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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: |
|  | | |
| **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: | |