

Catawba Valley Med Cnt IRB  
Informed Consent or Assent Waiver Request

I. General Information

Date	
Project Title	
Primary Investigator Name & Credentials	
Work Email	
Personal Email	
Work Phone Number	
Mobile Number	

II. Waiver of Informed Consent (check all that apply)

*The IRB may waive the requirement of informed consent under 45 CFR 46.116(d), if it finds that all the four following conditions are met:*

<input type="checkbox"/>	the research involves no more than minimal risk to the subjects;
<input type="checkbox"/>	the waiver or alteration will not adversely affect the rights and welfare of the subjects;
<input type="checkbox"/>	the research could not practicably be carried out without the wavier or alteration; <b>AND</b>
<input type="checkbox"/>	whenever appropriate, subjects will be provided with pertinent information after participation.

III. Waiver of Documentation of Informed Consent

*When the IRB has not waived the requirement for obtaining informed consent, it may waive the requirement for consent documentation for some or all subjects if it finds either that the:*

<input type="checkbox"/>	only record linking the subject and the research would be consent document and the principal risk would be potential harm resulting from a breach of confidentiality; <b>or</b>
<input type="checkbox"/>	research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context, e.g., drawing a blood sample, or asking shoppers in a mall about the ambient lighting or temperature.

IV. Waiver of Minor Assent

<input type="checkbox"/>	The age, maturity, or psychological state of the minor subjects is so limited they cannot reasonably be consulted, in the opinion of this PI.
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V. Justification of Waiver Request

*Provide rationale for why the research: 1) involves no more than minimal risk to the subjects, and/or, 2) cannot be practicably carried out without the waiver; or in the case of minors the reason(s) for limited capacity to provide assent. State plans for sharing pertinent study information with subjects after participation, or why subjects will not be informed. In the case of minors, provide the reason(s) for their limited capacity to provide assent. Note: Rationale is required for the IRB to consider waiving informed consent, documentation of informed consent, or minor assent.*

Justification rationale:	
PI Signature	
Sponsor Signature	