

INDIANA UNIVERSITY BLOOMINGTON INSTITUTIONAL REVIEW BOARD (IRB) REVIEW

CONTINUING REVIEW

STATUS: ONGOING – OPEN TO ENROLLMENT

IRB Study No. 08- 13060

**SECTION I: INVESTIGATOR INFORMATION**

Principal Investigator: McCormick, Alexander C. Department: Education/ELPS  
*(Last, First, Middle Initial)*

Building/Room No.: Eigenmann Hall, Suite 419 Phone: 856-5824 E-Mail: amcc@indiana.edu

Faculty Sponsor: \_\_\_\_\_ Department: \_\_\_\_\_  
*(Last, First, Middle Initial)*

Building/Room No.: \_\_\_\_\_ Phone: \_\_\_\_\_ E-Mail: \_\_\_\_\_

Project Title: Beginning College Survey of Student Engagement

Sponsor/Funding Agency: \_\_\_\_\_

**SECTION II: CURRENT STUDY STATUS**

**ONGOING – OPEN TO ENROLLMENT**

Date study was initiated: 2007

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 <b>CONSENTED</b>	0
	Total number of subjects who <b>FAILED SCREENING</b> (e.g. found ineligible to participate)	0
	Total number of subjects who have <b>WITHDRAWN</b> from the study	0
Since beginning of study	Total number of subjects <b>CONSENTED</b>	295,029
	Total number of subjects who <b>FAILED SCREENING</b> (e.g. found ineligible to participate)	0
	Total number of subjects who have <b>WITHDRAWN</b> from the study	0
Number of <b>ACTIVE</b> subjects		0
Number of subjects who have <b>COMPLETED</b> 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 administered to students between April and September each year.

INDIANA UNIVERSITY BLOOMINGTON INSTITUTIONAL REVIEW BOARD (IRB) REVIEW

**CONTINUING REVIEW**

**STATUS: ONGOING – OPEN TO ENROLLMENT**

**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If any subjects have withdrawn from the study since the last IRB review, please state the reasons: \_\_\_\_\_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: Last IRB review was January 2010. Subject recruitment will not begin until later this spring into the summer of 2011.

**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:

- |   |   |
|---|---|
| <input type="checkbox"/> Children             | <input type="checkbox"/> Pregnant Women and Human Fetuses         |
| <input type="checkbox"/> Prisoners            | <input type="checkbox"/> Economically/Educationally Disadvantaged |
| <input type="checkbox"/> Cognitively Impaired | <input type="checkbox"/> 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**

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

If ETHNIC and RACIAL category totals are not equal, please explain: **This is not a federally sponsored project**

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

No.

Yes. Please explain: \_\_\_\_\_

INDIANA UNIVERSITY BLOOMINGTON INSTITUTIONAL REVIEW BOARD (IRB) REVIEW

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: entering first-year students' past high school academic engagement, expected college engagement, and other beliefs regarding their upcoming college experiences.
- 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: **They are attached to the Summary Safeguard Statement as Appendices A, B, and C.**  
 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: Children Request Form. The Summary Safeguard includes all related documentation including informed consent.

**Include the following documents, as applicable:**

- Publications, if you answered YES to V.I.C. above
- Audit reports, if you answered YES to V.I.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: January 26, 2011

Recorded in the Minutes of: \_\_\_\_\_

INDIANA UNIVERSITY BLOOMINGTON INSTITUTIONAL REVIEW BOARD (IRB) REVIEW

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: 2.16.12. 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: *Sue Brand*

IRB Approval Date: 2.17.11

Recorded in the Minutes of: Mar 24, 2011

