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# Yale University Institutional Review Boards Procedure

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## Procedure 320 PR.1 Measures to be Taken When a Current Research Participant Becomes a Prisoner

Date: 1/31/09

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### 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 the IRB Review and Approval of the Participation of Prisoners in Research policy.

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### Investigator Responsibilities

1. 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 its policy.
2. The investigator must promptly secure approval from the State of Connecticut Department of Corrections Research Committee and any other involved entity (e.g., Department of Children and Families) before conducting research procedures with prisoners.
3. If the study was not previously reviewed and approved by the IRB to include the participation of prisoners, all research 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.
4. 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.
5. 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 Connecticut Department of Corrections or other involved entity (e.g., Department of Children and Families), 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 Connecticut Department of Corrections or other involved entity. If the participant can continue in the study (through agreement by the State of Connecticut 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.

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### **IRB Responsibilities**

Upon receipt of notification that a previously enrolled research participant has become a prisoner, the IRB will promptly re-review the protocol in accordance with the requirements of our policy if the principal investigator wishes to have the prisoner participant continue to participate in the research. The IRB review should take into special consideration the additional ethical and regulatory concerns for a prisoner involved in research, as well as the limitations of the facilities for adequate monitoring and follow-up in studies involving medication trials.