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**INSTITUTIONAL REVIEW BOARD (IRB) REVIEW FORM
FOR PROJECTS USING HUMAN SUBJECTS**

Investigators are responsible for ensuring that the rights and welfare of human subjects participating in research activities are protected and that methods used and information provided to gain subject consent are appropriate to the research. **The IRB will review only those assignments, activities, or investigations that are defined as research.** “Research” as defined by federal administrative bodies is “a systematic investigation designed to develop or contribute to generalizable knowledge” (45 CFR 46.102). Course projects whose primary intent and design are pedagogical and are not originally intended to contribute to the general body of knowledge, are not normally subject to IRB review. However, it is the position of the IRB that the individual faculty member retains ethical responsibility for the proper conduct of such instructional studies.

**All the research activities involving the use of human beings as research subjects** (participants) must be reviewed and approved by the Elon University Institutional Review Board (IRB), unless the IRB chair determines that the research falls into one or more of the categories of exemption established by federal regulation. These categories include research conducted in commonly accepted educational settings involving normal educational practices such as research on regular and special education instructional strategies, research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Also exempt is research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. However, each category of exemption contains specific exceptions. Please note that only the IRB may make the determination if the research qualifies for exemption under Title 45 CFR 46.101.

**Investigators may not solicit subject participation or begin data collection until they have received approval** or written concurrence that research has been determined to be exempt from the Institutional Review Board.

**Students may not serve as Principal Investigator** on an IRB study and should work with their faculty mentor, instructor, etc. as a Co-Investigator when submitting an IRB application.

**Application forms** are available on the Internet at [www.elon.edu/IRB](http://www.elon.edu/IRB). The form may be downloaded and applications should be submitted electronically via ***IRB Mentor*** System ([www.elon.edu/irbmentor](http://www.elon.edu/irbmentor)). If you have **questions** about the IRB application form, access to ***IRB Mentor*** or about the review process, contact:

**Marna Winter
Chair, IRB
Phone: 278 5881 /E-mail:** **mwinter2@elon.edu**

The Institutional Review Board generally meets on an ad hoc basis as proposals are submitted for review. Applicants must allow a minimum of 2 weeks for the review process. Proposals describing research that involves more than minimal risk to participants (any harm anticipated in the proposed research that is more probable or of greater magnitude than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests) will require a full review which will occur during the monthly standing IRB meeting. Contact the IRB Chair for meeting times.

A notice of the IRB’s action will be sent to the researcher(s). It is the responsibility of the researcher(s) to see that the form is given to any agency which may require it.

**Title 45 Code of Federal Regulations Part 46 (45 CFR 46) Protection of Human Subjects** specifies federal regulations for the conduct of research involving human subjects. See especially sections 46.102 Definitions, 46.116 General Requirements for Informed Consent, and 46.117 Documentation of Informed Consent. The document is available at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46\_1102. See references throughout this application to 45 CFR 46.

**INSTRUCTIONS:**

Your responses to the questions are basic to the Institutional Review Board’s determination about the protection of the rights and welfare of human subjects in your research. Your responses should be clear, complete, and easy to understand.

Place your response immediately under each question (not on a separate sheet). It is important that you answer every question. If you believe that a question does not apply to your research, enter a response such as “N/A” or “does not apply.”

Copies of the following must be included with this form:

1. The letter/recruitment flier/script that will be used to inform participants of the nature of the research.
2. The informed consent template the subject(s) will sign (samples appropriate to behavioral and biomedical research are available at [www.elon.edu/irbmentor](http://www.elon.edu/irbmentor) under IRB/Documentation/Example Applications).
3. Copies of surveys, instruments or measures, questionnaires, interview schedules, focus group questions and/or other materials used to collect data.
4. Merge all the materials together and save as a **pdf** document prior to submission.
5. All Principal Investigators must complete CITI Training and upload a completion certificate to IRB Mentor before an application will be considered. After completion, CITI certification is recognized for 4 years by the Elon IRB committee.

**Submit your application via the IRB Mentor System (www.elon.edu/irbmentor).**

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| **Research Project Title** |

**Principal Investigator**

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| **Name (First, Middle Initial, Last):** | **Campus Box/Phone:** |
| **Department:** | **Email:** |
| To the best of my knowledge, the plan of conduct for this research conforms to the policies and procedures for the use of human participants at Elon University. **Signature:** **Date:** | **Required CITI Training Completion Date -**  |

**Co-Investigator**

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| **Name (First, Middle Initial, Last):** | **Campus Box/Phone:** |
| **Department:** | **Email:** |
| To the best of my knowledge, the plan of conduct for this research conforms to the policies and procedures for the use of human participants at Elon University.**Signature:** **Date:** | **Required CITI Training Completion Date -**  |

**Co-Investigator**

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| **Name (First, Middle Initial, Last):** | **Campus Box/Phone:** |
| **Department:** | **Email:** |
| To the best of my knowledge, the plan of conduct for this research conforms to the policies and procedures for the use of human participants at Elon University.**Signature:** **Date:** | **Required CITI Training Completion Date -**  |

**Co- Investigator**

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| **Name (First, Middle Initial, Last):** | **Campus Box/Phone:** |
| **Department:** | **Email:** |
| To the best of my knowledge, the plan of conduct for this research conforms to the policies and procedures for the use of human participants at Elon University.**Signature:** **Date:** | **Required CITI Training Completion Date -**  |

**NOTE: If more than four co-investigators will be listed, copy the box on form and fill in additional information as needed.**

**Will this research involve working with minors? If so, have you completed the** [**protection of minors training**](https://www.elon.edu/u/academics/irb/required-training/)**?**

**YES \_\_\_\_\_\_\_ No\_\_\_\_\_\_**

**\*If not, please click on the link above to complete the training.**

**Application Questions**

**INTRODUCTION TO THE PROPOSED RESEARCH**

1. Provide the **date** when you propose to begin research and the date when you anticipate that research will be completed.

 Proposed start date: \_\_\_\_\_\_\_\_\_\_\_\_\_ Anticipated completion date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Indicate any source(s) of **funding** for the proposed research i.e., department funds or internal or external grants.

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**DESCRIPTION OF THE PROPOSED RESEARCH**

1. Provide a brief (1 page or less) description of the **purpose** of your research.

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1. Indicate the **setting or location(s)** where research will be conducted. Attach letters of support or agreement, as necessary, showing that you have permission to conduct research at that location. **Included in this letter should be an indication that you are aware of and able to adhere to all of the safety procedures required at the location(s) where data collection will occur.** If you are interacting with human subjects outside of the United States, describe what procedures are required to adhere to the human subjects mandates for the country where data collection will take place. If you are working in a school system you must document the procedures required to complete research in that specific school system.

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Does the proposed research require that you **deceive** participants in any way?

 \_\_\_\_ Yes \_\_\_\_No

1. If your response is “yes”, describe the type of **deception** you will use, indicate why it is necessary for this study, and provide a copy of the debriefing script.

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1. Describe **in detail** what will happen to or be required of subjects in your investigation.

(include a description of any instruments used, sample of questionnaires, focus group questions, etc.)

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**RISKS AND BENEFITS**

1. Describe any **potential physical or psychological risks or problems** that a research participant may encounter by participating in this investigation. Also, describe how you plan to minimize these risks. Examples of risks and problems include but are not limited to physical injury, painful simulation, deception, coercion, embarrassment, lack of confidentiality, lack of full disclosure, and lack of feedback for subjects. If appropriate, include a description of any special qualification or training by investigators that will be used to minimize risk for the subject (e.g. CPR certification). **When appropriate, describe the procedures you will use to minimize the risk of transmission of infectious disease (including COVID-19) between subjects, as well as between subjects and researchers.**

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1. Describe the **potential benefits** of conducting this research. List the benefits to the participants themselves, contributions to the field of knowledge, and benefits to society as a whole. If the research participants will not receive any direct benefits from participating in this study, indicate this in your response.

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1. **Will the principal investigator be present during all data collection procedures?**

 **\_\_\_\_ Yes \_\_\_\_No**

1. **If the answer is “no”, provide a description of the processes that will be used to ensure that all investigators will safely and effectively apply all procedures described in the protocol. If the project will involve student researchers, include a description of how the student(s) have been trained to carry out appropriate safety procedures.**

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**PARTICIPANTS**

1. Indicate the total **number of participants** you require, and **your sampling procedure** (convenience, random).

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1. Do you plan to use vulnerable subjects in your investigation? \_\_\_Yes \_\_\_No

***Examples of vulnerable subjects include students, children, prisoners, pregnant women, mentally disabled persons, or economically disadvantaged persons.***

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1. **If you answered “yes” provide a justification for inclusion of these subjects in your research protocol.**

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1. Describe **the type and source of subjects** required (i.e., single parents at Elon, psychology classes, patients at Alamance Regional Medical Center, sixth graders at Turrentine Middle School, etc.). Include any inclusion or exclusion criteria, if appropriate.

Note: Researchers working with minors or other groups may be required by an external entity, such as a school system, to complete specialized training or screening (e.g. Title IX, background check). It is the responsibility of the investigator to determine what these expectations are and meet them as required by the external entity.

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1. Provide an estimate of the **amount of time** that will be requested from each person who participates in this research study (number of sessions, amount of time per session, and duration of period of time over which the research will take place).

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**INFORMED CONSENT PROCEDURE (please include a copy of the Informed Consent)**

1. Describe what you have done to make sure your subjects are **fully informed** about their role in the research, that their confidentiality will be maintained, that their participation is **voluntary**, and that they can withdraw at any time without penalty. Include a description of how and by whom consent will be sought from subjects.

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1. Describe any **incentives, inducements, or reimbursements** (e.g. extra credit, research credit, cash payment, raffle, gift) that will be offered to the participants. Indicate whether participants will receive the incentives if they withdraw before the study has been completed.

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**CONFIDENTIALITY OF THE DATA** (Consult with Elon’s Director of Information Security if you need assistance with this section)

1. Will your research require you to collect, store, process or transmit regulated data such as medical information, patient data, personally identifiable information, student information, or any Elon sensitive information? \_\_\_\_\_\_\_\_ If yes, please describe the data involved in your research.

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1. Indicate the **intended use** of your data. Check all that apply.

 \_\_\_\_\_ Thesis \_\_\_\_\_ Publication/journal article

 \_\_\_\_\_ Capstone \_\_\_\_\_ Results released to participants/parents

 \_\_\_\_\_ Undergraduate honors project \_\_\_\_\_ Results released to employer or school

 \_\_\_\_\_ Conferences/presentations \_\_\_\_\_ Results released to agency or organization

 \_\_\_\_\_Other. Describe in the box below.

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1. The following outlines Elon IRB recommended practices and strategies to be implemented to ensure the confidentiality of collected data and reporting.
2. **Data Collection Methods:**a. All data collected will be stored securely and accessed only by PI and co-investigators.
b. Data will be collected without any personal identifiers whenever possible or will utilize coding or unique identifiers instead of direct personal information.
3. **Storage and Handling of Data:**a. Any physical documents containing sensitive information will be stored in a locked and secure location, accessible only by authorized personnel.
b. Electronic data will be stored in secure, password-protected systems. Access will be restricted to approved team members via individual login credentials.
4. **Data Transmission and Sharing:**a. Information will be transmitted through secure and encrypted channels.
b. Prior to any data sharing, all potentially identifying information will be removed or anonymized to protect participant confidentiality.
5. **Period of Data Retention and Destruction** a. Data will be kept for a period of three years. At the conclusion of the study, all data will be securely destroyed or anonymized to prevent any potential identification of participants.
6. **Data Reporting** - To safeguard the confidentiality of participants, all data and findings will be shared in a manner that respects ethical standards and privacy considerations.

**\_\_\_\_\_The data collection and reporting procedures described above will be followed to ensure confidentiality. (X to agree) If you will be using different procedures for Confidentiality Assurance in Data Collection and Reporting , in one or more of the 5 categories described above, please describe these below.**

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1. Will the results of this research be **made available** to the subjects involved?

 \_\_\_\_\_ Yes \_\_\_\_\_ No

1. If so, how and when?

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

**Elon University**

Title of the Project:

Principal Investigator: [Name, credentials, institutional affiliation]

Co-investigator: [Name, credentials, institutional affiliation]

Study Sponsor: [If any]

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

You are invited to participate in a research study. In order to participate, you must be [eligibility criteria; e.g., age, gender, language, etc.]. Taking part in this research project is voluntary.

**Important Information about the Research 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]. This study seeks to enroll [ approximate number of subjects involved in the study] participants.
* 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].

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)]. We expect this to take about [duration, number of interactions]. Specify the information to be gathered and identify the individuals granted access to the 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].

**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.

For research posing more than minimal risk to subjects include the following text: “Please tell the researchers if you have any injuries or other problems related to your 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 you are harmed as a result of being in this study.”

**How will we protect your information?**

I/We plan to publish the results of this study. To protect your privacy, I/we will/will not include any information that could directly identify you.

I/We will protect the confidentiality of your research records by [explain]. Your name and any other information that can directly identify you 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 you. These people work for Elon University, [the study sponsor, if any], and government offices that are responsible for making sure the research is done safely and properly.

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

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 the research involves the collection of identifiable private information or identifiable biospecimens include one of the following:

a) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility;

or

B). A statement that the subject’s information or bio specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

**Delete if this does not apply -** 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 project [is funded by the NIH and] holds a Certificate of Confidentiality (CoC) that offers additional protections for your identifiable research information, [biospecimens], and records. The most important protection is that members of the research team cannot be forced to disclose or provide any of your private identifiable information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding unless you provide permission. Disclosure of your research information may only occur in limited specific instances. [For mandatory reporters, include this statement: “For this study, the researchers may share your information with appropriate authorities if we learn about [include any legal requirements for abuse or public health reporting]].” For the full detailed description of the CoC protections and exceptions to those protections, please refer to CoC Summary attachment at the end of this document.”

**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](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](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.”

**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 the study.

Include one of these statements:

 [Describe how compensation will be determined if the subject withdraws from the research before the end of the study.]

Or

[If the subject will not be compensated for participation indicate it here with an appropriate statement]

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

Include one of these statements:

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

[If the subject will not incur any costs as a result of participation, indicate it here with an appropriate statement.

**Who can profit from study results?**

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

Where a potential Conflict of Interest (COI) for a member of the study team (or Elon University) has been identified, subjects must be informed about the nature of the conflict. Examples include:

* Investigators have an ownership, consulting, or similar financial relationship with a sponsor.
* A company or other organization has an ownership or other financial interest in the product or technology under study, and might profit or otherwise benefit from the outcome of the study whose product is being studied, particularly if the company/organization is also the sponsor of the study or has a financial interest with the investigators.
* Elon University may be paid licensing fees for the investigational technology, or could be paid in the future.

Sample text:

“[Name of conflicted individual] is a named inventor on patents or patent applications or is the creator of copyrighted material that is licensed or optioned to company name] that will be used in this research. This means [conflicted individual] could gain financially from this study.”

**What other choices do I have if I don’t take part in this study?**

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

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.

Sample text:

“There may be other ways of treating your condition if you don’t wish to be in this research. Check with your health care provider to discuss other options.”

**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].

**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].**

**The contact information for the study team must be bolded.**

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. The number will be in the following format: Phone: XXX+1-336-278-5555.

**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:

Marna Winter, M.Ed.

Chair, Elon University IRB

Phone: (336)278-5881

Email: mwinter2@elon.edu

For International Studies: List information for the local IRB or Ethics Committee, if any, first. Omit the information local to Elon and instead, include the U.S. calling code and exit number for the country of origin. The number will be in the following format: Phone: XXX+1-336-278-5881.

**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

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Signature Date

**Parent or Legally Authorized Representative Permission**

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

For more than minimal risk research involving children, signature by two parents may be required. Contact the IRB-HSBS for more information.

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

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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\_\_\_\_\_\_\_\_\_***

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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\_\_\_\_\_\_\_\_\_***

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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\_\_\_\_\_\_\_\_\_***

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Signature Date

***Note 1:*** *If your research holds a CoC, include Attachment A as the last page of the consent document. If there is no CoC for this research, delete Attachment A from the consent document.*

***Note 2:*** *Text in [brackets] is instructional and is not meant to be a part of the Attachment A language. The brackets and text within should be deleted from the final version.* ***Delete Notes from the final version of document.***

**Attachment A**

**Certificate of Confidentiality (CoC)**

This research holds a Certificate of Confidentiality from the National Institutes of Health.

***What is a Certificate of Confidentiality?***

With this Certificate, the researchers 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. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

***When are the researchers allowed by the CoC policy to disclose my information?***

* If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

* If you have consented to the disclosure, including for your medical treatment. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

* If it is used for other scientific research, as allowed by federal regulations protecting research subjects.

***When may the researchers disclose my research information for this study?***

* [*Use the following language as applicable; edit as necessary, e.g., if the research is federally funded but isn’t subject to the requirements of the FDA, do not include the second phrase.]* If the [name of federal or state agency], the agency funding this research, requests information to audit or evaluate our procedures; or if we must disclose information in order to meet the requirements of the federal Food and Drug Administration (FDA).
* [*Use the following language if you intend to disclose information covered by a Certificate, such as with potential child abuse, or intent to hurt self or others, in response to specific federal, state, or local laws.*] The CoC will not be used to prevent disclosure of [*list what will be reported, such as child abuse and neglect, or harm to self or others*], as required by federal, state, or local law. [OR, for non-mandatory reporters] If the researchers learn about child abuse or anything that leads them to think you might harm yourself or others, we may report this to the appropriate authorities.

* [*Use the following language if you intend to disclose information covered by a Certificate, with the consent of research participants.*] The CoC will not be used to prevent disclosure for any purpose you have consented to, as described in this informed consent document. This includes [*restate what will be disclosed, such as including research data in the medical record*].