**Please delete this page prior to uploading for IRB Review**

**Caregiver Informed Consent Template**

Informed consent is required to provide potential subjects, or their legally authorized representatives, with important information to make an informed decision about whether to participate in a research study.

Information in the consent document must present sufficient detail that a reasonable person would want to have about the research study. It must be organized and presented in a way that does not merely provide lists of isolated facts but rather facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate. As part of the informed consent process, participants must also have an opportunity to discuss the study details with the investigator.

Consent documents should be written in plain, nontechnical language, generally at the 6th - 8th grade reading level. The reading level can be higher if the targeted population tends to have a higher literacy rate than the general population.

For more information on plain language go to <http://www.plainlanguage.gov/>.

**INSTRUCTIONS:**

* Use a font size of 14, one-inch right margins, and an easily readable font such as Verdana or Arial
* Complete all required sections of the consent form, then delete all instruction boxes, italicized/bold instructions, brackets and/or omitted sections prior to submitting this form.
* Please note that the last page of this consent form is to be used for parental consent if your study involves children. If your study does not involve children, please delete that page.
* Remember that once a subject signs the consent form, you are required to give that person a copy.

For questions about informed consent, please contact the Belmont University IRB at irb@belmont.edu.

***Note: This document is adapted with permission from the University of Michigan***

***(***[***https://research-compliance.umich.edu/irb-health-sciences-and-behavioral-sciences-hsbs***](https://research-compliance.umich.edu/irb-health-sciences-and-behavioral-sciences-hsbs)

**Caregiver Consent**

Title of the Project:

Principal Investigator: **[Name, credentials, department]**

Co-investigator: **[Name, credentials, department]**

Faculty Advisor: **[Name, credentials, department]**

Study Sponsor: **[If any]**

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

We are inviting your child to participate in a research study. In order to participate, your child must be **[eligibility criteria; e.g., age, gender, language, etc.]**. Taking part in this research project is voluntary.

**Important Information About the Research Study**

Principal Investigator (PI) instructions: This section should be brief and no more than 250 words (1 page double spaced or less). You will be going into more detail later in this consent form.

Here are some things you should know about this study:

* The purpose of the study is to **[briefly describe study purpose]**.
* If you choose to allow your child to participate, your child will be asked to **[do what, when, where, and how]**.
* Your child’s participation 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. Your child does not have to participate and can stop at any time.

More details are provided below about this research study. Please take all the time you need to read this entire form. We will have time to talk so you can ask questions before deciding whether or not your child can 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]**.

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

**What will happen if your child takes part in this study?**

If you provide consent for your child to take part in this study, your child will be asked to **[provide a detailed description of what the subject will be asked to do in chronological order (what, when, where, how).** We expect this to take about **[duration, number of interactions]**.

PI instructions: Here is an example of details in chronological order:

“In this study you will be asked to do the following things:

1. Visit [location] \_\_ times for study visits.

2. Participate in either individual tutoring or group tutoring 3 times a week for \_\_\_ months.

3. Have an MRI scan \_\_\_\_ times.

4. Take math and reading tests \_\_\_ times.

5. Take surveys and answer questions about [describe general topics].

6. Keep a diary at home.”

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.

**How could your child benefit from this study?**

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

**What are the risks of being in this study?**

There are some risks your child 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.

The researchers must immediately be notified if your child has any injuries or other problems related to participation in the study. The University may be able to assist you with obtaining emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. By signing this form, you do not give up your right to seek payment if your child is harmed as a result of being in this study.

PI instructions: Primary risks include emotional/psychological discomfort, physical risks, 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/emotional 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 or by having a resource on call at the location of the interview if appropriate.

**How will we protect your child’s information?**

If we publish or present the results of this study at a conference, to protect your child’s privacy, we will not include any information that could directly identify you or your child.

PI instructions: 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 conference. The researchers will ask for separate written permission to include your name [or pictures, recordings] or other information that could identify you. This form is included at the end of this consent form.”

We will protect the confidentiality of your child’s research records by **[explain]**. Your name and/or the name of your child and any other information that can directly identify you or your child will be stored separately from the data collected as part of the project**. [OR]** **[Describe limitations to confidentiality, if any]**.

It is possible that other people may need to see the information we collect about your child. These people work for Belmont University, **[the study sponsor or government offices, if any]** and are responsible for making sure the research is done safely and properly.

PI instructions: 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.”

PI instructions: If you wish to record audio or video of participants as part of this research project, include the following language:

You consent to the use of the audio and/or video recording of your child’s words and/or actions as described above in this study. Recordings may be used as described in presentations, research reports, and other formats. You acknowledge that the study team will not be required to use the recording(s) in their work.

By checking “yes” below, you release investigators, sponsors, and successors from claims that could come from the use of the recordings. This includes claims of defamation, invasion of privacy, infringement of moral rights, rights of publicity or copyright, etc. You will have no ownership rights in the recordings of the research. Please ask any questions about the recordings prior to checking “yes” below.

Do you consent to the use of audio/video recording of your child’s words and/or actions for the purposes of participating in this project?

\_\_\_\_Yes

\_\_\_\_No

PI instructions: If you wish to collect and/or use specimens from child participants as part of this research project, include the following language:

*Briefly describe (using lay terminology) the way in which this material will be used within the research project. Describe the measures taken to ensure subject confidentiality. If the research will or might include whole genome sequencing, disclose this information here.*

You consent to the release of the material listed in the paragraph above for use in this research study. Your child’s confidentiality will be protected, although information obtained from the specimen(s) may be used in presentations, research reports, or other formats that provide research summaries. Additionally, you acknowledge that all rights to this tissue sample will belong to Belmont University, the PI of this project, the Sponsor of this project, etc., and there is no provision to pay you or your child for this material. Please ask any questions about the use of your child’s specimens prior to checking “yes” below.

Do you consent to the release of your child’s specimens for the purposes of participating in this research project?

\_\_\_\_YES

\_\_\_\_NO

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

We are required to keep research data for three years. Your or your child’s name and other information that can directly identify you and your child will be kept secure and stored separately from the research data collected for this project. **[OR]** You and your child’s name and other information that can directly identify you and your child will be deleted from the research data collected as part of the project. After three years, all of the research data will be destroyed.

\*REQUIRED\* Insert one of the following statements about the research involving the collection of identifiable private information or identifiable biospecimens:

Identifying information might be removed from your child’s private information collected as part of this research. The information could be used for future research or distributed to another Principal Investigator (PI) for future research without obtaining additional informed consent.

OR

Your child’s information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research.

PI Instructions: Federal regulations and Belmont policy require that research records be kept for three years. Additional standards from your discipline or requirements from research sponsors may also be applicable to your data storage plan. The bottom line is that it is good practice to retain data until there is no reasonable possibility that you will be required to defend against an allegation of scientific misconduct.

**Will you be paid for being part of the study?**

Your child will receive **[nature and total amount of incentive/compensation]** for participation in this study. **[Describe how compensation will be determined if the subject withdraws from the research before the end of the study]** **OR** You and/or your child will not receive anything for being in this study.

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

For your child to participate in the research, you will need to pay for **[indicate what costs, if any, subjects will have to pay (e.g., parking)]**. **[OR]** You do not need to pay anything for your child to participate in this study.

**What other choices do you and your child have if you don’t take part in this study?**

PI instructions: Describe any alternatives to participation. For most studies at Belmont, the alternative is simply not to participate. For projects that involve an intervention that might treat or improve a condition or a disease, describe alternatives to participation in the research study. These could include intervention or treatment available outside the research context.

If participants have an alternative way of completing a study procedure (e.g. filling out a paper instead of an online questionnaire, taking a survey home, going to a different location for a test, etc.) describe that option.

If there are no alternate choices, include the following language: There are no alternative choices if you decide that your child will not take part in this study.

**Is your child’s participation in this study voluntary?**

It is totally up to you to decide if your child will be in this research study. We will also be asking your child if they would like to participate. Participating in this study is voluntary. Even if your child is part of the study now, your child may stop at any time. Your child does not have to answer any questions they do not want to answer. If you or your child decide at any point that you do not want your child to participate in the study, you will not be treated differently, and you/your child will receive the same care and/or benefits as everyone else. If you decide to withdraw your child before this study is completed, **[provide details about disposition of data and potential consequences of early withdrawal, as applicable]. [Describe anticipated circumstances, if any, under which the subject’s participation may be terminated by the PI without the consent of the subject]**.

**Who should you contact if you have questions about the research or your child’s rights as a research participant?**

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

**Contact information for questions about your rights as a research participant**

If you have questions about your child’s 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 Erich Baker, Ph.D., Vice Provost for Research and Strategy Initiatives (615) 460-5867 or [erich.baker@belmont.edu](mailto:david.gregory@belmont.edu).

Also, if your child experiences an injury because of this study, please immediately contact **[PI name, and faculty advisor if PI is a student]**.

**What if new information becomes available?**

In the event new information becomes available that may affect your willingness to allow your child to participate in this research, the information will be given to you so that you can make an informed decision about whether or not to continue your participation.

**Parent or legally authorized representative permission**

PI instructions: If your study involves children, parental/guardian permission is always required. In most cases, child assent is required as well. Use the following guidelines for determining child assent: Up to 7 years of age: The IRB can grant a waiver of assent if the capability of the child/children is limited in understanding and providing assent. 7 – 12 years old: In most cases, children of this age should be able to participate in the assent process and should sign the form. 13- 17 years old: In most cases, adolescents should be fully informed of the research study and able to sign the assent form.

Please see assent form on the Belmont IRB website <http://www.belmont.edu/irb/forms-instructions.html>.

By signing this document, you are agreeing **to [your child’s OR the person named below]** participation in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records. 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