APPENDIX A

# INFORMED CONSENT WAIVER rEQUEST

This form must be completed to request a waiver of written documentation for implied, verbal, and electronic consents, assent, or parental permission forms, for a full waiver or alteration of informed consent, assent or parental permission, and for the use of a passive (opt-out) parental permission form..

**Select the type of waiver(s) requested for the proposed research. Complete the corresponding section for the type of waiver(s) selected below. The additional information provided in these sections will assist the IRB evaluate your waiver request.**

### Waiver of Written Documentation of Informed Consent

When the IRB grants a **waiver of documentation of consent**, the investigator needs to obtain the subject’s consent but not the subject’s signature to document it. The investigator can document that consent was administered through documenting it directly on the verbal consent form or to confirm and receive acknowledgement from the participant electronically and store their electronic or implied consent in the study participant file.

Under the 2018 Common Rule, the IRB approval of a waiver of written documentation for informed consent may be granted for projects that include participants who are members of a cultural group in which signing forms is not a normal/acceptable practice.

**Implied Consent,** no hardcopy signature; consent obtained online used commonly for web-based anonymous surveys or questionnaires (e.g., embedded within Qualtrics). When implied consent is used, the study participant is invited to complete the survey/questionnaire and if, after reviewing information about the study, the participant decides to complete the anonymous document, then by completing the survey/questionnaire, they have agreed to participate in the research, and their consent is implied. The participant may also be instructed, via an email, to select a checkbox indicating “I agree to participate [link to survey]”. The IRB will approve such requests in limited circumstances, based on appropriate justification and information regarding the consent process.

Complete **Section A.1: Requesting a Waiver of Written Documentation (Implied Consent)** and provide a copy of the **implied consent document** for IRB review.

**Verbal Consent (English), Waiver of Written Documentation of Informed Consent,** the individual administering consent reads or explains a verbal version of a consent form. Participants should be given the opportunity to ask questions and be provided with a copy of the information sheet about the study without obtaining their signature or mark. If it is not feasible to provide subjects with an information sheet – for example, the only contact is by phone, the IRB must review a **consent script** to evaluate the consent process. If this method of consent is used, the consent discussion must be documented in the research file and include if there were any issues raised by the participant.

To confirm a participant’s understanding of the research when administering consent verbally, a set of questions should be included to test their comprehension.

Complete **Section A.2: Requesting a Waiver of Written Documentation (Verbal Consent),** provide a copy of the **consent script** or **information sheet**, if applicable**,** and includethe **comprehension questions.**

**Electronic Consent, Waiver of Written Documentation of Informed Consent,** some studies may utilize an electronic consent if any or all of the consent process takes place remotely and is not personally witnessed by study personnel. Using the electronic consent should include a method to ensure the participant has the opportunity to consider whether or not to participate and can ask questions about the study at any time during the participant’s involvement in the study. This may be accomplished by in-person discussions using an interactive electronic-based technology such as Zoom or FaceTime. If live chat or video conferencing is used, study personnel should remind subject to conduct the discussion in a private location to help ensure privacy and confidentiality.

For such studies, the consent document should include most or all of the elements of a consent form (e.g., purpose, procedures, risks, benefits, etc.), but not the subject’s signature. To confirm a participant’s understanding of the research, a set of questions should be included at the end of the consent to test their comprehension and the participant should confirm their consent by clicking “Agree” or “Continue” if they wish to participate. A copy of the electronic consent should be provided to the participant in an electronic format and may be provided via email. If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks must remain valid and the information should be accessible until study completion.

Complete **Section A.3: Requesting a Waiver of Written Documentation (Electronic Consent)** and provide a **copy of the electronic consent** for IRB review**.**

**NOTE:** **For studies requiring signed consent, investigators may utilize an appropriately secure electronic signature (e.g., DocuSign or REDCap system) when written informed consent is required. If a secure electronic signature will be utilized, a waiver of written documentation is not required.**

**Verbal Consent (non-English language), Waiver of Written Documentation of Informed Consent,** using a non-English language verbal consent is allowed if the individual administering consent is serving as an IRB-approved interpreter for the non-English speaking study participant. If applicable, the participant should be provided with a copy of the Short Form Consent in the non-English language unless providing a document increases a potential risk to the participant. To confirm a participant’s understanding of the research when administering consent verbally, a set of questions should be included to test their comprehension.

Complete **Section A.2: Requesting a Waiver of Written Documentation (Verbal Consent)**, provide a copy of the **Verbal Consent Script** in the English language and non-English version, and the **comprehension questions.**

**Short Form Consent, Waiver of Written Documentation of Informed Consent,** if an interpreter is used to consent a non-English speaking potential participant, a copy of the **Short Form Consent**, formatted in the non-English language, should be provided to the participant unless it increases a potential risk to the participant. If the individual is able to read in their native language obtaining their signature or mark would be acceptable, but it is not required. If applicable, provide a copy of the **Short Form Consent in English and non-English language**.

### Waiver or Alteration of Informed Consent

For research that is no more than minimal risk the IRB may approve a request to waive some or all of the required elements of informed consent under specific circumstances. Waivers of informed consent are primarily requested for projects involving the secondary analysis of existing data or in projects involving deception.

Under the 2018 Common Rule, the IRB approval of an informed consent waiver request may be granted if the research involves identifiable private information or identifiable biospecimen, if the research could not be carried out practicably without using the information/specimen in an identifiable form.

**Full Waiver or Alteration of Informed Consent,** an IRB may waive a consent procedure which does not include, or which alters some or all of the elements of informed consent. A large percentage of these type of waiver requests involve existing medical records or specimens that are retrospective and it is not practicable for the research to be conducted, since it would be, or would not have been possible to obtain consent.

Complete **Section B: Requesting a Waiver or Alternation of Informed Consent**. If an alteration of the informed consent will be used, provide a copy of the **altered informed consent document.**

### Verbal Assent – Waiver of Written Documentation of Assent

**Verbal Assent** Using a verbal assent process should be developmentally appropriate given the ages and other characteristics of the children to be approached and there should opportunities for them to express and discuss their willingness or unwillingness to participate. Although written assent may not be appropriate for children under the age of 7, it is important that these potential participants should be provided with information verbally even if they are not able to provide written assent. Investigators should document any child who expresses their unwillingness to participate even if the parent/guardian has provided permission to participate. Permission from a parent/guardian or legally authorized representative (LAR) must be obtained to allow the child to participate, regardless if a verbal assent or full waiver of assent is utilized.

Complete **Section C: Verbal Assent** and provide a copy of the **verbal consent script**, if applicable**.**

### Full Waiver of Assent

**Waiver of Assent** This type of consent is typically requested when very young children (i.e., newborn or toddler participants) will be involved in the research. It is important that any potential participants, if possible, should be provided with information about the proposed study activities even if they are not able to provide written assent. Permission from a parent/guardian or legally authorized representative (LAR) must also be obtained to allow the child to participate.

Complete **Section D: Waiver of Assent.**

### Waiver of Parental Permission

**Parental Permission Form, Passive (Opt-Out) -** written hardcopy signature is obtained **only** if a parent or guardian objects to their child’s participation in the research through distributing an **Investigator Letter for Parental Permission**. If a parent or guardian consents to their child’s participation, hard copy signature is not required and the form does not need to be returned. For example, if research will be performed in the schools, it may be possible to send information home to parents that allows them to opt out. The IRB requires the investigator to make a compelling and persuasive argument for why parental permission is not a necessary condition for proceeding with the research.

Complete **Section E: Requesting a Waiver of Parental Permission, Passive (Opt-Out)** and provide a copy of the **Investigator Letter Using a Passive Parental Permission Form.**

**Parental Permission Form, Full Waiver –** this type of request is usually, but not always, limited to minimal risk research, such as surveys, interviews or focus groups. Research about sexuality, drug use, teen driving habits or other topics of importance to adolescents may not be possible without a waiver. The parents of these teens may not be accessible and therefore, may not be a reasonable requirement. If the IRB determines that the research protocol is designed for conditions or from a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children, or using adolescent subjects that involve medical procedures and treatment that the adolescent can consent to without parental knowledge (i.e., contraceptive, treatment of STDs, treatment of alcohol and drug abuse), it may waive the consent requirements provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and that the waiver is not inconsistent with Federal, State or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

Complete **Section F: Requesting a Full Waiver of Parental Permission**

**Investigator Instructions:**

**Complete the following section for the type of consent waiver that has been requested for this study.**

### Section A.1: Implied consent – Waiver of written Documentation of Informed Consent

**A.1.1** **Describe the process for providing pertinent information to subjects. How will subjects contact the Principal Investigator if they have questions after completing the research study?**

Click here to enter text.

**A.1.2** **Explain how, in the absence of a signed written consent form, the Principal Investigator and/or study personnel will document and manage a participant’s agreement to participate in the research.**

Click here to enter text.

**A.1.3** **If the written documentation requirement is waived for obtaining informed consent, will the investigator offer to provide the participant with a written statement regarding the research?**

Click here to enter text

If **YES**, attach a copy of the **written statement** for IRB review.

If **NO**, clarify if providing a copy of the consent or written statement would potentially harm the participant if his/her identify is compromised.

Click here to enter text

**A.1.4** **Will the study participant have the option to save or print a copy of the implied consent or to refuse a copy after acknowledging their willingness to participate?**

If **YES**, has this option been embedded into the implied consent document?  **YES**  **NO**

If **NO**, please explain why the option to obtain a copy of the implied consent is not being offered to participants.

## Click here to enter text

### Section A.2: Verbal Consent, Waiver of Written Documentation of Informed Consent

**A.2.1** **Please explain how in the absence of a signed written consent form, the Principal Investigator and/or study personnel will document a participant’s agreement to participate in the research.**

Click here to enter text

**A.2.2** **If the written documentation requirement is waived for obtaining informed consent and the study information will be provided only through verbal consent, will the investigator offer to provide the participant with a written statement (i.e. Information Sheet) regarding the research?**

If **YES**, provide a copy of the **written statement** for IRB review.

If **NO**, clarify if providing a copy of the **consent or written statement** would potentially harm the participant if his/her identity is compromised. How will the investigator document that the participant accepts or refuses a copy of the study information sheet?

Click here to enter text

**A.2.3** **How will subjects contact the Principal Investigator if they have questions during and after completing the research study if consented verbally?**

Click here to enter text

### Section A.3: Electronic Consent, waiver of written documentation of Informed Consent

**A.3.1**  **Describe the process that will be used to obtain individuals emails to send an electronic consent to participate in the research.**

Click here to enter text

**A.3.2** **If administering consent remotely, describe how a participant’s understanding about the proposed project will be confirmed and how participants can reach the study team if they have questions throughout their participation in the study.**

Click here to enter text

**A.3.3 If an enrolled study participant chooses to withdraw from the study, what is the process for the participant to request their withdrawal and documenting it in the study.**

## Click here to enter text

### Section B: Full Waiver or Alteration of Informed Consent

**B.1**  **If you are requesting a full waiver of informed consent, explain why a waiver would not adversely impact the subjects (i.e., recognizing the rights of individuals to determine whether or not to participate in research).**

Click here to enter text

**B.2** **Breach of confidentiality is frequently a risk for research involving a waiver request. Describe the protections that will be in place to protect subject confidentiality.**

Click here to enter text

### Section C: Verbal Assent

**C.1** **If a verbal assent procedure is requested for conducting research with children, for example in an elementary school classroom setting, explain how the research will be introduced to the potential participants and how parental permission will be managed?**

Click here to enter text

**C.2** **If the written documentation requirement is waived for obtaining assent and the research study will be introduced verbally to a child or group of children, how will the investigator provide opportunities for a child to express their willingness or unwillingness to participate?**

Click here to enter text

**C.3 If a child expresses an unwillingness to participate in the proposed research, what alternative activities will be provided to the child while the research interventions are being conducted?**

Click here to enter text

### Section D: Full Waiver of Assent

**D.1** **If a full waiver of assent is requested, provide the justification and the circumstances for not obtaining a form of assent.**

Click here to enter text

**D.2** **Does the capability of some, or all, of the proposed study participants (i.e., young children) so limited that they cannot reasonably be consulted? Briefly explain the circumstances.**

Click here to enter text

### Section E: Parental Permission Form, Passive (Opt-Out)

The term “implied” or “passive” consent is sometimes used in research with children to describe situations in which the investigator can assume that a parent is permitting a child to participate. For example, researchers collecting survey and behavioral data from children at school provide parents with information regarding the study by providing an **information sheet** and ask the parent(s) to return a form if they do NOT want their child to participate. Sometimes this practice is referred to as an opt out procedure, which not consistent with the regulatory requirement for seeking and obtaining parental permission. If the conditions for a waiver of parental permission can be met, then the IRB could waive the requirement for parental permission under 45 CFR 46.408(d), and parents could be given the opportunity to refuse permission even when the IRB has waived the regulatory requirement to obtain parental permission.

**E.1** **If this research will be conducted in a daycare center, pre-school, or elementary/secondary school, has the appropriate letter of support been obtained to document the school district or school’s support of this research? Attach a copy of the letter of support** with this IRB application.

If **NO**, a letter of support must be provided before IRB approval will be granted.

**E.2 If a passive (opt-out) parental permission form will be utilized in this research, how will parents or guardians be informed of the proposed research?** **Describe the procedure and timeline for informing the parents/guardians, receiving opt-out responses, and the implementation of the research interventions.**

Click here to enter text

**E.3** **If an information sheet will be sent to parents and guardians about the proposed research, will any school personnel be involved in this process? If so, please describe their involvement. Will a separate email be distributed to parents or guardians from school administrators? If so, provide a copy of all communication that will be distributed regarding the proposed research.**

Click here to enter text

**E.4 Describe how the opt-out responses will be coordinated and managed with the child assents.**

Click here to enter text

**E.5 Describe what activity(ies) will be arranged for any child(ren) who may have opt-out requests from their parent or guardian, if the research activity is conducted during the regular classroom with other students.**

Click here to enter text

### Section F: Parental Permission Form, Full Waiver

**F.1** **If you are requesting a waiver of parental permission, provide the justification for why parental permission is not necessary for proceeding with the research?**

Click here to enter text

**F.2** **Is the proposed research designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (example, neglected or abused children)?**

If **YES**, explain the study conditions.

Click here to enter text

**F.3 If a Full Waiver of Parental Permission is granted by the IRB, what appropriate mechanisms are in place to protect the children (i.e., appointing a child advocate or an assent monitor) for protecting children participating in research. Explain the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and the child’s age, maturity, status, and condition (45 CFR 46.408 (c)). Describe what additional safeguards will be implemented to protect the subjects.**

Click here to enter text