



Prisoner Data in Clinical Research:

identifying it, protecting it, and appropriately using it

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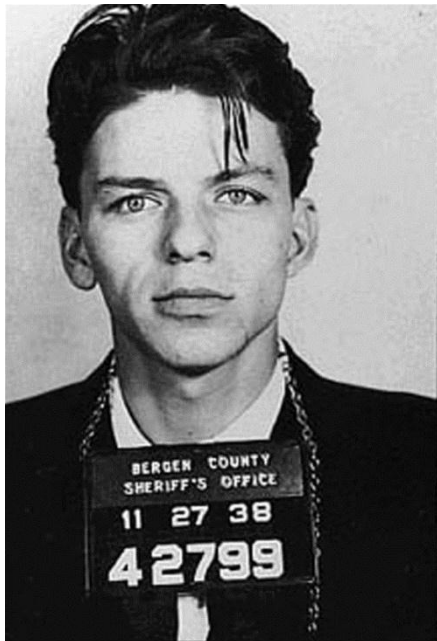
Why are you here?



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?

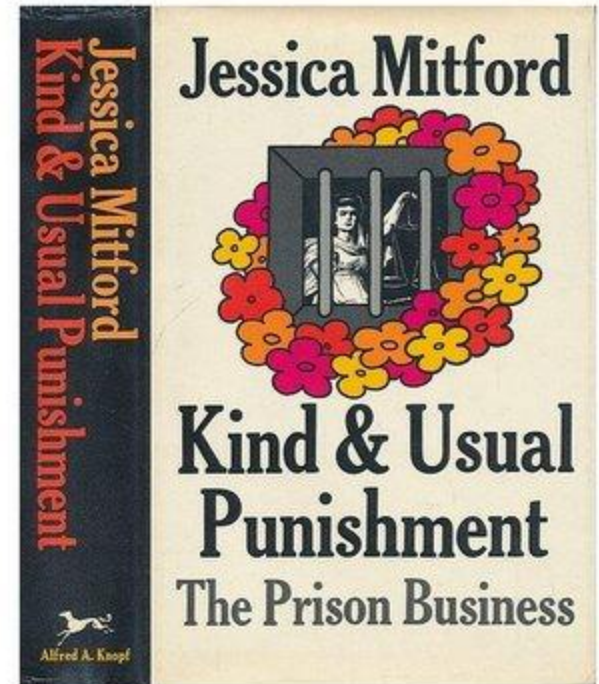
- Study validity
- Distributive justice
- Questions specific to prisons and prison populations





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

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- 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

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- 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*

- 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:

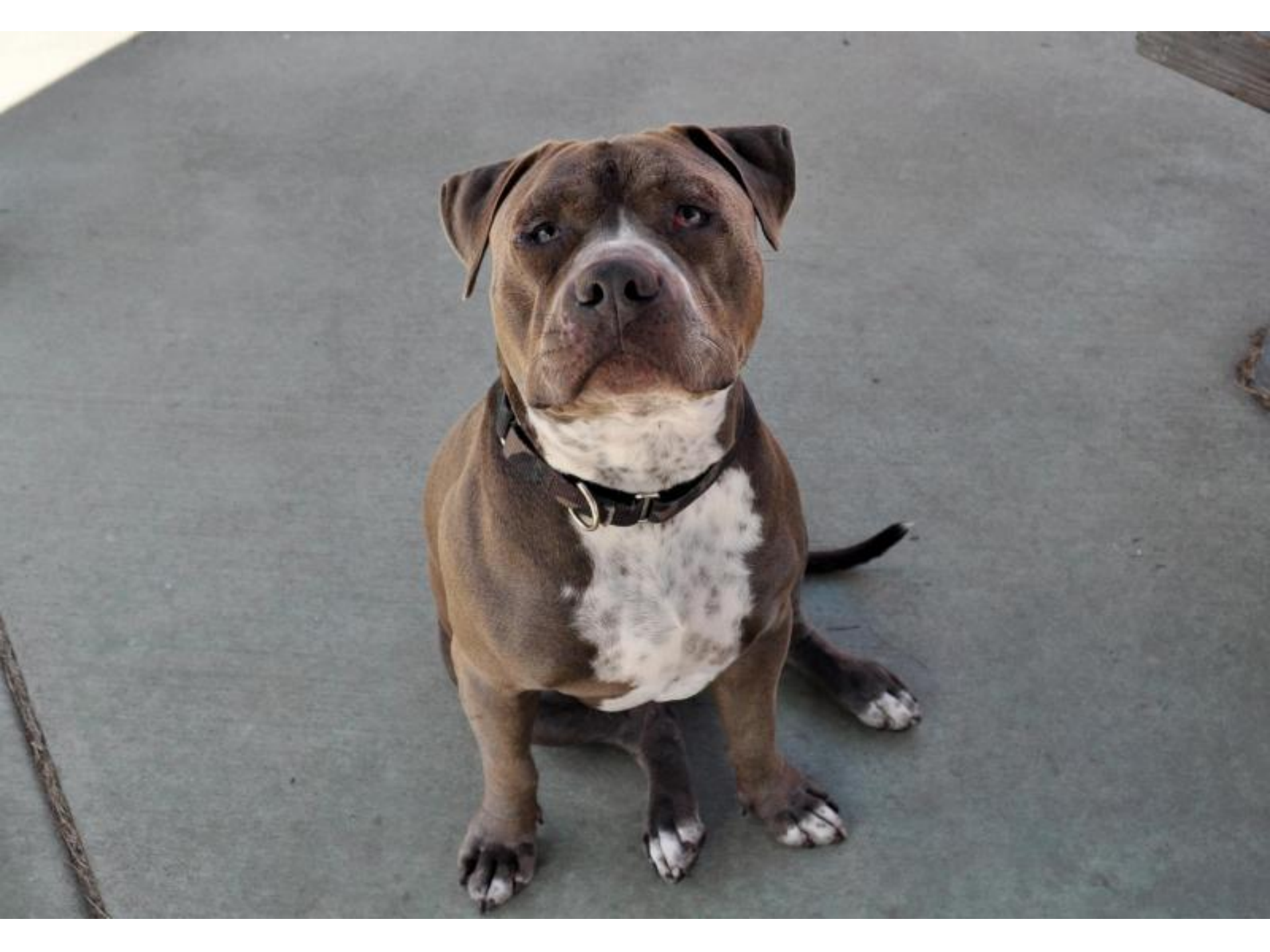
- Describe the prevalence or incidence of disease by identifying all cases

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



S Afr Med J 2012



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!!