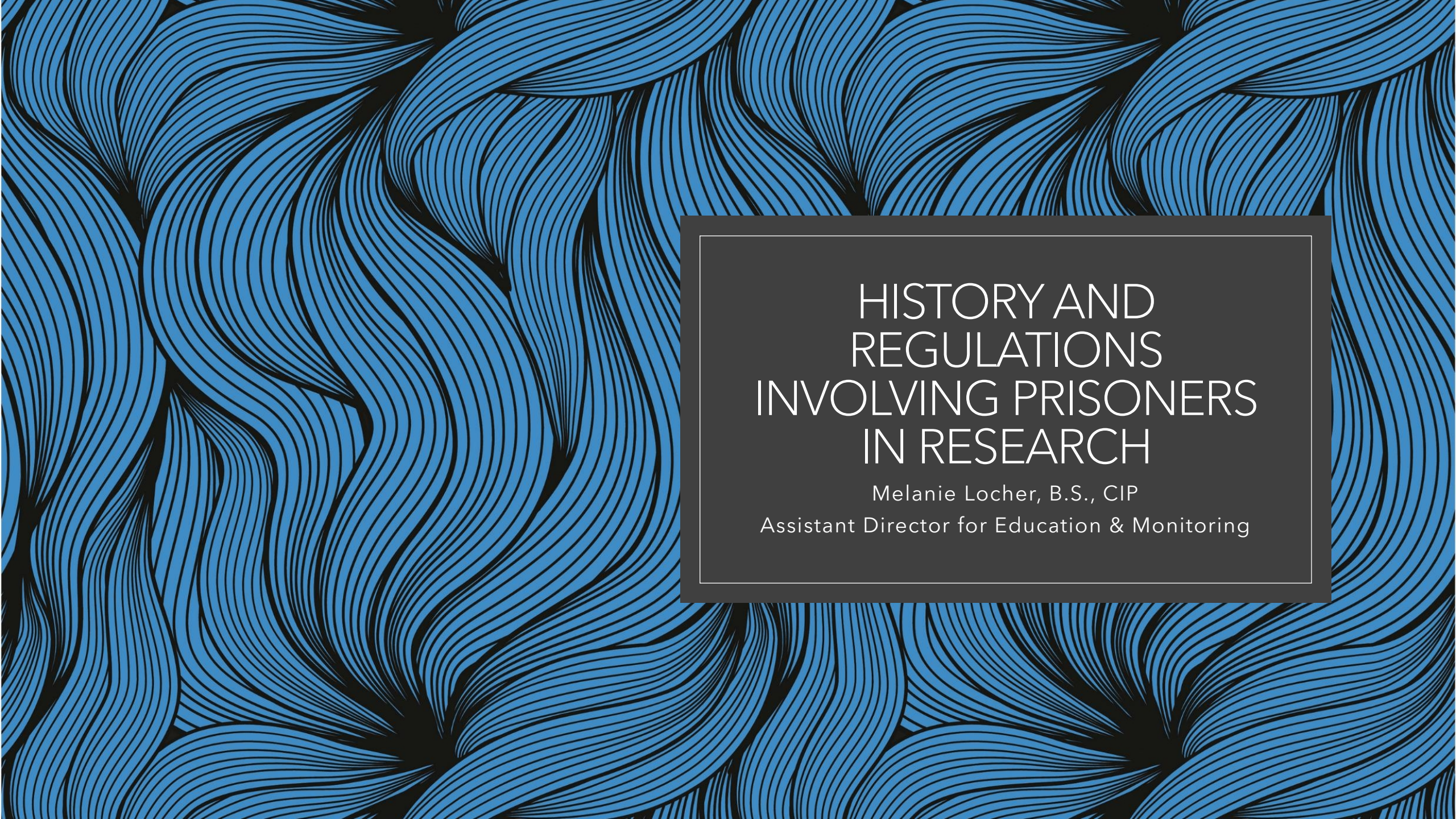

HISTORY AND REGULATIONS INVOLVING PRISONERS IN RESEARCH

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A Long US history of inmate experimentation

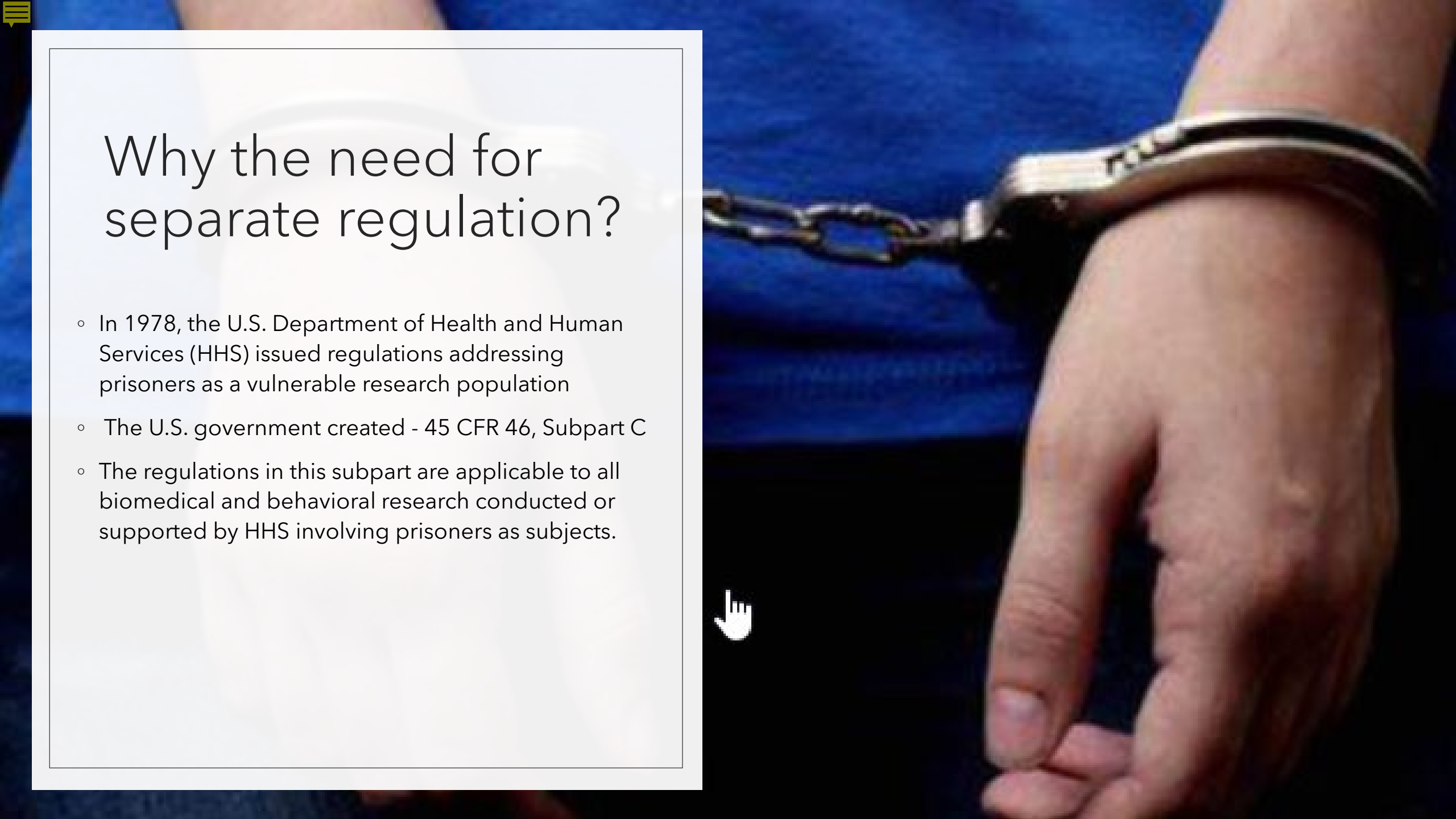
- 1944 - Illinois's Statesville Prison
- 1947 – American Medical Association (AMA) approved using prisoners as subjects as long as voluntary consent from subjects was given, prior animal experimentation had occurred, and conducted under the authority of properly qualified clinical researchers.
- Prisoners consented to participate in medical experiments in exchange for reduced sentences, more comfortable surroundings or money
- Prison research was considered to be ethically acceptable
- 1952 - Prison research became so common that critics argued heinous criminals should not be allowed to reap the benefits of the inducements

Holmesburg Prison Philadelphia, Pennsylvania

- Albert Kligman, MD Dermatologist
- 1951 - Initially invited into the prison to control athlete's foot at the request of prison officials
- Through 1974 dozens of experiments were conducted on hundreds of prisoners

Why the need for separate regulation?

- In 1978, the U.S. Department of Health and Human Services (HHS) issued regulations addressing prisoners as a vulnerable research population
- The U.S. government created - 45 CFR 46, Subpart C
- The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by HHS involving prisoners as subjects.



Why do prisoners need special protections?

1. The ability of prisoners to exercise free choice is limited because their autonomy is restricted.
2. Confidentiality of participation is difficult to maintain due to limited privacy of prison spaces.
3. Inducements offered by researchers to prisoners may create undue influence.
4. Prisoners may represent a population of convenience for researchers
5. Prisoners may not reap the benefits from research participation due to the limits of their incarceration.

What does the definition of prisoner encompass?

"Prisoner" is defined by HHS regulations as "any individual involuntarily confined or detained in a penal institution.

Encompasses 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 in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners

Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners

Parolees who are detained in a treatment center as a condition of parole are prisoners

What does the definition of prisoner NOT encompass?

Individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.

Individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to nonpenal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.

Persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.

Probationers and individuals wearing monitoring devices are generally not considered to be prisoners

What are the four categories for permissible research involving prisoners? (45 CFR 46.306)

Minimal risk is 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.

Category 1

- The research proposes to study the possible causes, effects, and processes of incarceration, and of criminal behavior. The study must be ***no more than minimal risk*** and no more than inconvenience to the participants. 46.306(a)(2)(i).

Category 2

- The research proposes to study prisons as institutional structures or to study prisoners as incarcerated persons. The study must be ***no more than minimal risk*** and no more than inconvenience to the participants. 46.306(a)(2)(ii)

Secretary of the Department of Health and Human Services has consulted with appropriate experts in penology medicine and ethics. The Secretary must also publish notice in the Federal Register of his/her intent to approve the research.

Category 3

- The research proposes to study the conditions particularly affecting prisoners as a class. (For example: A vaccine trial and other research on hepatitis, which is much more prevalent in prisons than elsewhere or research on social and psychological problems such as alcoholism, drug addiction and sexual assaults.) 46.306(a)(2)(iii)

Category 4

- Research on practices, both innovative and accepted, that 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 that may not benefit from the research 46.306(a)(2)(iv)

WHAT CONDITIONS MUST BE MET FOR AN IRB TO APPROVE RESEARCH INVOLVING PRISONERS?

ADDITIONAL FINDINGS THAT THE UVM IRB MUST MAKE AT TIME OF REVIEW 45 CFR 46.305(a)

(1) the research under review represents one of the 4 categories of permissible research

(2) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

(4) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that research project;

(5) the information is presented in language which is understandable to the subject population;

(6) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, considering the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

TRAINING SPECIFIC TO PRISONER POPULATIONS

Additional training requirements through the CITI module are required for all key personnel working on research protocols involving more than minimal risk protocols that include a prisoner population.

How is the IRB composition revised when reviewing research involving prisoners?

- The convened UVM IRB committee must include at least one member who is a (45 CFR 46.304) prisoner or a prisoner representative with appropriate background and experience to serve in that capacity

What happens if a research participant becomes a prisoner during the research?

- All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must be suspended immediately
- the investigator must promptly notify the IRB
- the IRB must promptly re-review the proposal in accordance with the requirements of subpart C if the PI wishes to continue their participation
- If the proposal is federally supported, the institution(s) engaged in the research involving the prisoner subject must send a certification to OHRP and wait for a letter of authorization.

* EXCEPTION - If the PI asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the subject may continue to participate in the research until the requirements of subpart C are satisfied. This is a rare exception that must be discussed with the Committee Chair and show a benefit to the subject.

QUESTIONS?