

Cambridge College Institutional Review Board Checklist to Assess Completeness of the Informed Consent Form

Use this checklist to ensure that all of the required elements are included in your study's consent form. This checklist is not exhaustive. Provide additional information as necessary.

I. Introduction (does the consent form document include):

- The title of the study appears at the top
- Investigator(s) are listed, and her/his/their affiliation with Cambridge College is described/explained.
- The following opening statement is included:

“The purpose of this form is to provide you information that will help you decide whether or not you want to participate in a research study. [Optional: The person performing the research will describe the study to you and answer all your questions.] Read the information below carefully and ask any questions you may have before making your decision. If you decide to be involved in this study, this form will be used to record your consent.”

Should the research involve children under the age of 18:

“The purpose of this form is to provide you (as the parent or guardian of a prospective research participant) information that will help you decide whether or not to let your child participate in this research study. [Optional: The person performing the research will describe the study to you and answer all your questions.] Read the information below and ask any questions you might have before deciding whether or not to give your permission for your child to take part. If you decide to let your child be involved in this study, this form will be used to record your permission.”

II. Purpose of this Research Project (does the consent form document include):

- A clear statement that the study involves research
- The purpose for conducting the research (what question do you hope to answer with this project?)
- The total number of research participants involved

III. Procedures (does the consent form document include):

- A step-by-step explanation of what the study participants can expect (what will they do/experience?)
- A description of the length and frequency of each of the study's procedures
- The total time commitment for the research participant and where the research will be conducted
- A description and explanation of the instruments / documents that will be used (in lay language)
- An explanation of the experimental conditions involved (if applicable)
- If participants will be audio/video recorded include the following: “You (your child) will be [audio/video] recorded.”

IV. Risks (does the consent form document include):

- A description of all potential risks (mental, social, financial, legal, dignity, or physical), including the likelihood of the risk occurring.
[Note: If risks are minimal include the statement: “There are no foreseeable risks to participating in this research study.”]
[Note: Survey questions of a sensitive nature may pose emotional distress caused by remembering unpleasant experiences]
- An explanation of the safeguards you will employ to reduce or minimize risks (only necessary if there is a foreseeable risk)

V. Benefits (Note: Compensation should not be included/described in this section):

- A description of all direct or indirect benefits of study participation (**not to be exaggerated**)
- If no benefits accrue to the participant, a description of the potential societal benefits of the study
- Statement “No promise of benefits has been made to encourage you to participate”
- Optional: Checkbox for participants/parents/guardians to indicate whether they would like a summary of the research results when they become available

VI. Compensation (does the consent form document include):

- An explanation of whether or not participants will be compensated
- The amount of compensation (including extra credit), if applicable and how participants will be paid
If extra credit is offered to study participants, what comparable alternative means of obtaining extra credit will be offered to those who decline to participate in the study.

VII. Freedom to Withdraw (does the consent document include):

- A statement that participants are free to withdraw from the study at any time without penalty
“You may decline to participate - your (your child’s) participation in this study is completely voluntary. Should you agree to participate in the study now, you are free to change your mind later. No negative consequences of any kind will come to anyone who wishes not to participate or who initially agrees to be in the study and later changes their mind. Withdrawal or refusing to participate will not affect your (your child’s) relationship with Cambridge College (or name of organization where research participants are recruited) in any way.
- If study involves compensation, statement that participants will be compensated for the portion of their time spent in the study (if applicable) or fully compensated should they choose to withdraw
- Statement that participants are free not to answer any questions or free not to respond to experimental situations without penalty.
- If applicable: For research with children or youth under the age of 18, include the following:
“Your child will be asked whether or not he or she wants to participate in this study. If you child does not want to participate, he or she will not be included in the study. No negative consequences of any kind will come to children who wish not to participate or who initially agree to be in the study and later change their mind.”
- Optional: Statement describing that there may be circumstances under which the investigator may determine that a study participant should not continue with the study. Should such a case occur, the participant must be compensated for the portion of the project she/he completed.

VIII. Extent of Anonymity and Confidentiality (does the consent document include):

- An honest description of the extent to which research participants will be identifiable
- An explanation of how the study will provide the utmost confidentiality or anonymity
[confidentiality = when individual study participants can be identified directly or through identifiers, but the researcher promises not to divulge that information; anonymity = individuals cannot be identified by anyone, including the researcher]
- An explanation of the use of study ID/codes, if applicable
- Optional: Include the following statement “At no time will the researchers release the results of this study to anyone other than the individuals working on this project without your written consent.”
- An explanation of who will have access to the data
- A description of when the data/recordings/artifacts collected for the study will be destroyed

IX. Contact Information for Investigator and IRB

- Contact information of investigator(s), including email address and phone number
- Statement:
“Prior, during or after your participation you can contact the researcher **[INSERT NAME HERE]** at **[PHONE NUMBER]** or send an email to **[EMAIL ADDRESS]** for any questions or if you feel that you (your child) have (has) been harmed as a result of participating in this study. This study has been reviewed and approved by Cambridge College’s Institutional Review Board and the study number is **[STUDY NUMBER].**”
- Statement:
“For questions about your rights or any dissatisfaction with any part of this study, you can contact, anonymously if you wish, Dr. Laurie Rosner, the Coordinator of the Institutional Review Board by phone at 413.565.1404 or email at lrosner@baypath.edu.”

X. Permission & Signatures (does the consent document include):

- Statement:
“You are asked to decide whether or not you want to (allow your child to) participate in this study. Your signature below indicates that you have read and understood the information provided above and that you have decided to (allow your child to) participate in the study. If you later decide that you wish to withdraw (your permission), you may discontinue (his or her) participation at any time. You will be given a copy of this document for your records.”
- Signature line for research participant and date
- Signature line for researcher and date
- A statement saying that the person signing the consent form will receive a copy of that form
- For research that recruits children under the age of 18, the signature line is for the parent/guardian and an additional line should be included on which to write the research participant’s (the child’s) name.

XI. Structure of Consent Document

- The language of the consent form is directed toward the individual signing the form.
- The text and readability of the consent form is appropriate for the age, mental capacity and maturity of the individual signing the form (avoiding the use of jargon, scientific terms, and concepts not readily comprehended by the average adult).
- The consent form does not contain any exculpatory language in which the research participant is made to waive or appear to waive any of the her or his rights.
- The final draft of the consent document has been reviewed for grammatical and typographical errors.