UNEXPECTED

Research With Prisoners

Rozelle Copeland, PhD
Associate Director, IRB Administration
Wayne State University

WAYNE STATE UNIVERSITY

Yikes! A Participant Became a Prisoner After Enrollment!

3 Options:

1) Retain participant and have IRB review the research for subpart C (IRB may need to refer study to another IRB that review's prisoner research).

2) Withdraw participant from the study.

3) Stop all research activities with the participant and **then resume activities after the participant has concluded his/her prisoner status.**

- ✓ **In all options, The PI should let the IRB know about the unexpected prisoner and which option is being pursued.**

What to Do with the Unexpected… Option 1

- **PI must notify the IRB immediately**. UP report
- **PI must immediately stop all research activities** with the participant who became a prisoner and stop obtaining identifiable information.
- **Get prison's permission and submit an amendment to the IRB**.
- **IRB** reviews study according to prisoner regulations.
- **OHRP** reviews and approves the research.

2 Exceptions

- **In participant's best interest to stay in the study while incarcerated:** If the **IRB Chair concurs** with justification, participant continues while IRB reviews study under subpart C.
- **Research is not conducted or supported by DHHS**: No certification to OHRP required, but the IRB may extend FWA & subpart C to all research.
  FDA: no specific provisions.

Process for Review of Research with Prisoners

1) IRB must include prisoner or prisoner representative in the review process

2) IRB must find that research falls into a permissible category and make six other findings (45 CFR 46, Subpart C)

3) IRB submits findings to OHRP

4) IRB & PI must receive OHRP authorization prior to re-starting research with the prisoner participant

What Does Subpart C Say?

- **Applies to all biomedical and behavioral research conducted or supported by Dept of Health and Human Services** that involves prisoners as participants
- **Purpose is to provide additional safeguards** for prisoners who are under constraints which could affect their ability to make a truly voluntary and un-coerced decision about participation.

(45 CFR 46, Subpart C 46.301-46.306)

Definition of Prisoner

- **Any individual involuntarily confined or detained in a penal institution (jail, juvenile detention facility).**
- Includes those pending arraignment, trial or sentencing;
- Civil and criminal statute;
- Those with alternatives to criminal prosecution or incarceration (psychiatric or substance abuse treatment facility).
- If wearing monitoring device-- ask OHRP

Process for Review: 1) The IRB

IRB must include prisoner or prisoner representative in the review process

- At least one ***voting* member/alternate must be a prisoner or prisoner representative** with the appropriate background and experience; must review the research; and be at meeting.
- Majority of the board's **members must have no association with the prison involved, *exclusive of the prison members*.**
- **The IRB composition requirements apply to all reviews: initial, continuing** (unless no one enrolled) and **amendments.**

Prisoner or Prisoner Reps (P/PR) IRB Models

1) **Register IRB with a standing P/PR** member/alternate (model WSU uses).
2) **Register 2 IRBs,** with "prisoner research" IRB being evoked and used when reviewing PR.
3) **Register IRB with P/PR that only counts** toward quorum when P/PR **attending** and reviewing PR.

Process for Review: 2) Categories

2) IRB must find that research falls into 1 of 4 permissible categories (or waiver) and make 6 other findings (45 CFR 46, Subpart C)

Four categories: N/A for unexpected prisoner

#4 Research on practices, either innovative or accepted, which have the intent and reasonable probability of **improving health and well-being of the participant**.

Some sub-questions in the categories may be N/A for a previous enrolled participant who unexpected becomes a prisoner. IRB should note this as N/A when they certify to OHRP.

Process for Review: 2) 6 IRB Findings

2) IRB must find that research falls into a permissible category and make six other findings (45 CFR 46, Subpart C)

1) Possible advantages given to the prisoner through participation in research **do not deter the person's ability to weigh risks against the advantages** in the limited-choice environment.

2) Risks involved in research are similar to risks that would be accepted by non-prisoner volunteers

3) Information is presented in **language that is understandable** to the participant population

IRB Findings:

4) Selection of participants within prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.

5) If needed, **adequate follow-up examination or care** at the end of research.

6) Assurance that **parole board will not consider prisoner's participation *and*** each **prisoner is clearly informed <u>in advance</u>** that participation will have no effect on his or her parole- may need to re-consent.

More Regulations for Research with Prisoners

- **Exemptions** do not apply to prisoners if subpart C is checked on the FWA.
- Prisoners cannot be involved in certain **emergency research** where the requirement for informed consent is waived.
- **Dept of Defense** prohibits research with prisoners unless for investigational new drug or device for a condition that the prisoner already has– see regs.

What about expedited review?

- **If possible, OHRP recommends that all prisoner research be reviewed by a convened IRB.**
- If expedited, OHRP recommends/ AAHRPP states that the **expedited review include the P/PR.**
- If the research does not involve interaction with prisoners, then the P/PR doesn't have to review it.
- AAHRPP requires that the **P/PR concur** with the determination that research is no greater than minimal risk.

Process for Review: 3) Submit a Certification Letter to OHRP

3) IRB submits findings to OHRP

- **IRB submits Certification Letter to Secretary, through OHRP**, documenting that the IRB reviewed the research, chose a category and made the six other required regulatory findings.
- Submit research proposal, grant # and IRB forms;
- Institution name, address, OHRP Assurance #, IRB # for designated IRB, dates of IRB meetings and subpart C review.

This info is on the OHRP website.

Process for Review: 4) OHRP Authorization

4) IRB & PI must receive OHRP authorization prior to re-starting research with the prisoner participant

- **OHRP will send Authorization letter to institution.**
- PI informed that **research activities can re-start for the participant who became a prisoner.**

Questions?

Rozelle Copeland, PhD
rcopeland@wayne.edu
Associate Director
IRB Administration
Wayne State University