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

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| **1.** | What are you requesting? ***(Choose ONE.)*** |
| [ ]   | Waiver of the requirement to obtain informed consent [45 CFR 46.116(e)(1)] |
| [ ]  | Alteration of one or more of the required elements of informed consent. [45 CFR 46.116(e)(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:       |
|  |
| **2.** | Is this request for (***Choose ONE***): |
| [ ]   | All subjects |
| [ ]  | Some subjects. Identify group of subjects and provide rationale:       |
|  |
| **3.** | The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:[ ] Public benefit or service programs[ ] Procedures for obtaining benefits or services under those programs[ ] Possible changes in or alternatives to those programs or procedures[ ] Possible changes in methods or levels of payment for benefits or services under those programs. |
| The research could not practicably be carried out without the waiver or alteration.Explain:       |