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| **PI NAME** |       |
| **STUDY TITLE** |       |

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| **1.** | **DO NOT USE THIS FORM** for:* FDA-regulated research. Most research that involves a drug, device, supplement, biologic, or botanical is FDA-regulated.
* Research involving public benefit and service programs conducted by or subject to the approval of state or local officials. For the waiver/alteration of consent for this type of research, please submit F-18, Request for Waiver or Alteration of Consent – Public Benefit and Service Programs.
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| **2.** | What are you requesting? (***Choose ONE***) |
| [ ]   | Waiver of the requirement to obtain informed consent [45 CFR 46.116(f)(1)] |
| [ ]  | Alteration of one or more of the required elements of informed consent. [45 CFR 46.116(f)(2)] Identify the element(s): [ ]  All basic elements of informed consent in 45 CFR 46.116(b)[ ]  All additional elements of informed consent in 45 CFR 46.116(c)[ ]  Other. Please identify:       |
|  |
|  **3.** | Is this request for (***Choose ONE***): |
| [ ]   | All subjects |
| [ ]  | Some subjects. Identify group of subjects and provide rationale:       |
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| **4.** | The research involves no more than minimal risk to the subjects.Explain:       |
| The research could not practicably be carried out without the requested waiver or alteration.Explain:       |
| If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. Explain:       |
| The waiver or alteration will not adversely affect the rights or welfare of the subjects.Explain:       |
| Whenever appropriate, the subjects or legally authorized representative, will be provided with additional pertinent information after participation.Explain:       |