

**UNEXPECTED**

## Research With Prisoners

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### Yikes! A Participant Became a Prisoner After Enrollment!



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### 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.

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### 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.

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### 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.



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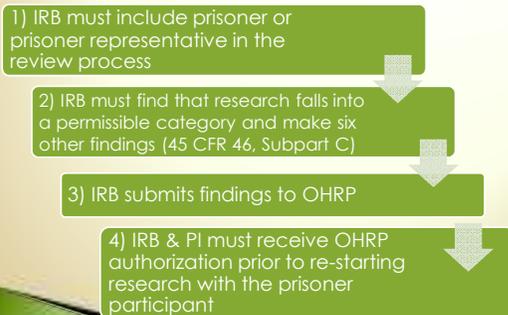
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### Process for Review of Research with Prisoners



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### 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)

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### 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

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### 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.**

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### 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.

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### 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.*

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### 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

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### 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 in advance** that participation will have no effect on his or her parole- may need to re-consent.

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### 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.




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### 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.




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### 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.**

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### 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.**

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### Questions?



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