

Mini Case: Inclusion of Prisoners in COVID Vaccine Trials

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Disclaimer

The views expressed in this talk are my own.
They do not represent the position or policy of
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In what way are Prisoners vulnerable?

Regulations: When Prisoners can be Included

- (i) Study of the **possible causes, effects, and processes of incarceration**, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
- (ii) Study of **prisons as institutional structures** or of **prisoners as incarcerated persons**, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

Regulations: When Prisoners can be Included

(iii) Research on **conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere;** and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

Regulations: When Prisoners can be Included

(iv) Research on practices, both innovative and accepted, which have the **intent and reasonable probability of improving the health or well-being of the subject**. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research

What are reasons in favor of inclusion?

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- Early access to a potentially efficacious vaccine
- Option offered to non-incarcerated individuals
- Could shorten amount of time to outcome given rates of infection

What are reasons against inclusion?

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- Benefit not guaranteed
- Risks heightened among those with underlying health conditions
- Lack of advanced health care on-site
- Lack of access to other methods of prevention