance with the IRB-approved protocol, HHS/FDA regulations and the IUB policies governing human subject research. You also certify that the information contained on or with this form is accurate.

Signature of Principal Investigator: Alexander C. McCormick Date: 9/22/2009

CONTINUING REVIEW

STATUS: ONGOING – OPEN TO ENROLLMENT

SECTION VII: IRB APPROVAL

*** For Office Use Only ***

Type of review:

☐ Full Board

☒ Expedited, Category: 7

IRB Reviewer:

☒ Check here to confirm that the most recent informed consent statement has been reviewed and no additional information needs to be provided to subjects based on any new findings.

STATUS OF STUDY: ONGOING, Open to Enrollment

This continuing review has been reviewed and approved as meeting the criteria for IRB approval as outlined in 45 CFR 46.111(a) by the IU Bloomington IRB. Based on the criteria for determining the frequency of continuing review and the level of risk, this study will expire on: 9-28-10. If the study is not re-approved prior to that date all research activities must cease on that date, including enrollment of new subjects, intervention/interaction with current participants, and analysis of identified data.

Authorized IRB Signature: Sara Brand IRB Approval Date: 9-29-09

Recorded in the Minutes of: _____