

INDIANA UNIVERSITY BLOOMINGTON INSTITUTIONAL REVIEW BOARD (IRB) REVIEW
REQUEST FORM FOR THE INCLUSION OF CHILDREN IN RESEARCH

Principal Investigator:

IRB Study: **08-13060**

Study Title: **Beginning College Survey of Student Engagement (BCSSE)**

This form is to be completed for any research study targeting or enrolling children.

SECTION I: CATEGORY OF RESEARCH FOR CHILDREN

State the necessity for involving children in the research:

The target population is entering college students, some of whom are likely to be under 18 years old. No questions on the survey are deemed sensitive, embarrassing, or potentially incriminating, so there is no additional risk to this group of students. Most of these students will be completing the survey on campus without the presence of their parents/legal guardians. Therefore it is not practical or feasible to require parental consent for student participation in the project.

Pursuant to 45 CFR 46, Subpart A, the IRB must determine which of the four categories of research apply to the study. As such, identify in which category it is believed the study falls and respond to the additional questions.

Category 1 (§46.404): Research not involving greater than minimal risk to children.

Please explain how adequate provisions are made for soliciting the assent of the children and the permission (parental/guardian informed consent) of each parent or guardian and provide justification if permission from only one parent or guardian will be solicited.

We are requesting a waiver of parental consent pursuant to 45 CFR 46.116(c), specifically that the research could not be practically carried out without the waiver given that the students are away from home attending college and that research is conducted by approval of the institution to evaluate college programs. In addition, We believe this project complies with all subsections of 45 CFR 46.116(d). See Section II below.

Category 2 (§46.405): Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child. The anticipated benefit must justify the risk and the relation of the anticipated benefit to the risk must be at least as favorable as that of alternative approaches.

Please explain why the risk is justified by the anticipated benefit to the child.

Please explain why the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

Please explain how adequate provisions are made for soliciting the assent of the children and the permission (parental/guardian informed consent) of each parent or guardian unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child..

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- Category 3 (§46.406):** Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the child's disorder or condition. The risk must represent only a minor increase over minimal risk, the intervention or procedure must present experiences to the children that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations, and the intervention or procedure must be likely to yield generalizable knowledge about the children's disorder or condition which is a vital importance for understanding or amelioration of the disorder or condition.

Please explain why the risk represents a minor increase over minimal risk.

Please explain why the intervention or procedure presents experiences to subject that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.

Please explain why the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition, which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.

Please explain how adequate provisions are made for soliciting the assent of the children and the permission (parental/guardian informed consent) of each parent or guardian unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

- Category 4 (§46.407):** Research not otherwise approvable under one of the above categories, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. The Secretary of HHS must approve the research, after publicizing the proposed study for public comment and consulting with a panel of experts..

Please explain why the proposed research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

Please explain how adequate provisions are made for soliciting the assent of the children and the permission (parental/guardian informed consent) of both parents or guardians unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

NOTE. When research is covered by categories **§46.406** and **§46.407**, the informed consent must be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

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SECTION II: CHILD ASSENT

I will be obtaining assent from all children.

OR

I am requesting a waiver of assent:

For all children.

For some children.

Please justify waiving child assent using one of the following options:

Assent from children will not be obtained because the study meets the adult criteria for waiving consent pursuant to 45 CFR 46.116(d) (**for minimal risk research procedures**). Please address how the following criteria are satisfied.

1. The research involves no more than minimal risk to the subjects. Please explain.

Student responses to questions asked on BCSSE pose no risk to children. The only anticipated risk due to participation would be the possible loss of confidentiality of the responses as part of the data distribution process. The consequences of such loss of confidentiality would be minimal due to the nature of the questions asked on the BCSSE survey, which do not cover topics that would generally be considered of a sensitive nature. Survey questions are not of a nature that would tend to embarrass students or place them at risk of physical, psychological, social, or legal harm.

2. The waiver will not adversely affect the rights and welfare of the subjects. Please explain.

The rights and welfare of subjects will not be adversely affected in any way.

3. The research could not practicably be carried out without the waiver. Please explain.

BCSSE is typically administered to incoming first-year college students during new student orientations, welcome week activities, or at other times during the summer and early fall. Rarely are parents present with their child during the time of administration of the survey.

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. Please explain.

There is no specific mechanism for providing pertinent information to the student after participation. However, each student is provided an informed consent which summarizes the project and whom to contact for more information (paper or printable statement on web survey).

5. **The research is not FDA-regulated.**

YES

NO

OR (If the waiver does not meet the minimal risk criteria above, then it must meet the waiver option below for the IRB to approve a waiver of assent. Please note that the IRB does not generally approve waiver of assent for research that poses greater than minimal risk)

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- Assent from children is not possible because the capability of the child(ren) is so limited the child(ren) cannot reasonably be consulted. Please explain.

I am requesting a waiver of documentation of assent:

- For all children.
 For some children.

Please check which of the following criterion is met:

- The only record linking the subject and the research would be the assent document and the principal risk would be potential harm resulting from a breach of confidentiality, and the research is not FDA-regulated. Each subject will be asked whether he/she wants documentation linking him/her with the research and the subject's wishes will govern.

OR

- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Please explain: Student responses to questions asked on BCSSE pose no risk to children. The questions are general in nature and not of a sensitive subject.

If none of the waiver justifications apply, you must obtain assent from all children.

NOTE: If the IRB grants a waiver of assent, the investigator will be required to make an accounting of the number of waivers employed, including the justification for the waivers, at the time of continuing review.

SECTION III: PARENTAL/GUARDIAN PERMISSION (CONSENT)

- I will be obtaining parental/guardian permission (consent) for all children. Please answer the questions below.

1. **When (in what timeframe) and where (what setting) will consent take place?** Indicate any waiting period between informing the parent/guardian and obtaining their consent. The timeframe and any waiting should ensure the parent/guardian is provided sufficient opportunity to consider whether or not their child should participate in the study.

N/A

2. **Who will be responsible for obtaining initial and ongoing consent?** (check all that apply)

- Principal Investigator
 Co-Investigator
 Research Coordinator
 Other (specify):

NOTE: Individuals who will be obtaining consent must be listed in Section XXI of the summary safeguard statement.

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a. Explain how these individuals will be adequately trained to conduct the consent interview and answer subject's or parent's/guardian's questions:

- Passed the Indiana University human subjects protection test
- Passed the Investigator 101 test
- Received study-specific training from study personnel
- Other (specify):

b. Indicate in what language(s) the consent interview will be conducted:

- English
- Spanish
- Other (specify):

c. If the consent interview will be conducted in a language other than English, state how the interview will be conducted (e.g. use of a translator). Please note that if non-English speaking individuals are expected to enroll in the research, a language-appropriate consent document must be developed, submitted and approved by the IRB and used when enrolling those participants:

NOTE: Ensure that language-appropriate consent documents are submitted with the application.

3. **Explain how subjects' and parents'/guardians' privacy will be protected during the consent process.** This refers to how access to subjects and parents/guardians will be controlled (e.g. time, place, etc. of consent procedures).

4. **Indicate any factors that might result in the possibility of coercion or undue influence. (check all that apply)**

- the research will involve students of the PI
- the subjects will be recruited through institutions with which the PI has a close relationship
- Other (please specify):

Describe steps taken to mitigate the possible coercion:

I am requesting waiver of parental/guardian permission (consent). Please justify waiving parental/guardian permission (consent) using one of the following options:

Parental/guardian permission (consent) will not be obtained because the study meets the criteria for waiving consent pursuant to 45 CFR 46.116(d) (**for minimal risk research procedures**). Please address how the following criteria are satisfied.

Please check here if the criteria have already been explained in Section II: Child Assent above.

1. The research involves not more than minimal risks to the subjects. Please explain.

2. The waiver will not adversely affect the rights and welfare of the subjects. Please explain.

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3. The research could not practicably be carried out without the waiver. Please explain.

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. Please explain.

5. **The research is not FDA-regulated.**
 YES
 NO

OR (If the waiver does not meet the minimal risk criteria above, than it must meet the waiver option below for the IRB to approve a waiver of parental/guardian permission (consent). Please note that the IRB does not generally approve waiver of parental/guardian permission for research that is greater than minimal risk)

Parental/guardian permission (consent) will not be obtained because the research is designed for conditions or for a participant population for which parental or guardian permission (consent) is not a reasonable requirement to protect the participants (for example, neglected or abused children). Please explain.

1. An appropriate mechanism for protecting the children who will participate as subjects in the research must be used. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition. Please explain.

If none of the waiver justifications apply, you must obtain parental/guardian permission (consent) for all children.