Case Study: Incarcerated Individuals

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Vulnerable Populations

Vulnerable populations are groups who can be involved in research but may be easily susceptible to coercion and/or additional risk and, therefore, require enhanced protections.

The US Code of Federal Regulations (CFR) outlines protections for three central vulnerable populations: pregnant individuals (and the associated fetus/neonate), children, and incarcerated individuals.

In addition, some IRBs outline additional special populations who may require protections or additional considerations in a research protocol or recruitment plan. These groups may include, but are not limited to, students or employees of an institution where research is being conducted, terminally ill individuals, low-income populations, and individuals with cognitive impairments.

Case Study: Current Study Participant Becomes Incarcerated

Connie, a patient with ovarian cancer, was being treated by her physician, Dr. Lee, and qualified for a Phase III clinical trial. The trial combined standard of care chemotherapy with new investigational drug (or placebo). Connie signed informed consent, went through screening, was found eligible, and was randomized to treatment.

After two cycles of treatment, Connie informed Dr. Lee that she was scheduled to be incarcerated in the coming month, but she wanted to remain on the trial. She had spoken to her attorney and the prison. They agreed that Connie would be allowed to continue treatment at the site under supervision of an assigned officer.

Key Considerations

- Connie is now a vulnerable population participant.
- It is unclear if Connie will be allowed to receive treatment at the institution under supervision or if her treatments must take place at the prison healthcare facility.
- Additional IRB approval must be obtained.

Research Coordinator Responsibilities

1. When a previously enrolled research subject becomes incarcerated and the relevant research protocol was NOT reviewed and approved by the IRB in accordance with HHS regulations, you (or the PI) should ***promptly notify the IRB of the event.*** Once notified, the IRB should promptly re-review the protocol in accordance with the CFR requirements previously outlined.

2. The PI will need to assert that it is in the best interests of the subject to remain in the study while incarcerated.

3. All research interactions and interventions with, as well as obtaining identifiable private information about, the now-incarcerated prisoner-subject ***must cease*** until the CFR Requirements are satisfied as determined by the IRB Chairperson. Your IRB representative will provide guidance on if/when research activities may resume.

4. Once the CFR requirements have been met and the convened IRB committee approves the protocol, the PI can continue treatment and collection of potentially identifiable information from Connie.

IRB Process

In order to satisfy the US Department of Health and Human Services (HHS) requirements outlined in 45 CFR 46 Subpart C, when an IRB reviews a protocol involving prisoners as subjects, the composition of the IRB must satisfy the following:

- A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB
- At least one member of the IRB must be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity
  - ◊ *If a prisoner or former prisoner cannot be chosen, the IRB should choose a representative who has a close working knowledge, understanding, and appreciation of prison conditions from the perspective of a prisoner.*

Should a change to the IRB roster occur involving the addition of a prisoner or a prisoner representative, the IRB must notify the Office for Human Research Protections (OHRP).