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**Boston College Office of Research Protections Informed Consent Overview and Example Template**

**What is informed consent?**

Informed consent is required to provide potential subjects or their legally authorized representatives with the information necessary for them to make a decision about participating in research. It is an ongoing process and not just a one-time signature on a form.

Information in the consent document must be organized to facilitate comprehension. Consent documents should be written in plain language, generally at the 8th grade reading level. The reading level can be higher if the target population tends to have a higher literacy rate than the general population. For child assent documents, the reading level and complexity of the information provided should be appropriate for the age level of the child.

We are including this template as an example to help you create consent documents for your research study. Please note:

1. Regulations now require that federally-sponsored research projects contain a concise and focused presentation of the key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. The key information must be presented first and must include the following:
	1. Identification of the project as a research study and that participation is voluntary
	2. Purpose of the research, duration of participation, and a description of research procedures

Foreseeable risks or discomforts, if any

* 1. Expected benefits to subjects or others, if any
	2. Alternative procedures or treatments that might benefit the subject

(Note: applies primarily to clinical research)

Many IRB studies have brief consent documents (2 or 3 pages) that meet this new requirement without the need for a separate key information section. However, if your project is complex or involves numerous research procedures, this summary is required for federally-sponsored projects and strongly recommended for all others.

1. Text in [brackets] represents information about your study that you should add (in plain text).
2. A backslash indicates that you must make a selection depending on the procedures for your study (e.g., “will/will not” or “I/we”).
3. Additional instructions or sample text are provided in boxes.
4. Before you upload your consent document to your CyberIRB application, delete this cover page, brackets, and boxes. The finished document should reflect what you will give to the subject.
5. Use a file name for each consent document that clearly identifies the type of consent and for which subjects it is intended (e.g. child assent, parental permission, adult consent, teacher consent, etc.).

For questions about informed consent, please contact the Office for Research Protections – (617) 552-4778 or irb@bc.edu.

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**Boston College Consent Form**

**Boston College [***School or Department name***]**

**Informed Consent to be in study [***Title of Study***]**

**Researcher:** [*name of PI*]

**Study Sponsor:** [*if any*]

**Type of consent [Adult Consent Form** or other applicable consent form such as **Parental Permission Form]**

**Invitation to be Part of a Research Study**

You are invited to participate in a research study. You were selected to be in the study because [eligibility criteria; e.g., age, gender, language, etc.]. Taking part in this research project is voluntary.

Note that if the subjects of your study are BC undergraduates, you must indicate here that the subjects have to be at least 18 years old to participate. Otherwise, you will need to collect parental consent.

**Important Information about the Research Study**

For research projects that involve numerous research procedures that will require more than a 2-3 page consent document, provide a concise and focused presentation of key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. Organize information to facilitate comprehension.

**Delete this section if not necessary for the study.**

Things you should know:

* The purpose of the study is to [briefly describe study purpose]. If you choose to participate, you will be asked to [do what, when, where, and how]. This will take approximately [period of time].
* Risks or discomforts from this research include [briefly describe].
* The study will [description of potential direct benefits to subjects – or no benefits].
* Taking part in this research project is voluntary. You don’t have to participate and you can stop at any time.

Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

**What is the study about and why are we doing it?**

The purpose of the study is [describe the study purpose]. The total number of people in this study is expected to be [insert number – optional if your study is an itnervention].

If you have used the summary above, provide additional details in this section.

**What will happen if you take part in this study?**

If you agree to take part in this study, you will be asked to [provide a detailed description of what the subject will be asked to do in chronological order (what, when, where, how). [Be sure to specify if audio/video recordings will be used to collect data]. We expect this to take about [duration, number of interactions]. [Indicate if information collected will be linked to other data (e.g., research data, protected health information, or administrative data such as US Census data).]

For projects involving the collection of sensitive information or the inclusion of questions that might be upsetting, include examples of the type of questions that will be asked or describe the sensitive topic areas that are involved.

If applicable, include a statement about whether clinically relevant research results will be shared with the subject and under what conditions. For example: “We may learn information about your health as part of the research. We will/will not share this information with you [how/why not].”

**How could you benefit from this study?**

Although you will not directly benefit from being in this study, others might benefit because [insert details]. **[OR]** You might benefit from being in this study because [insert details].

Please note that payment/compensation is **never** to be considered a benefit, but rather in recognition of the time and energy spent participating. As such, do not include any information about compensation in this section.

**What risks might result from being in this study?**

There are some risks you might experience from being in this study. They are [describe specific risks, and indicate what the study team will do to minimize those risks.]. **[OR]** We don’t believe there are any risks from participating in this research.

Primary risks include physical, psychological, or informational risks. For informational risks (e.g., those involving breach of confidentiality), describe what you will do to protect the data during collection, while stored or during transmission of the data in the section below. Psychological risks (e.g., those associated with the completion of a particularly sensitive survey or interview) could be mitigated by providing subjects with contact information for counseling resources. If resources will be given to participants, please include them in your application.

**How will we protect your information?**

The records of this study will be kept private. In any sort of report we may publish, we will not include any information that will make it possible to identify you. Research records will be kept in a locked file.

If you wish to use identifying information in a publication or presentation, including photographs, audio or video recordings, include the following, as appropriate:

“The results of this study may be published or presented at a scientific meeting. The researchers will ask for separate written permission to include your name [or pictures, recordings] or other information that could identify you.”

If your project is NIH-funded and collects identifiable, sensitive information, it will be covered by a **Certificate of Confidentiality (CoC)** –**or**– if you will apply for a CoC for non-NIH-sponsored research collecting health-related, identifiable, sensitive information, insert the following language:

“This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it used for other scientific research, as allowed by federal regulations protecting research subjects.”

Use the following language as applicable: “The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [The Agency] which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connect with the research, you must provide consent to allow the researchers to release it.”

The following language should be included if the researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws: “The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].”

The following language should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants: “The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.”

Note: you should edit the suggested consent language as necessary for your study population, for example, lower literacy or non-English speakers, so long as all relevant points related to disclosure and consent are covered. See this site for more detail: [***https://humansubjects.nih.gov/coc/suggested-consent-language***](https://humansubjects.nih.gov/coc/suggested-consent-language)

**For projects not involving a CoC**, if you are **a mandatory abuse** reporter and it seems likely you will encounter reportable events as part of the study, insert the following: “If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.”

If your project meets the definition of an **NIH clinical trial**, include the following: “A description of this study will be posted on a public website, <http://ClinicalTrials.gov>, and summary results of this study will be posted on this website at the conclusion of the research, as required by the National Institutes of Health (NIH), the study sponsor. No information that can identify you will be posted.”

If you will **register your project on ClinicalTrials.gov** voluntarily or in order to meet journal or other sponsor requirements, include the following: “A description of this study will be posted on <http://ClinicalTrials.gov>, and summary results of this study may be posted on this website at the conclusion of the research. No information that can identify you will be posted.”

All electronic information will be coded and secured using a password-protected file.

If at the time of data collection, subjects’ research data will be linked to individual identifiers (such as names, email addresses, student ID numbers, etc.) then include the following:

“We will assign to each participant a unique, coded identifier that will be used in place of actual identifiers. We will separately maintain a record that links each participant’s coded identifier to his or her actual name, but this separate record will not include research data.”

If you will know the identities of the people who participate but will not have the ability to link any participant to the research data he/she provides (such as in the case where you are entering names into a raffle or need to give students credit for participating, include the following:

“The researchers will not be able to link your survey responses to you, but they will know that you participated in the research. This will enable the researchers to [insert reason for keeping track of who participated.]”

If you will remain blinded to the identities of the participants, include the following:

“The [survey/instrument] does not ask you to identify yourself, and the researchers will have no ability to learn the identities of the people who participate.”

[If audio or video tape recordings are made, explain specifically who will have access to them, if they will be used for educational purposes, and when they will be erased/destroyed and indicate how they will be destroyed or erased.]

The Institutional Review Board at Boston College and internal Boston College auditors may review the research records. State or federal laws or court orders may also require that information from your research study records be released. Otherwise, the researchers will not release to others any information that identifies you unless you give your permission, or unless we are legally required to do so.

**What will happen to the information we collect about you after the study is over?**

I/We will/will not keep your research data to use for [future research or other purpose]. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project. **[OR]** Your name and other information that can directly identify you will be deleted from the research data collected as part of the project.

I/We may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you. [If data must or will be deposited in a public or other repository, briefly describe.] **[OR]** [We will not share your research data with other investigators.]

Sample text:

Data collected as part of this research will be provided to the XXX repository for future use by other researchers. This data will not contain information that could directly identify you.

**How will we compensate you for being part of the study?**

You will receive [nature and total amount of incentive/compensation] for your participation in this study.

Describe how compensation will be determined if the subject withdraws from the research before the end of the study. Compensation should not be contingent upon completion of the study. To avoid potential coercion, please pro-rate or give the amount in full if a participant ends the study early.

If there will be no compensation, state so.

**What are the costs to you to be part of the study?**

To participate in the research, you will need to pay for [indicate what costs, if any, subjects will have to pay – such as parking].

**OR**

There is no cost to you to be in this research study.

**Your Participation in this Study is Voluntary**

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this study is completed, [provide details about disposition of data]. [Describe anticipated circumstances, if any, under which the subject’s participation may be terminated by the PI without the consent of the subject].

If you choose not to be in this study, it will not affect your current or future relations with the University or [if conducting research through a school or other institution, add the name here].

**Getting Dismissed from the Study**

The researcher may dismiss you from the study at any time for the following reasons: (1) it is in your best interests (e.g. side effects or distress have resulted), (2) you have failed to comply with the study rules [add if applicable: or (3) the study sponsor decides to end the study].

**Contact Information for the Study Team and Questions about the Research**

If you have questions about this research, you may contact [PI name, email, phone (and faculty advisor contact info if PI is a student)].

For International Studies: List the name, email and phone of the local collaborator, if any, first. Be sure to include the U.S. calling code and exit number for the country of origin.

**Contact Information for Questions about Your Rights as a Research Participant**

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

Boston College

Office for Research Protections

Phone: (617) 552-4778

Email: irb@bc.edu

**Your Consent**

Required for projects obtaining a signature only – delete this paragraph for projects that will request a waiver of documentation. The document must be dated by the person signing.

For projects involving a waiver of documentation, include the following statement: Before agreeing to be part of the research, please be sure that you understand what the study is about. We will give you a copy of this document for your records [or you can print a copy of the document for your records]. If you have any questions about the study later, you can contact the study team using the information provided above.

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree to take part in this study.*

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Printed Subject Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

**Parent or Legally Authorized Representative Permission**

**Delete this section if not applicable to the study.**

By signing this document, you are agreeing to [your child’s **OR** the person’s named below] participation in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree for [my child* ***OR*** *the person named below] to take part in this study.*

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Printed Subject Name

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Printed Parent/Legally Authorized Representative Name and Relationship to Subject

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Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Parent Name and Relationship to Subject (when 2 signatures are required)

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Signature Date

You may also need to obtain dated consent for specific activities when those activities are ***optional*.** Whether an activity is required or optional must be clearly described in the main body of the consent above. Some common optional research activities are included below:

**Consent to be Audio/video Recorded**

*I agree to be audio/video recorded.*

***YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

**Consent to Use Data for Future Research**

*I agree that my information may be shared with other researchers for future research studies that may be similar to this study or may be completely different. The information shared with other researchers will not include any information that can directly identify me. Researchers will not contact me for additional permission to use this information.* (Note: This separate consent is not necessary if you will only store and share deidentified data.)

***YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

**Consent to be Contacted for Participation in Future Research**

*I give the researchers permission to keep my contact information and to contact me for future research projects.*

***YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date