Prisoner Data in Clinical Research: identifying it, protecting it, and appropriately using it

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Why are you here?

And why in the world am I here??
Who is a prisoner?

- Any individual involuntarily confined or detained in a penal institution such as a prison, jail, or juvenile offender facility
Further prisoner definition

**Prisoner**
- Court ordered substance abuse treatment
- Individuals with psychiatric illness committed involuntarily as an alternative to criminal prosecution
- Detained pending arraignment, trial, or sentencing

**NOT a prisoner**
- Voluntarily admitted to an institution for treatment
- Receiving non-residential court-ordered treatment
- Civilly committed to nonpenal institutions for treatment
- Sentenced to community-supervised monitoring
Why include prisoners in research studies?

• Study validity
• Distributive justice
• Questions specific to prisons and prison populations
Prisoners as a vulnerable population

- History of exploitation and mistreatment
- Research subjects incentivized by clemency
- 1976 Nation Commission’s report and recommendations for research involving prisoners
- Since 1978 prisoners have been protected as a vulnerable population under HHS regulation
Federal Regulation: Subpart C

• Permissible categories:
  – Study of the possible causes, effects, and process of incarceration, and of criminal behavior
  – Study of prisons as institutional structures or of prisoners as incarcerated persons
  – Research on conditions particularly affecting prisoners as a class
  – Research on practices which have the intent and reasonable probability of improving health or well-being of the subject
– Study of the possible causes, effects, and process of incarceration, and of criminal behavior
– Study of prisons as institutional structures or of prisoners as incarcerated persons

• With no more than **minimal risk** and no more than inconvenience to subjects
• MINIMAL RISK: the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons
Federal Regulation: Subpart C

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• Can proceed only:
  – after HHS Secretary has consulted with the appropriate experts (in penology, medicine, and ethics)
  and
  – after publishing a notice of intent to approve the research in the Federal Register
Waiver for epidemiologic research

Federal Register Vol. 68 No. 119

Research must have the sole purpose to:

• Describe the prevalence or incidence of disease by identifying all cases

OR

• Study potential risk factor associations for a disease

Can present no more than minimal risk and no more than inconvenience to prisoner subjects

OHRP must provide authorization prior to initiating research
Waiver for epidemiologic research

IRB responsibility in review

1) Fits into one of the permissible categories
2) Advantages don’t impair subjects’ ability to weigh risks
3) Risk are commensurate with risks that would be accepted by non prisoner volunteers
4) Selection is fair and control subjects must be selected randomly from available prisoners
5) Information is presented in a language understandable to the population
6) Participants are clearly informed that participation will have no effect on parole
7) Where needed, provision is made to make follow-up examinations or care available
Incidental prisoner subjects

What if a subject becomes a prisoner?

• Promptly notify the IRB
• All research interaction, interventions, and obtaining identifiable private information must suspend immediately if the research has not been approved for enrollment of prisoners
  – *exception
• IRB must re-review in accordance with subpart C and send certification to OHRP
Preemptive action by investigators

- Researchers can have subpart C review in anticipation of subjects becoming prisoners during the course of a study
- Include a check box in the consent form to ask subjects if they agree to be contacted if they become incarcerated
- Fill out the INSPIR protocol to reflect that incarcerated subjects may be enrolled in the research
- Create a separate consent form that addresses procedures that occur when a subject is incarcerated
- Draft a letter used to contact correctional facilities to request permission to contact individuals for research
Other regulations to consider

• Exempt research
• Expedited research
• Waiver of informed consent
• Amendments
Conclusions

• Excluding prisoners from human subjects ≠ protecting prisoners
• HHS protects prisoners as a vulnerable population in Subpart C
• There are specific permissible categories of research in which prisoners can be included
• OHRP must authorize IRB approval of research involving prisoners
• Look out for new BUMC IRB policies regarding inclusion of prisoners in research
Thank you!!