Obtaining Consent from Incarcerated, HIV-Positive Participants

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Max Researcher has planned an NIH-funded double-blind randomized placebo-controlled trial of a pharmaco-therapeutic agent, studying its impact on reducing high rates of relapse to opioid use upon release from incarceration and its association with poor HIV treatment outcomes. Persons with opioid use disorders with or HIV infection are concentrated within the criminal justice system.

Institutional Review Boards (IRB) at Max Researcher's medical school, and research committees at three correctional institutions review and approve all study procedures. The Office of Human Research Protections (OHRP) also approves the study protocol. The study is registered at www.clinicaltrials.gov. Additional protections are provided by the OHRP at the Department of Health and Human Services and a Certificate of Confidentiality (CoC) was obtained.

Infectious disease nurses will screen prisoners from three participating correctional facilities in a Northeastern state. Initial study inclusion criteria are: 1) HIV-seropositive; 2) incarcerated at one of three participating sites; 3) meets DSM-5 criteria for opioid dependence; 4) able to provide informed consent; 5) speaks English or Spanish; and 6) 18 years or older. Prisoners that meet screening criteria are asked to sign a release of information (ROI) so that research staff can meet them to describe the research study and perform informed consent procedures. After receiving the ROI, Research Staff schedule appointments with each inmate in a confidential setting to review additional eligibility criteria.

If the individual is eligible, the study staff member completes informed consent procedures and assesses the participant's willingness to enroll in the study. All participants receive counseling. To ensure that there is no real or perceived coercion for enrollment during incarceration, all participants undergo a second written informed consent process upon release from the correctional facility to confirm their interest in study participation. The pharmaceutical intervention will begin prior to release.

Post-release research follow-up will be conducted onsite at Max Researcher's medical school by research nursing staff. These activities included baseline physical exam and weekly in-person assessments of opioid craving, drug treatment satisfaction, side effects, weekly urine screening. Baseline and quarterly blood tests were obtained. Baseline adherence counseling is provided for all participants regardless of study arm assignment. Counseling consisted of a standardized, 15-minute video that addressed the importance of medication adherence, its HIV-specific benefits, and dealing with missed doses. At six months, all subjects reviewed the video again.

Questions:

- With respect to *authorization of data release to assess eligibility prior to consent,* what protections should be afforded to incarcerated populations?
- With respect to *consent of data use for research* (ROI), what additional protections should be provided to incarcerated populations to prevent coercion?
- What additional privacy protections should be in place for prisoners and former prisoners?
- Do different considerations apply if screening data is collected as part of prison intake vs. research procedures?
- What considerations apply if the study design included plans to continue data collection if a participant is re-incarcerated after release?
- Does there need to be another consent if someone is re-incarcerated?
- What are the implications of using the data that was collected when the patient was not incarcerated?

Title	Response
Description	The researcher conducts pharmaceutical RCT with prisoners and former prisoners who are HIV-positive and opioid dependent. Study outcomes can only be assessed after prisoners are released.
Primary actor /participant	Researcher
Support actor /participant	Jails, corrections department, probation department
Preconditions	• Researcher has IRB approval from Medical School and approval from research committees of corrections department, jails and prisons to collect, combine, and analyze data directly obtained from Subjects. • DUA with corrections department to receive data about parole/probation violations, arrests and incarceration. • Certificate of Confidentiality obtained from HHS.
Post conditions	• Information was collected and combined using a researcher generated unique beneficiary identifier.
Alternatives	• Prisoners under drug court mandate to participate in post-release substance use and HIV treatment. • Persons under age 21 are included
Considerations	• Prisoners must not be coerced into participating in the study

Data Elements Considered	Clinical data from survey/biometric data from subjects, corrections data about violations and contact with criminal justice system
Purpose of the Data Collection	Research, criminal justice
Purpose of Data Use	Analysis under a specific IRB approved research protocol
Terms of Transfer to the Data Holders	Direct consent from subjects to researcher for survey/biometric data and criminal justice data, DUA between criminal justice and researcher's medical school
Terms of Transfer to Researchers	IRB approval, research committee approval, DUA
Frequency	Criminal justice data transfer quarterly

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