

{*Place on departmental or applicable institutional letterhead}*

## **Parental Consent Form for the Participation of Children: Selected Elements**

**(Use this in conjunction with the CHILD ASSENT FORM.) Fill out the information for each bolded heading, place on department letterhead and edit (and/or delete) any blue text before submitting to the IRB.**

**Eliminate any wording in RED. Provide information, if applicable, prompted by the BLUE statements. Return all text to black when complete and before submission.**

**Consent forms should be written at an 8th grade reading level. Participants should receive a copy of the consent form for their records. Student Researchers are only permitted to provide their email addresses.**

**Parental Informed Consent**

TITLE of STUDY

**If your consent form is longer than 3 pages you must begin the form with a concise and focus presentation of key information that is likely to assist potential subjects in understanding whether or not they want to participate. Skip this section for now and only complete the section in green if your form is longer than 3 pages. If your form is shorter than 3 pages delete all green text.**

[Key Information

Study of purpose:

Major Requirements of Study:

Significant Risks:

Potential Benefits:

Duration of Participation:

You are being invited to participate in a research study of [general statement about study]. You were selected as a possible participant because [describe inclusion criteria]. We ask that you read this form and ask any questions you may have before agreeing to be in the study. Participation is completely voluntary.]

You are being asked to allow your child to participate in a research study. This form provides you with information about the study. The person in charge of this research will also describe this study to you and answer all of your questions. Please read the information below and ask any questions you might have before deciding whether or not to take part. Your child’s participation is entirely voluntary. Your child can refuse to participate without penalty or loss of benefits to which they are otherwise entitled. You can stop your child’s participation at any time and your refusal will not impact current for future relationships with Radford University or participating sites. To do so simply tell the researcher you wish to stop participation. The researcher will provide you with a copy of this consent for your records.

The purpose of this study is to *{insert purpose of study}.*

If you agree to be in this study, we will ask your child to do the following things: [*Provide narrative and/or bullets describing what your child will be asked to do to participate in this study*. *All methods included in the IRB application should be included here in simple language. Include description of data to be gathered that is not received directly from the participant. Include if there will be audio/video recording here*]

Total estimated time to participate in study is [*insert description and amount of time estimated for participation.]*

This study has {*more risk than/no more risk than*} you may find in daily life. *{If there are risks, then state them. Any risks provided in the IRB application should be included here. Please include how those risks will be minimalized.*

* This *[treatment, procedure, intervention, or describe other]* may involve risks that are currently unforeseeable. If you wish to discuss the information above or any other risks your child may experience, you may ask questions now or call the Principal Investigator listed on the front page of this form.

Benefits of being in the study: [*provide narrative and/or bullets describing any benefits to your child regarding his or her participation in this study*. *Do not include compensation here.*]

Compensation: [*provide narrative and/or bullets describing any compensation or lack thereof regarding participation in this study*.]

Confidentiality and Privacy Protections: *[Describe the protections that you will implement to protect child and parent privacy. Also, include the text below, or edit as appropriate:]*

The data resulting from your child’s participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate your child with it, or with your child’s participation in any study.

The records of this study will be stored securely and kept confidential. Authorized persons from Radford University, members of the Institutional Review Board, *and (study sponsors, if any)* have the legal right to review your child’s research records and will protect the confidentiality of those records to the extent permitted by law. All publications will exclude any information that will make it possible to identify your child as a subject. Throughout the study, the researchers will notify you of new information that may become available and that might affect your decision to allow your child to remain in the study.

*{Listed below are various privacy/confidentiality examples for different types of data. Include only the information relevant to your study and delete the rest. Please feel free to modify accordingly.}*

*If collected data will be anonymous:*The data collected in this study are anonymous. This means that not even the research team can match you to your data.

*If collected data will be confidential:*The data collected in this research study will be kept confidential. Participation in research may involve some loss of privacy. We will do our best to make sure that the information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in the research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law, such as pursuant to a court order. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

We will collect your information through *[recordings, interviews, qualtrics survey, etc].* This information will be stored *[in a restricted access folder, an encrypted cloud based system, locked office cabinet, etc. If identifiers will be separated from data, describe storage plan for the identifiers and how long they will be retained.]*

*[Indicate what steps you will take to keep data confidential / secure (e.g. use of a coding system, secure storage, using summary data from a whole group, use of pseudonyms for direct quotes).]*

*If data collected has the potential to trigger mandatory reporting responsibilities:*There are two circumstances where we would be required to break confidentiality and share your information with local authorities. The first is if we become aware or have a reason to believe that a child, an elder, or a disabled individual is being abused or neglected. The second is if you make a serious threat to harm yourself or others.

*If data is collected using an online survey or data collection tool (even if anonymous):*The research team will work to protect your data to the extent permitted by technology. It is possible, although unlikely, that an unauthorized individual could gain access to your responses because you are responding online. This risk is similar to your everyday use of the internet.

*If data is collected in a focus group:*

We will request that all participants respect the confidentiality of the group and do not share any other participant’s responses outside of the group. However, we cannot guarantee your privacy or confidentiality because there is always the possibility that another member of the group could share what was said. Pseudonyms will be assigned to each participant, and during the course of the interview and in all notes, you will only be referred to by your pseudonym.

*If photographs/audio/visual recordings will be collected:*

*[Photographs/Audio/visual recordings]* will be collected during this study and used to *[describe purpose].* The recordings will be *[kept indefinitely, destroyed after transcription, destroyed after X years, etc].* The recordings [will/will not] be shared *with [the general public or other researchers].* You *[do or do not]* have to agree to be recorded in order to participate in the main part of this study.

*If direct quotes may be used in dissemination:*

If you give the research team permission to quote you directly, the researchers will give you a pseudonym and will generalize your quote to remove any information that could be personally identifying.

*If collecting identifiable information or biospecimens one of the following statements is required:*

Identifiers might be removed from your *[information/biospecimen]* and the de-identified *[information/biospecimen]* might be used or distributed to other researchers for future research without your additional consent.

Identifiable *[information/biospecimens]* might be used or distributed to other researchers for future research without obtaining additional consent from you.

Your *[information/biospecimens]* will not be used or distributed for future research studies.

*If collecting biospecimens this statement is required:*

Biospecimens collected for this study will become property of Western Carolina University. You will not share in any commercial value or receive compensation if any commercial products are developed using the biospecimens.

*If this project is funded by NIH and collects identifiable information, all of the following is required:*

This research is covered by a Certificate of Confidentiality issued by the Department of Health and Human Services. This means that we cannot disclose or provide any identifiable information about you to any federal, state, local, civil, criminal, administrative, or legal proceeding. For example, your identifiable information may not be subpoenaed pursuant to a court order.

This certificate does not limit the ability of personnel from the federal or state government agency sponsoring this research to request information needed for auditing or program evaluation purposes or for information that must be disclosed to meet the requirements of the Food and Drug Administration (FDA).

The information protected by this certificate may not be disclosed to anyone outside the research team except in the following situations: if there is a federal, state, or local law that requires disclosure (such as mandatory reporting of child abuse or communicable disease); if you have consented to disclosure, including for medical treatment; or if your information is used for other scientific research as allowed by federal regulations governing research involving human participants.

This certificate does not prevent you from voluntarily releasing information about yourself or your involvement in the research. If you would like the research team to release your information to an insurer, medical care provider, or other individual not connected to the research, you must provide additional consent to the allow the researchers to release it.

Contacts and Questions:

If you have any questions about the study please ask now. If you have questions later, want additional information, or wish to withdraw your child’s participation call *[PI NAME]* conducting the study at *[PI PHONE # with area code – please make all phone number formats match including Dean Orion Rogers’ phone number below]*.

If you have questions about your child’s rights as a research participant, complaints, concerns, or questions about the research please contact Dean Orion Rogers, Institutional Officer for Research, Artis College of Science and Technology, Radford University, jorogers@radford.edu, 1-540-831-5958.

You will be provided a copy of this consent form.

You are making a decision about allowing your (son/daughter/child/infant/adolescent youth) to participate in this study. Your signature below indicates that you have read the information provided above and have decided to allow him or her to participate in the study. If you later decide that you wish to withdraw your permission for your (son/daughter/child/infant/adolescent youth) to participate in the study, simply tell me. You may discontinue his or her participation at any time.

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

Printed Name of (son/daughter/child/infant/adolescent youth)

Printed Name of Parent(s) or Legal Guardian

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

Signature of Parent(s) or Legal Guardian Date

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

Signature of Investigator Date

*[Note – you may add extra lines appropriate for the number of researchers expected to sign this document. Make sure that all spacing is properly aligned and professional looking.]*

Note: A signed copy of this form will be provided for your records.

*[Example: Use when direct quotes or audio/video may be used]*

I do □ or do not □ give my permission to the investigators to quote me directly in their research.

The investigators may □ or may not □ digitally record this interview.

Participant Name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_