Appendix W: Request for Waivers Involving the Informed Consent Process

*This form is to be used if you are requesting either a waiver of documentation of consent (Section A) or a waiver of consent (Section B).* Complete only the appropriate section

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| PI Name: | IRB#: |
| Protocol/Project Title: | |

**General Statements about the Research Project** *(please check the relevant response)*

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| --- | --- | --- |
|  | **\*Yes** | **No** |
| Is the research subject to FDA regulation? |  |  |
| Is the research proposed more than minimal risk? |  |  |
| Will the human participant be a patient in a health care facility during the research project? |  |  |
| Is any investigator also a physician or other health care provider and will the subject also be a patient under the care of that health care provider? |  |  |

***\*If any “Yes” box is checked, STOP - this protocol is NOT eligible for waiver. A waiver of documenting consent may be possible if the only boxes checked "Yes" are the final two.***

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| **Section A: Request for Waiver of Documentation of Consent**  A consent process that contains all of the required elements of consent must still be in place (e.g. this could be done verbally or other ways) but participants can opt out of signing a form.  One of two conditions must be met; check the condition that applies: | |
| **Condition 1:** The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. *This refers to email or other surveys or brief interviews that elicit non-sensitive information.* |  |
| **Condition 2:** The only record linking the participant and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. *This refers to instances where participants could be seriously harmed if it became known that they were participants in the research. Each participant will be given the option to sign or not sign a consent form.* |  |

In the space below, provide a brief explanation of why you feel it is essential that documentation of consent should NOT be obtained and how you will ensure that participants are appropriately informed of their risks and rights. *If the participants are members of a distinct cultural group or community in which signing forms is not the norm, please note that here.*

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| **Section B: Request for Waiver of Consent**  When the IRB grants a waiver of consent it is either waiving the requirement of a consent process entirely or waiving the requirement to fully disclose all elements of consent. If appropriate and possible, subjects should be provided with additional pertinent information after participation (debriefed).  In order for the IRB to grant this type of waiver, your project must meet ALL of the  following conditions. Please check the conditions that apply: | |
| **Condition 1:** The research presents no more than minimal risk of harm to participants. |  |
| **Condition 2:** The waiver will not adversely affect the rights and welfare of the participants. |  |
| **Condition 3:** The research could not practicably be carried out without the waiver. *“Practicably” means there is no practical way to either implement a consent procedure or disclose all of the elements of consent without jeopardizing the validity of the study.* |  |

In the space below, provide an explanation of why the research could not be practicably carried out without a waiver. *If using identifiable private information or identifiable biospecimens, explain why the research could not practicably be carried out without using the information or biospecimens in an identifiable form.* Alternatively, provide a detailed description of the modified consent process that will be used, including when and how participants will be provided with pertinent information afterwards (for example in studies involving deception).

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***You must attach scripts and other documents to be used with the protocol, along with this Appendix Form when submitting your application to the IRB.***