|  |
| --- |
| **Request for a Waiver of the Informed Consent Process** |
| **All forms must be typewritten and submitted to the Lakeland Regional Health IRB at www.irbnet.org.** |

**Section 1. PROTOCOL INFORMATION**

|  |
| --- |
| **1.1. Principal Investigator:** |
| **1.2. IRBNet Number:** |
| **1.3. Project Title:** |
| **1.4. Is this research regulated by the US Food and Drug Administration?** [[1]](#footnote-1)  Yes  No |
| **1.5. Is this research regulated by the US Department of Defense?** [[2]](#footnote-2)  Yes  No |

**Section 2. REQUEST FOR WAIVER**

**A protocol which does not include an informed consent process may be approved by the IRB under certain conditions. To request IRB approval of a protocol which does not include an informed consent process, please provide a response to all of the following questions. Please be specific in explaining why each statement is true for this research.**

|  |
| --- |
| **2.1. Explain why and how the research involves no more than minimal risk to the subjects.** |
| **2.2. Explain why the waiver will not adversely affect the rights and welfare of the subjects.** |
| **2.3. Is the research team accessing identifiable private information and/or identifiable biospecimens?**  Yes  No  **If yes, explain why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.** |
| **2.4. Explain why the research could not be practicably be carried out without the waiver of informed consent.** |
| **2.5. If a waiver of informed consent is approved by the IRB, will subjects be provided with additional pertinent information after participation?**  Yes  No  **Explain/describe why:** |

## 

1. FDA regulated research is not eligible for a waiver of alteration of informed consent. [↑](#footnote-ref-1)
2. If the research subject meets the definition of ‘experimental subject,’ a waiver of consent is prohibited unless a waiver is obtained from the Secretary of Defense. If the research subject does not meet the definition of ‘experimental subject,’ the IRB may waive consent. [↑](#footnote-ref-2)