**Informed Consent is a Process not a Form**

As a researcher, it is your responsibility to educate the participants about the study purpose, the procedures, the risks and benefits, and obtain their consent before involving them in your research, and keep them informed. While a consent document that gives this information, and more, is a vital part of the process, the opportunity to discuss any questions or concerns with a knowledgeable research team member is also necessary. This is the "informed consent process".

It is essential that consent forms be written in plain language that research subjects can understand, generally at 8th grade reading level. The consent document should always be revised if there are changes in the study that might affect the participant or when additional information will improve the consent process.

In addition, the consent form should not contain any exculpatory language. That is, subjects should not be asked to waive (or appear to waive) any of their legal rights, nor should they be asked to release the investigator, sponsor, or institution (or its agents) from liability for negligence.

**Instructions in Using this Consent Form Template**

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

1. Text in brackets [ ] represents information about your study that you should add (in plain text). Add text and remove the brackets
2. A backlash / indicates that you must make a selection depending on the procedures for your study (e.g., emotional distress/embarrassment).
3. Additional instructions or sample text are provided in yellow boxes.
4. Add a document date and version number to the document footer.
5. Before you upload your consent document, delete this cover page, brackets, and instruction boxes. The finished document should reflect what you will give to the participants.
6. Use a file name for each consent document that clearly identifies the type of consent and for which participants it is intended (e.g. Child Assent, Parental Consent, Adult Consent, Consent\_Control or Treatment, etc.)

For questions about informed consent, please contact the Office of Research Protections and Integrity at (704) 687-1871 or (704) 687-8341 or uncc-irb@charlotte.edu.

**[Insert UNC Charlotte letterhead and/or logo]**

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

***Delete this box and the text in it before submitting the consent form for IRB review.***

If the study will involve different groups or different activities and there will be separate consent forms or each group and/or activity, consider how to title the consent form to differentiate between the forms.

Example when a study involves different participant groups:

* Consent to Participate in a Research Study (Administrator)
* Consent to Participate in a Research Study (Community Member)
* Consent to Participate in a Research Study (Students)

Example when a study involves different activities:

* Consent to Participate in a Research Study (Focus Group)
* Consent to Participant in a Research Study (Interviews)

Title of the Project:

Principal Investigator: [Name, credentials, institutional affiliation]

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

Faculty Advisor: [Name, credentials, institutional affiliation]

You are invited to participate in a research study. Participation in this research study is voluntary. The information provided is to help you decide whether or not to participate. If you have any questions, please ask.

**Important Information You Need to Know**

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| --- |
| ***Delete this box and the text in it before submitting the consent form for IRB review.*** * Consent forms **MUST** contain a concise and focused presentation of key information before being given other information. The intention of this section to assist potential subjects with understanding the reasons **why one might or might not want to participate** in the research. When writing this section, think about what a reasonable person from the study population would want to know.The information must be presented and organized in a way that facilitates comprehension.
* Key information:
	+ Statement that the project is research and participation is voluntary.
	+ Purpose of the research, expected duration of participation, and the research procedures.
	+ Reasonably foreseeable risks or discomforts to the prospective participant.
	+ Benefits to the prospective participant or others that may reasonably be expected.
	+ Appropriate alternative procedures or courses of treatment (if appropriate for the study).
* Key Information is intended to be concise. Details are provided later in the consent form.
* Complex studies, involving complicated or extensive study procedures must still provide a concise summary of information that will help prospective participants in deciding if they want to participate or not.
 |

* The purpose of this study is to [briefly state the purpose.]
* You will be asked to [state the research activity that the participants will do. E.g. a computer-based task/an online survey/an in-person individual interview/phone interview/will be observed, etc.].
* If you choose to participate it will require [state the duration. e.g. 15 minutes, one hour, or a total of 3 hours] of your time.
* Risks or discomforts from this research include [state greatest risks to participants, e.g. emotional distress/embarrassment].
* Benefits may include [describe potential direct benefit to participants or state no benefits to participants].
* If you choose not to participate, you may [state alternative procedures if any].

Please read this form and ask any questions you may have before you decide whether to participate in this study.

**Why are we doing this study?**

The purpose of this study is [describe the study *purpose* in more detail and in plain language.]

**Why are you being asked to be in this research study.**

***Delete this box and the text in it before submitting the consent form for IRB review.***

If there will be selection criteria used to select participants from the pool of those who meet eligibility criteria.

For example, if the study is open to anyone over age 18 but the study goal is to have participants from various age ranges. E.g., 10 participants in age range 18-25, 10 participants in age range 25-40, etc. Therefore, from those who are eligible, the age ranges will be used as selection criteria to proceed with the participant’s participation in the study.

You are being asked to be in this study because [describe eligibility criteria; e.g., age, gender, language, etc.].

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

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| --- |
| ***Delete this box and the text in it before submitting the consent form for IRB review.*** * Explain what the participant will be asked to do and what will be expected of them. This description should give participants a clear understanding of what will occur throughout their participation.
* Indicate if there are forms, surveys, and questionnaires to be completed or if there are one-on-one in-person /phone/other web-based tool (i.e. Zoom, Google Meet) interviews or focus group.
* When using audio or video recording explain how and when recording will occur, how the recordings will be used, if recordings will be used or shared publicly (e.g., audio/video snippets, still images, etc.). If video recordings will be maintained beyond the conclusion of the study and/or used for more than data collection (e.g. presentation, publication, training), a separate video release may be needed.
* If some procedures are experimental, explain the procedures in lay language.
* Explain how long it will take to complete each activity/task.
* Explain and provide examples of the questions and/or a thorough discussion of the types of questions (topics) that will be asked in surveys, interviews, etc.
* If your study will involve collection of Private Health Information (PHI) explain what health information will be collected and how it will be used. In addition, a separate authorization to release may be needed.
* If clinically relevant research results will be shared or not, this **must** be disclosed. And include a discussion of why information will not be shared or if applicable, what information will be shared and how.
* **Biospecimens:** If your study involves the collection of biospecimens, explain how specimens will be used. Explain whether the biospecimens may be used for commercial profit and whether the participant will or will not share in the commercial profit.

For example: Your [specific samples] [may or may not] be used for commercial profit and you will not share in any of the commercial profit from the use of your [specific samples]. Further, explain whether the research will or might include whole genomic sequencing (i.e. of human germline or somatic specimens with the intent to generate the genome or exome sequence of that specimen).  |

If you choose to participate in this study, you will be asked to [provide detailed description of what a participant will experience. Provide information to explain what, when, where, how].

You time commitment will be about [state the duration. e.g. 15 minutes, one hour, or a total of 3 hours for each activity, including follow-up, and total duration of the study.]

We will also collect information [explain if information collected will be linked to any other data, e.g. administrative data, student records, health information, etc.]

**What are the benefits of this study?**

[State study benefits. How the individual participant may benefit IF applicable AND/OR how others might benefit if not the individual participant.]

[Note: Incentives, whether monetary incentives or non-monetary incentives (e.g., extra credit) are NOT benefits to the participants. Do not include incentive information in the study benefits discussion.]

You will not benefit directly from being in this study. However, others might benefit because/by [provide details].

**What risks might I experience?**

|  |
| --- |
| ***Delete this box and the text in it before submitting the consent form for IRB review.*** * Risks may include psychological, social, economic, legal, physical risks, or informational risks (breach of confidentiality).
* Do not say there are no risks or that risks “should be” minimal.
* Provide details/acknowledge the risks and explain how risks will be minimized. For example, for informational risks – what will you do to protect the data during collection, storage and transmission of data?
* For studies with probable physical risks, include the following text:

“All research involves a chance that something bad might happen to you.  This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. UNC Charlotte has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.” |

[State risks participants may experience OR explain that you do not believe there are any risks, including privacy or confidentiality risks, from participating in this research.]

You may experience [describe risk]. To minimize this risk, we will [describe procedures to minimize risk].

**How will my information be protected?**

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| --- |
| ***Delete this box and the text in it before submitting the consent form for IRB review.*** * Refer to the [Guidelines for Data Handling](https://itservices.uncc.edu/iso/guideline-data-handling). Research data are handled as Level 2. Some research data may be subject to Level 3 requirements. Should you want to store and handle the data in ways that do not align with Level 2 requirements, you must consult with your College [Data Security Officer](https://docs.google.com/spreadsheets/d/1nFNtQSdLekJTE0sGzG5bAw4RTMTZdvgyrYw1TTkVzqQ/edit#gid=0) to develop a Data Security Plan and provide this DSP with your IRB protocol application.
* Avoid using the terms “anonymous” and “anonymity.” Depending on the study design anonymity cannot be guaranteed, including in online studies (email addresses and IP addresses are identifiers).
* Differentiate between data being non-identifiable versus the study participant’s privacy. A researcher may keep the data non-identifiable but the participant themselves may be identifiable.

For example, if an incentive is being offered, anonymity is not applicable to the participant because the participant’s identity must be known. However, data collection procedures can be such that the participant’s responses/data are never identifiable. * Discuss the plans for audio/video recordings and transcripts. Particularly if recordings will be kept/retained; explain why.
* For studies involving **focus groups**, include the following (or similar) text:

“We will do everything we can to keep your identity private and your responses confidential. However, given the nature of focus groups, we cannot make guarantees about how others in the group might use your information. We ask that you respect the privacy and confidentiality of the group and group members to keep the discussion private and confidential.”* Do not make statements to the effect that only the research team will have access to the data.
* For studies involving internet/online implementation, be aware that absolute confidentiality of the data provided by participants cannot be guaranteed. Be sure to review the commercial survey tool and/or App and/or other online page or site’s privacy and security statements and terms of use agreements.
* **NIH-funded studies** that collect identifiable, sensitive information will be covered by an [NIH Certificate of Confidentiality (CoC)](https://grants.nih.gov/policy/humansubjects/coc.htm). Researchers may also apply for a CoC for non-NIH sponsored research collecting health-related, identifiable sensitive information. Note: NIH defines identifiable, sensitive information broadly and focuses on identifiability and not on the sensitivity of the information.

Example language (adjust as appropriate depending on your study): “We have a Certificate of Confidentiality from National Institutes of Health. This helps us protect your privacy for data that we store. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information. You or a member of your family can share information about yourself or your part in this research if you wish. We can’t use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. [If research information will be added to the subject’s medical, or other record, include these two sentences. Research information that is placed in your medical record may not be protected by this Certificate. Ask a member of the study team for information about what research information will be placed in your medical record.]There are some limits to this protection. We will voluntarily provide the information to:* a member of the federal government who needs it in order to audit or evaluate the research;
* individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
* the federal Food and Drug Administration (FDA), if required by the FDA;
* individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
* [Insert or modify as appropriate] authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.”

[NIH Example Informed Consent Language](https://grants.nih.gov/policy/humansubjects/coc/suggested-consent.htm): “This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.”* **Mandatory Reporting:** If there are legal mandatory reporting requirements that supersede confidentiality, such as the requirement to report abuse, include a description of the legal duty and the circumstances when reporting is required.

For example: “There may be exceptions to confidentiality. We are required by law to make a report to proper authorities in cases involving risk of harm to self or others by the child or caregiver, or physical or sexual abuse of the child. It is important that you understand that confidentiality will be broken in the situations described above.”**Note:** North Carolina has a “universal mandate” for reporting. This means that everyone is considered a mandated reporter, regardless of profession. * **Clinical Trials:** Projects that meet the definition of an **NIH clinical trial**, include the following text: “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.”

**Other clinical trials** may also be registered on ClinicalTrials.gov voluntarily or in order to meet journal or other sponsor requirements, include the following text: “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.”* Projects that are funded by the **National Institute of Justice/Department of Justice must include additional information.**

The consent form needs to include a statement describing the extent to which confidentiality of records identifying the subject will be maintained. For studies sponsored by NIJ the subject should be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the subjects need to be explicitly notified. If the investigator intends to disclose any information, the subject needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The subject must be informed of any potential risks which may result from this disclosure and must explicitly provide prior written consent. <https://nij.ojp.gov/funding/informed-consent-requirements> Under the National Institute of Justice privacy certificate, current or past domestic, child or elder abuse is not reportable, unless a separate consent to allow this reporting is obtained from the subject. A template for the separate consent is available at: <http://www.nij.gov/funding/humansubjects/Pages/faqs.aspx> and <https://nij.ojp.gov/media/document/16921> Example text for NIJ/DOJ funded research: “To help us protect you and the information we will be collecting from you, the researcher submitted a privacy certificate that was approved by the National Institute of Justice and, therefore, is covered by the Department of Justice statute. This privacy certificate makes the identifiable data collected for this study immune from any legal action. The researchers will use the Certificate to resist any demands of information that would identify you, except as explained below. Your private, identifiable information will be kept confidential and will only be used for research and statistical purposes. Only de-identified data will be submitted to the National Archive of Criminal Justice Data. If the researchers become aware that you may cause serious harm to yourself or others, the researchers may report this to the appropriate authorities without your consent.”[If applicable]: “If the research shows that you have a reportable communicable disease (for example, tuberculosis [TB] or HIV/AIDS), the researchers may report this to state and/or federal public health authorities without your consent.” **Note:** Under the National Institute of Justice privacy certificate, current or past domestic, child or elder abuse is not reportable, unless a separate consent to allow this reporting is obtained from the subject. A template for the separate consent is available at: <http://www.nij.gov/funding/humansubjects/Pages/faqs.aspx>. |

[Describe how participant identity (privacy) will be protected and confidentiality of the data or limitations to confidentiality.]

We will do our best to keep study data safe and confidential but we cannot make any absolute promises. The following are the ways we will protect the data:

To protect your privacy, your identifying information will be removed or changed. You will not be identified in any publication from this study. We will protect the confidentiality of the research data by [provide details – including if identifiers will be stored separately or with data collected and when identifiers will be destroyed.]

[Describe limitations to confidentiality.]

Other people may need to see the information we collect about you, to make sure that we are conducting this study appropriately and safely, including people who work for UNC Charlotte, the study sponsor [if applicable], and other agencies as required by law or allowed by federal regulations.

Due to [identify why you are a mandatory reporter (e.g., your professional role as XXX, local/state/federal reporting requirements, etc.)], I am required to report [child neglect and abuse, sexual abuse, elder neglect and abuse, sexual discrimination and harassment, etc.]. This means that if I observe instances of, or you tell me about [insert topics that would lead to reporting], I am required to report.

**How will my information be used after the study is over?**

|  |
| --- |
| ***Delete this box and the text in it before submitting the consent form for IRB review.*** * Consent forms **MUST** include a statement about future research use and sharing: This statement needs to include reference to study data and/or biospecimens. “After this study is complete, identifiers will be removed from the data and biospecimens and the data and biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent.” **OR**  “The data and/or biospecimens collected will not be used or distributed for future research studies even if identifiers are removed.”
* **Charlotte Mecklenburg Schools (CMS):** CMS has an internal research review process that is required for research involving CMS employees, students, and/or families. CMS does not all data to be used or shared for future research. Use the following or similar language: “Data will not be used or distributed for future research studies. After this study is complete, data results may be shared in a professional publication or conference. The data results we share will not include information that could identify you.”
* **NIH Data Management and Sharing:** NIH funded studies must include information about data sharing and archiving including whether data that will be shared/archived can be linked back to the identity of the participant or not. Refer to the NIH resource for [Informed Consent for Secondary Research with Data and Biospecimens](https://osp.od.nih.gov/wp-content/uploads/Informed-Consent-Resource-for-Secondary-Research-with-Data-and-Biospecimens.pdf) for more information and sample language.

The consent form will need to explain if the data will be archived, where it will be archived, whether archived data will be identifiable, coded with a GUID (Global Unique Identifier) that can be used to link a participant’s data across studies, or de-identified.  |

[Describe if research data will or will not be used for future research or other purposes.]

After this study is complete, study data and/or biospecimens may be shared with other researchers for use in other studies without asking for your consent again or as may be needed as part of publishing our results. The data we share will NOT include information that could identify you. OR We may share your research data with other investigators and/or use your biospecimens in future studies without asking for your consent again. The information we share with these other investigators will not contain information that could directly identify you. There still may be a chance that someone could figure out that the information is about you.

[Describe if data must or will be deposited in a public archive/repository, other type of archive/repository, and if the data will be identifiable or not.]

**Will I receive an incentive for taking part in this study?**

|  |
| --- |
| ***Delete this box and the text in it before submitting the consent form for IRB review.*** * Explain if the incentive is cash, check, or gift card. If gift cards will be used, specify the gift card vendor(s).
* Do not use the terms “lottery” or “raffle;” these imply that participants must buy a chance to win. Use the word “drawing” instead.
* Researchers are expected to consult with the appropriate University Office (Financial Services, Budget Office, and/or Grants & Contracts) to confirm the appropriate payment method and tax reporting requirements.
* Please refer to Financial services – [Human Subjects Payments, How to Pay guide](https://finance.uncc.edu/resources/how-guides/human-subject-payments-how-pay). Payments resulting from human subjects research are considered taxable income.
	+ Financial Services’ has special considerations and requirements for UNC Charlotte employees who will be paid participant incentives. Carefully review the guidance document for tracking and tax reporting requirements.
	+ Financial Services’ has special considerations and requirements for paying foreign nationals. Researchers should consult with the Tax Office and their College/Department business officer to confirm what requirements must be met.
	+ [Gift card payments](https://finance.uncc.edu/resources/how-guides/gift-cards-gift-certificates-how-pay) requiring tracking and reporting in accordance with Financial Services policy and procedure.
* Include the following or similar language: “Payments to subjects are considered taxable income. Therefore, we are required to give the University’s Financial Services division a log with the names of all individuals who received a payment. This log is for tax purposes only and will be kept separate from study data. If your total payments from UNC Charlotte are greater than $600 in a calendar year, this information will be submitted to the Internal Revenue Service (IRB) for tax reporting purposes.”
* If incentives will be paid by check or electronic deposit, the consent form should explain the need to provide the University with their name, Social Security number, and address. Use the following or similar language: “Payment will be sent within X weeks of study completion; a check/electronic deposit in the appropriate amount will be mailed/deposited. You will be required to provide your name, address and social security number in order for the check/electronic deposit to be issued. This information will be kept separate from study data and not linked in any way to study data. If you do not receive your check/electronic deposit within X weeks of study completion, please notify the researcher.”
* Participants may waive receipt of any payment if they still wish to enroll in the study but do not want to provide their personal information that is needed to pay the incentive.
* **Non-payment:** If there is any reason or circumstance when a participant would not be paid the incentive/payment/compensation, this **MUST** be explained in the consent form in detail.

For example, should a survey include attention check or verification questions that a participant must answer correctly in order to receive the incentive payment, explain this in detail in the consent form.  |

[If applicable, describe any and all forms of compensation and amounts. Explain also if participant will receive this incentive or not if he/she did not complete the entire study or has stopped at any time. If not applicable, delete this section.]

You will be included in a drawing for three, $5 Starbucks gift cards at the completion of participation.

**What are the costs of taking part in this study?**

[If applicable, describe any costs participants may incur such as parking, childcare, travel costs, etc. If not applicable, delete this section.]

**Who is sponsoring this study?**

***Delete this box and the text in it before submitting the consent form for IRB review.***

* This section is required only if there is funding (internal or external) for the research.
* NIH, NIJ, and DoD require that the consent identify the study sponsor.

The study team and/or UNC Charlotte is receiving [financial support OR describe other type of support] from [insert sponsor’s name].

**Who can profit from this study?**

[If applicable, describe any direct or potential conflicts of interest. This may include financial or other personal considerations that may compromise or have the appearance of compromising an individual’s judgment in conducting this research. If not applicable, delete this section.]

The study Investigator developed the software application being used in this study. This means the Investigator main gain financially.

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

[If applicable, describe any appropriate alternative procedures or courses of treatment that might be advantageous to the subject. If not applicable, delete this section.]

There may be other ways to treat your condition if you choose not to be in this research.

**What are my rights if I take part in this study?**

It is 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.

[Describe how data will be handled/used for participants who withdraw.] [Describe circumstances, if any, under which the participant’s participation may be terminated by the PI without the consent of the participant].

**Who can answer my questions about this study and my rights as a participant?**

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

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 Office of Research Protections and Integrity at uncc-irb@charlotte.edu.

**General Data Protection Regulations**

***Delete this box and the text in it before submitting the consent form for IRB review.***

This section is applicable if a study includes participants who are in the European Economic Area. If this is not applicable to your study, do not include any of this content.

* 1. The GDPR is a European law that details conditions under which it is lawful to collect, use, disclose or process personal data. For this research project, the information being <select one: collected or processed> is \_\_\_\_\_\_\_\_\_. <Insert name of researcher> is collecting this data and you can find their contact information at the top of this form. This information is <select one: collected or processed> by <insert method>. The reason this is being <select one: collected or processed> is \_\_\_\_\_ and one lawful basis for doing so is your consent. The information will be used for <insert time frame> and will be used for research purposes. The data will be stored for <insert time frame> and the data will be shared with <insert information about with whom data will be shared>. The information <select one: will or will not> be shared with someone in another country under the lawful basis of your consent and the legitimate interest of research. If the data is shared, it will be shared in <select one: an identifiable format, a completely de-identified format>The effect of the <select one: collection or processing> of this data to you is \_\_\_\_\_. The use of your information is unlikely to cause harm to you. If you would like to request access to the information from this project about you, rectify the information about you, or remove all of your information from this research project, you may do so by contacting the researcher named above unless it is impossible to identify your information amongst the other data. The EEA representative that you may contact is \_\_\_\_\_.

Because the data will be collected from European Union countries, please confirm the below statements by checking the box.

[the items in red can be adjusted for the specific study or removed if the procedures are not applicable to the study. Additional items may need to be added depending on the specifics of the study – please delete this text in the final consent document]

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without any adverse consequences [choose appropriate item: academic or other penalty].

\_\_\_\_\_\_\_ (initial)

I understand that research data collected during the study may be looked at by designated individuals from University of North Carolina at Charlotte where it is relevant to my taking part in this study. I give permission for these individuals to access my information and research data.

\_\_\_\_\_\_\_ (initial)

I understand that this study will collect special categories of personal data that includes sensitive information about me. I understand why this information is being collected, how it will be used, and how it will be stored.

\_\_\_\_\_\_\_ (initial)

I understand who will have access to personal data provided, how the data will be stored and what will happen to the data at the end of the project.

\_\_\_\_\_\_\_ (initial)

I understand how this research will be written up and published.

\_\_\_\_\_\_\_ (initial)

I consent to being audio recorded.

\_\_\_\_\_\_\_ (initial)

I consent to being video recorded.

\_\_\_\_\_\_\_ (initial)

I consent to having my photograph taken.

\_\_\_\_\_\_\_ (initial)

I understand how audio recordings / videos / photos will be used to aid in data analysis.

\_\_\_\_\_\_\_ (initial)

I understand the results of this study may be used for teaching, publications, or for presentation at scientific meetings.

\_\_\_\_\_\_\_ (initial)

I agree for research data collected in this study to be given to researchers, including those working outside of the EU, to be used in other research studies. I understand that any data that leave the research group will be fully anonymized so that I cannot be identified.

\_\_\_\_\_\_\_ (initial)

I agree for my name and contact to be kept in a secure database for the purpose of contacting me about future studies.

\_\_\_\_\_\_\_ (initial)

**Consent to Participate**

***Delete this box and the text in it before submitting the consent form for IRB review.***

* Take into consideration the consent process proposed in your IRB application and edit the content to apply. For example, if consent will not be documented and you requested a waiver of documentation of consent (45 CFR 46.117), the content should not refer to “signing” this document.
* **Charlotte Mecklenburg Schools:** CMS requires that participants consent (Yes/No) to each study activity separately. If you will be requesting identifiable teacher-level data, you must also include a line for the teacher to provide the employee ID#.

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. You will receive a copy of this document for your 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.

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

Name (PRINT)

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

Signature Date

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

Name and Signature of person obtaining consent Date

**Parent or Legally Authorized Representative Consent**

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| --- |
| ***Delete this box and the text in it before submitting the consent form for IRB review. This section should also be deleted if the participant is adult and have the capacity to consent.**** To use this template for parental consent or consent by a legally authorized representative (LAR), the consent sections/content must be written as if you are speaking to the parent for their child’s participation in the study or to the LAR for the person they represent.
* **Charlotte Mecklenburg Schools:** CMS requires that participants consent to each study activity separately. If you will be requesting identifiable student-level data, you must also include a line for the parent to provide the student CMS ID#.

For example: I consent to my child’s participation in the science activity: \_\_\_\_ Yes \_\_\_\_\_No I consent to the use of videotape during the science activity: \_\_\_\_ Yes \_\_\_\_\_NoI consent to my child’s participation in the baseline and follow-up questionnaires. \_\_Yes \_\_No |

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. You will receive a copy of this document for your 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.

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

Participant Name (PRINT)

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

Parent/Legally Authorized Representative Name and Relationship to Participant (PRINT)

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

Signature Date

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

Name and Signature of person obtaining consent Date

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| ***Delete this box and the text in it before submitting the consent form for IRB review.*** **The following are additional consent choices that may or may not be applicable to your study.** If these items are included, be sure that the protocol application includes details about the associated procedures. **Consent to Use Data for Future Research**(Note: This separate consent is not necessary if you will only store and share deidentified data.)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. YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature Datexxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx**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 Datexxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx**Consent to be audio recorded**To assist with accurate recording of participant responses, interviews may be audio recorded [*explain if names will not be used during recording*]. Participants have the right to refuse to allow such recording without penalty. Please select one of the following options:\_\_\_\_\_\_\_\_I consent to the use of audio recording.\_\_\_\_\_\_ \_\_\_\_\_\_\_\_I do not consent to the use of audio recording.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature Datexxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx**Consent to be video recorded**To assist with accurate recording of participant responses [or observation], interviews/observation may be video recorded [*explain if faces will be blurred out later*]. Participants have the right to refuse to allow such recording without penalty. Please select one of the following options:\_\_\_\_\_\_\_\_I consent to the use of video recording.\_\_\_\_\_\_\_\_I do not consent to the use video recording.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature Datexxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx**Consent to be audio and visually recorded**With your permission, you will have the following done during this research (check all that apply): \_\_\_\_\_ photography/still visual shots \_\_\_\_\_ video recording \_\_\_\_\_ audio recordingTo assist with accurate recording of participant responses, assessment and follow-up appointments may be audio or visual recorded [*explain if faces will be blurred out later for photos and videos and if names will not be used during recording*]. Participants have the right to refuse to allow such recording without penalty. Please select one of the following options:\_\_\_\_\_\_\_\_I consent to the use of audio/visual recordings for research purposes.\_\_\_\_\_\_\_\_I do not consent to the use audio/visual recordings for research purposes \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature Date |