

## Informed Consent Documentation Waiver Request Form

**Instructions:**

Please review the following regulations prior to submitting the waiver request form: 21 CFR part 56.109(c) and 45 CFR part 46.117(c). The requests must meet the applicable requirements in the regulations in order to qualify for informed consent waiver. It is Total IRB's policy to not review or approve exceptions from informed consent for emergency research according to 21 CFR part 50.24 research.

<b>I. STUDY INFORMATION</b>	
Protocol Number:	
Protocol Title:	
Sponsor name and/or Funding Agency:	
<p>1. This request is submitted for:</p> <p><input type="checkbox"/> All subjects in the trial</p> <p><input type="checkbox"/> A subset of subjects in the trial. If a subset, what subset of subjects and rationale:</p>	
<p>2. Has this request been submitted to another IRB?    <input type="checkbox"/>Yes*    <input type="checkbox"/>No</p> <p>*If Yes, list the name of the IRB(s), and the outcome of the review. Attach copies of correspondence from the IRB(s):</p>	
<p>3. Is this request for an exception from informed consent for emergency research according to 21 CFR part 50.24?    <input type="checkbox"/>Yes*    <input type="checkbox"/>No</p> <p>* It is Total IRB's policy to not review or approve research in these types of emergent settings where informed consent is not planned to be obtained.</p>	

## II. FOR FDA REGULATED RESEARCH - 21 CFR part 56.109(c)

Respond to the following statements:

The research presents no more than minimal risk of harm to subjects.  Yes\*  No

\* If Yes, provide Sponsor rationale for minimal risk designation:

The research involves no procedures for which written consent is normally required outside of the research context.  Yes  No

**If either of the above two statements are marked No, the research does not meet the requirements for waiver of informed consent.**

## III. FOR FEDERALLY FUNDED RESEARCH - 45 CFR 46.117(c)

**Either** of the criteria may be used to waive documentation of consent. Note that waiver of documentation does not waive the process of consent itself. For studies invoking HIPAA, a waiver of authorization will also be required. *The waiver is not applicable to FDA regulated research.*

1. The only record linking the subject and the research will be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

Yes  No

2. 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.

Yes  No

Sponsor rationale for minimal risk designation:

## IV. FOR ALL RESEARCH

Describe in detail why this waiver of documentation of informed consent is required:

**V. PERSON COMPLETING FORM**

I certify that the information contained in this form is complete and accurate and that no facts have been suppressed or misstated. I am requesting for Total IRB to review the information submitted and provide approval or disapproval information. I understand that Total IRB has the authority to oversee this study and suspend the research study at this site if necessary to protect the rights and welfare of the study subjects. I agree to provide all information requested to conduct initial and continuing reviews of this study on time. I understand that if information is not provided, Total IRB may suspend the study. I agree to conduct the study in accordance with the conditions above. The Principal Investigator (PI) is aware of all information in this form and I am authorized to submit to the IRB on the PI's behalf.

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**Form Completed By**

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**Date**

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**Title, Company****Phone:****Email:**