|  |  |
| --- | --- |
| **ID:** | Click or tap here to enter text formatted as Submission Number – PI Last Name. |
| **Notes:** | Click or tap here to enter text. |

Can a subject who is unexpectedly incarcerated in non-exempt research continue in the research?[[1]](#endnote-1),[[2]](#endnote-2),[[3]](#endnote-3)

One of the following categories must be met:

|  |
| --- |
| 1. Research NOT Conducted or Supported by DHS, HHS, or VA (Check if **“Yes”**. All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. The research is NOT conducted or supported by DHS, HHS, or VA
 |
| [ ]  | * 1. One of the following is true **(Check box that is true)**:
 |
|  | [ ]  | * + 1. The 2018 Requirements of 45 CFR 46 Subpart A are in effect for all new HHS research
 |
|  | [ ]  | * + 1. The institution conducting this research has verified that they have NOT voluntarily applied HHS regulations to this research
 |
| [ ]  | * 1. The rights and well-being of the subject are NOT in jeopardy
 |
| [ ]  | * 1. The subject can continue to consent to participate
 |
| [ ]  | * 1. The subject is capable of meeting the research protocol requirements
 |
| [ ]  | * 1. The terms of the subject’s confinement does NOT inhibit the ethical conduct of the research
 |
| [ ]  | * 1. There are NO other significant issues preventing the research from continuing as approved
 |
| [ ]  | * 1. A prisoner representative or a subject matter expert having the expertise of a prisoner representative has been consulted
 |
| [ ]  | * 1. Approval is limited to the individual subject and does NOT allow recruitment of prisoners as subjects
 |
| [ ]  | * 1. One of the following is true **(Check box that is true)**:
 |
|  | [ ]  | * + 1. The research is NOT conducted or supported by DOD
 |
|  | [ ]  | * + 1. The Human Research Protections Officer (HRPO) of the DOD component will be notified in 30 days to obtain concurrence and the subject will not continue to participate while a prisoner until concurrence is confirmed[[4]](#endnote-4)
 |
| 1. Research Conducted or Supported by DHS, DOD, HHS, or VA, and Approvable Under Subpart C (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. The research is conducted or supported by DHS, DOD, HHS, or VA
 |
| [ ]  | * 1. A qualified IRB has approved the research under 45 CFR §46 Subpart C
 |
| [ ]  | * 1. The regulatory agency will be notified within 30 days
 |
| [ ]  | * 1. For DoD conducted or supported research, the subject will not continue to participate while a prisoner until the Human Research Protections Officer (HRPO) of the DOD component has concurred with the IRB
 |
| 1. Research Conducted or Supported by DHS, HHS, or VA, and NOT Approvable Under Subpart C (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. The research is conducted or supported by DHS, HHS, or VA
 |
| [ ]  | * 1. The IRB has determined that the research is NOT approvable under 45 CFR §46 Subpart C
 |
| [ ]  | * 1. The IRB has determined that there are ethical reasons why the prisoner should remain a subject in the research.
 |
|  | Provide study-specific findings justifying the above determination:Click here to document study-specific findings justifying the above determination. |
| [ ]  | * 1. One of the following is true **(Check box that is true)**:
 |
|  | [ ]  | * + 1. The regulatory agency will be notified within 30 days to obtain concurrence
 |
|  | [ ]  | * + 1. The regulatory agency has provided concurrence
 |

**Footnotes**

1. . 45 CFR §46 Subpart C, [DHS Directive 026-04](https://www.dhs.gov/xlibrary/assets/foia/mgmt-directive-026-04-protection-of-human-subjects.pdf), [DoD Instruction 3216.02](https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.PDF?ver=8zK7VbUyB5_Lwy4vLWSP6A%3d%3d), [VHA Handbook 1200.05](http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=8171). [↑](#endnote-ref-1)
2. . AAHRPP Tip Sheet 18: Review of Research involving Prisoners and the Role of the Prisoner Representative [↑](#endnote-ref-2)
3. . In this checklist, "research" means <Research as Defined by HHS> involving <Human Subjects as Defined by HHS>, and "subject" means <Human Subject as Defined by HHS>. [↑](#endnote-ref-3)
4. . Send to the Human Research Protections Officer (HRPO) of the DOD component, which is the individual who is delegated the responsibilities as defined in paragraph 48 CFR 252.235. There may be more than one HRPO in a DOD Component. Some DOD Components may use a different title for the person(s) with the defined responsibilities. [↑](#endnote-ref-4)