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| **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**

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| **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.**

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| **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:**       |

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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)