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ELECTRONIC SUBMISSION REQUIRED

APPENDIX D2
Waiver of Consent Documentation

Complete this form to request a waiver of consent documentation for the proposed research. DHHS regulations permit waivers of documentation of the consent process if the research meets certain conditions. DHHS and FDA regulations differ regarding when an IRB may waive the requirement to document the informed consent process.

Do not complete this form to request a waiver or alteration of the consent process, use Appendix D1.

Investigator Name		
1. Is the research subject to FDA regulations (e.g., involves use of a food, drug, biologic, device)?	Yes	
	No	

If Yes, only section (2) may be used to request waiver of consent documentation.

If No, either section (2) or (3) may be used to request waiver of consent documentation.

Documentation of consent cannot be waived under the conditions of the last section below if the research involves a product regulated by FDA or the results of the research may be submitted to FDA as part of a marketing application.

2. Both answers below (2a and 2b) must be **No** for a waiver of consent documentation:		
a. Does the research present greater than minimal risk?	Yes	
	No	
b. Does the research involve procedures for which written consent is normally required outside the research context?	Yes	
	No	
If No, explain how the research meets both (2a and 2b) of the conditions above.		

3. Both answers below (3a and 3b) must be **Yes** for a waiver of consent documentation:		
a. Would the only record linking the participant and the research be the consent document?	Yes	
	No	
b. Would the principal risk to the participant be potential harm resulting from a breach in confidentiality? ***Note: The participant should be asked whether he/she wants documentation linking the participant with the research; the participant's wishes will govern.***	Yes	
	No	
If Yes, explain how the research meets both (3a and 3b) of the conditions above.		