

II4A-C PR1 Measures to Be Taken When a Current Research Participant Becomes a Prisoner

Overview

This procedure should be followed when a previously enrolled research participant becomes a prisoner and the relevant research protocol was not reviewed and approved by the IRB in accordance with the requirements of Policy II4A-C Participation of Prisoners in Research.

II4A-C1 Investigator Responsibilities

If a research participant becomes a prisoner after enrolling in a research study, and the investigator wishes for research interactions and interventions or the collection of identifiable private information to continue while a participant is incarcerated, the investigator is responsible for promptly reporting the event in writing to the IRB. This is not required when the study was previously approved by the IRB for the participation of prisoners, in accordance with IRB Policy II4A-C and 45 CFR 46 Subpart C.

The investigator must promptly secure approval from the State of Nevada Department of Corrections and any other involved entity (e.g., Department of Children and Families) before conducting research procedures with prisoners.

If the study was not previously reviewed and approved by the IRB to include the participation of prisoners, all research, specifically interactions and interventions with and obtaining identifiable private information about the now-incarcerated prisoner-participant, must cease until the requirements of the IRB policy have been satisfied with respect to the relevant protocol. This is necessary because it is unlikely that the design of the research and the informed consent document contemplated the constraints imposed by the possible future incarceration of the participant.

II4A-C1a Requirements for Continuation or Termination of Participation

If a subject becomes a prisoner while enrolled in a research study that was not reviewed according to Subpart C the additional requirements itemized below must be addressed.

- The investigator must confirm that the subject meets the definition of a prisoner.
- The investigator may terminate enrollment or, if it is feasible for the subject to remain in the study, resubmit the protocol for IRB review under 45 CFR 46 Subpart C.
- Before terminating the enrollment of the incarcerated subject, both the investigator and the IRB must consider the risks associated with terminating the subject's participation in the study.

- If the subject cannot be terminated for health or safety reasons, the investigator may keep the subject enrolled in the study. In such cases, the IRB must review the research under Subpart C.

Note: With consideration for the latter: If some the requirements of Subpart C cannot be met but it is in the best interests of the subject to remain in the study, the investigator may keep the subject enrolled. In such cases, the IRB must inform DHHS OHRP of the decision and justification of same.

- Alternatively, if the subject cannot be terminated for health or safety reasons, the investigator may, with IRB approval and modification of the protocol, remove the subject from the study but keep the subject on the study intervention under an alternate mechanism such as compassionate or off label use.

II4A-C1b Considerations for Temporary Incarceration

If the subject is incarcerated temporarily while enrolled in a study and the temporary incarceration

1. has no effect on the study, keep the subject enrolled, or
2. has an effect on the study, handle according to the above guidance.

II4A-C2 Additional Considerations

In special circumstances in which the principal investigator believes that it is in the best interests of the participant to remain in the research study while incarcerated, the investigator may appeal in writing to the IRB Chair, who may determine that the participant can continue to participate in the research until the requirements of the policy are satisfied.

If the participant was involved in a drug trial in which precipitant withdrawal of the medication could imperil the subject's health, then the investigator must notify the IRB Chair in writing with a plan for notification of appropriate directors of medical departments in the State of Nevada Department of Corrections or other involved entity, and plans for appropriate monitoring and interventions for withdrawal from the medication or for appropriate continued dosing. If the study involves a double blind administration of medication, when the investigational medication requires tapering for withdrawal, the investigator is responsible for breaking the blind to determine appropriate withdrawal action and inform the appropriate directors of medical departments in the State of Nevada Department of Corrections or other involved entity. If the participant can continue in the study (through agreement by the State of Nevada Department of Corrections or other involved entity), then the investigator must collaborate with the medical director to assure that proper administration, monitoring, and taper is conducted while the participant is incarcerated.

NOTE: These considerations may also be relevant for other interventions such as implanted devices.