

## Office of Research and Creative Scholarship

Please utilize these two forms to request to waive documentation of informed consent (page 1) or request to waive informed consent (page 2). While documentation of informed consent may be granted, the IRB still requires researchers to submit the consent language that they will be providing subjects.

<b>Title of Study:</b>	
<b>Principal Investigator:</b>	<b>Co-Investigator:</b>
<b>WAIVER OF DOCUMENTATION OF INFORMED CONSENT:</b> Please note to waive this requirement <b>at least one</b> of the criterion <u>must</u> be met (see <a href="#">45 CFR 46.117(c)(1)</a> ). N/A <input type="checkbox"/>	
<input type="checkbox"/>	<p>The only record linking the subject to the research would be the consent document <u>and</u> the principal risk of the research would be a potential harm resulting from a breach of confidentiality.</p> <p><b>Note:</b> If this criterion is met, each subject must still be asked whether the subject wants to document consent and the subject's wishes must govern.</p> <p><b>Please provide rationale for how this criterion is met:</b></p>
<input type="checkbox"/>	<p>The 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., diagnostic tests).</p> <p><b>Please provide rationale for how this criterion is met:</b></p>
<input type="checkbox"/>	<p>If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects <b>AND</b> provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.</p> <p><b>Please provide rationale for how this criterion is met:</b></p>
<b>Principal Investigator's Signature:</b>	
<b>Date:</b>	

### REQUEST TO WAIVE DOCUMENTATION OF INFORMED CONSENT

## REQUEST TO WAIVE INFORMED CONSENT

<b>WAIVER OF INFORMED CONSENT</b> A waiver can only be granted if <u>all</u> of the following criteria are met (see <a href="#">46.116(f)(3)</a> ). N/A <input type="checkbox"/>			
<input type="checkbox"/>	The research involves <b>no more than minimal risk</b> to subjects <b>Please provide rationale for how this criterion is met:</b>		
<input type="checkbox"/>	The research <b>could not practicably be carried out</b> without the waiver or alteration <b>Please provide rationale for how this criterion is met:</b>		
<input type="checkbox"/>	If the research involves <b>using identifiable private information or identifiable biospecimens</b> , the research could not practicably be carried out without using such information or biospecimens in an identifiable format <b>Please provide rationale for how this criterion is met:</b> <input type="checkbox"/> N/A		
<input type="checkbox"/>	The waiver or alteration <b>will not adversely affect</b> the rights and welfare of the subjects <b>Please provide rationale for how this criterion is met:</b>		
<input type="checkbox"/>	Whenever appropriate, the subjects or legally authorized representatives will be provided <b>with additional pertinent information</b> after participation <b>Please provide rationale for how this criterion is met:</b>		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%; padding: 5px;"><b>Principal Investigator's Signature:</b></td> <td style="padding: 5px;"><b>Date:</b></td> </tr> </table>		<b>Principal Investigator's Signature:</b>	<b>Date:</b>
<b>Principal Investigator's Signature:</b>	<b>Date:</b>		