

CHECKLIST: Unexpected Incarceration

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This checklist is used to determine whether a subject who incidentally becomes a <Prisoner> in non-exempt <Human Research> can continue in the research.

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All criteria in 1, 2, or 3 must be met

1. Research not subject to DHS, HHS, or VA regulation

- 1.1 The research is not subject to DHS, HHS, or VA regulations
- 1.2 The rights and well-being of the subject are not in jeopardy
- 1.3 The subject can continue to consent to participate
- 1.4 The subject is capable of meeting the research protocol requirements
- 1.5 The terms of the subject's confinement does not inhibit the ethical conduct of the research
- 1.6 There are no other significant issues preventing the research from continuing as approved
- 1.7 A prisoner representative or a subject matter expert having the expertise of a prisoner representative has been consulted
- 1.8 Approval is limited to the individual subject and does not allow recruitment of prisoners as subjects
- 1.9 One of the following is true:
 - The research is not subject to DOD regulation
 - The Human Research Protections Officer (HRPO) of the DOD component will be notified within 30 days to obtain concurrence (see Footnote 1)

2. Research subject to DHS, HHS, or VA regulation and approvable under Subpart C

- 2.1 The research will be subject to review and approval by a qualified IRB under 45 CFR §46 Subpart C
- 2.2 The regulatory agency will be notified within 30 days

3. Research subject to DHS, HHS, or VA regulation and not approvable under Subpart C

- 3.1 The federal agency will be notified within 30 days to obtain concurrence

4. Notes

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5. Footnotes

- 5.1 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.