**Request for Waiver of Documentation of Informed Consent**

Please indicate which of the two regulatory options your research activities fall into for IRB approval of a request for waiver of the requirement for documentation of informed consent.

The only record linking the subject and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality.

OR

Option 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.

Is the research FDA regulated?  Yes  No

*Please note that for FDA regulated research, you may not select Option 1 above. Waiver of Documentation of Informed Consent can only be considered under Option 2 for FDA regulated research. For DHHS supported and non-federally regulated research you can choose Options 1 or 2. For DHHS supported research that is also FDA regulated, you cannot choose Option 1.*

Please explain in the space below how your research meets the option you have selected above.

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**Please note that even if the IRB approves your request for a waiver of documentation of informed consent, the subjects must still be provided oral or written information including all required and appropriate elements of informed consent.**

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| For IRB Office Use Only  Approved  NOT Approved  Name of Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |