



Human Subjects

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Subpart C: Research with Prisoners

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Why do we have extra protections for prisoners?

- University of Chicago malaria studies
- University of Pennsylvania
- Holmesburg Prison
- Atomic Energy Commission



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IRB Composition

- A majority of the IRB members must have no association with the prison(s) involved
- 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



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Defining Prisoner

Any individual involuntarily confined or detained in a penal institution. This includes:

- individuals sentenced to such an institution under criminal or civil statute,
- individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration
- individuals detained pending arraignment, trial or sentencing



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What do the regs allow?

1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior.
2. Study of prisons as institutional structures or of prisoners as incarcerated persons.
3. Research on conditions particularly affecting prisoners as a class.
4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subjects



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Consent Issues

- Free Choice
- Use of Incentives
- Confidentiality



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Assessing Risk

- Harm in asking questions
- Breach of confidentiality



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Required IRB Findings

- Must fall under one of the 4 categories mentioned earlier
- Any advantages...when compared to the general living conditions, are not of such a magnitude...that they impair the subjects ability to weigh risks/benefits
- Risks are commensurate with risks that would be accepted by non-prisoner volunteers



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Required IRB Findings Continued

- Subject selection must be fair and immune from arbitrary intervention by prison authorities or prisoners
- Study info is presented in language understandable to the subject population
- Participants are clearly informed that research participation will have no effect on eligibility for parole



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Other stuff about research with Prisoners

- Cannot be exempt
- Can be expedited*
- May be approved with a waiver or alteration of informed consent*
- If it is funded by the U.S. Department of Health and Human Services, including (NIH), must be certified by OHRP.



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**All of these findings must
be documented in the
meeting minutes.**



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