

USU Institutional Review Board Training Series: Research with Justice- Involved Populations



UtahStateUniversity

*January 30, 2024
Dr. Ronald Gillam, Dr. Michael
Gerald, & Ms. Nicole Vouvalis*

Welcome & Housekeeping

Welcome to the USU Institutional Review Board Spring 2024 Training Series!

Upcoming Training Dates:

February 21, 2024: Assessing Cognitive Capacity

March 27, 2024: Avoiding and Managing Bots & Fraudulent Respondents

April 8, 2024: Collecting Data on Children in Schools

Let us know what training topics you want to see addressed in Fall 2024!

<https://research.usu.edu/irb/feedback>

Welcome & Housekeeping

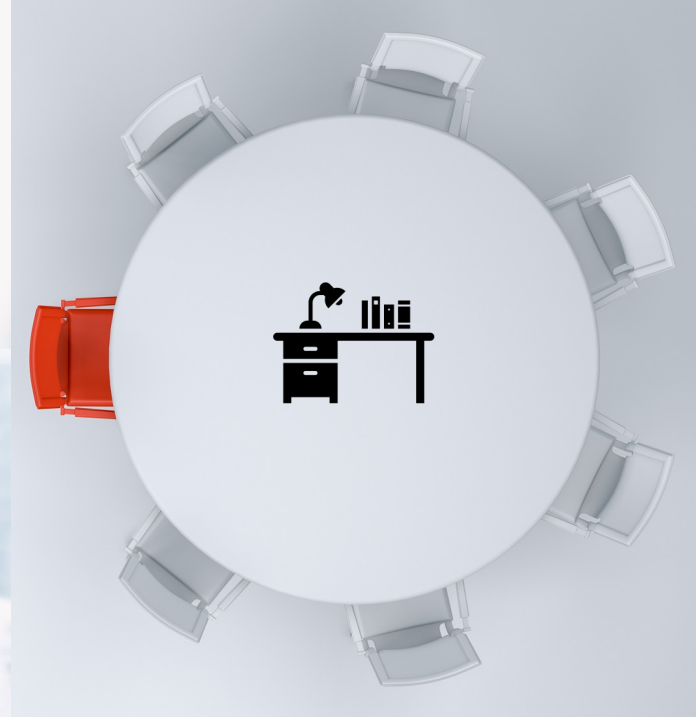


To ask a question, use the Q&A function at the bottom of this webinar screen. Anonymous questions are permitted.



All sessions will be recorded, and the recordings and/or slides from the presentation will be posted to the IRB's website, which can be accessed at irb.usu.edu.

The Institutional Review Board



The Human Research Protection Program

VP for Research

Responsible for overseeing all aspects of USU's Human Subjects Research portfolio & ensuring appropriate access to resources for a well-functioning Human Research Protection Program (HRPP)



Human Research Protections Office

Manages the day-to-day aspects of implementing and overseeing the HRPP, including:

- Researcher training
- Coordination with COI, IBC, ICOI, SPO processes
- Receiving complaints, concerns, and questions from research participants

The IRB

Reviews all proposed human subjects research at Utah State University according to:

- Established ethical standards,
- Policies & procedures, and
- Best practices

Researchers

Responsible for carrying out and overseeing research with human participants in a manner that:

- Complies with the terms of IRB's review,
- Ensures adequate resources and training for the safe conduct of the research, and
- Takes proactive steps to ensure the health, safety, and well-being of research participants

The IRB & Justice-Involved Participants



Dr. Ronald Gillam
IRB Chair
Raymond & Eloise
Lillywhite
Professor in
Speech Language
Pathology



Nicole Vouvalis
Executive Director,
Human Research
Protections



Dr. Michael Gerald
IRB Prisoner's
Advocate
Assistant Professor,
Special Education &
Rehabilitation
Counseling



- Prisoners (45 C.F.R. 46-utilized terminology)
- Incarcerated Persons/Individuals
- Inmates

Historical Context

- 1915: Rankin State Prison Farm Experiments
- 1934: Tuberculosis Vaccine Experiments
- 1939 – 1945: Nazi experimentation on imprisoned men, women, & children

The “Gilded Age of Research” – 1945 to 1970

“the benefits [of using prisoners in research] seem so much greater than the costs... there are no groups or individuals prominently opposing such an ethic.”

Utah State University IRB Review Standards

Utah State University's Institutional Review Board conducts its reviews according to two prevailing ethical standards:

Belmont Report

- Respect for Persons
- Justice
- Beneficence

45 C.F.R. 46 (The Common Rule)

- Subpart A: General Review standards
- Subparts C, D: Vulnerable Population Requirements

Subpart C: Prisoners

45 C.F.R. 46.302: “prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research.”

“Additional safeguards for the protection of prisoners involved in [research] activities” are therefore necessary

Incarcerated Participants Defined

Subpart C defines a prisoner as “any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a 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.”

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45 C.F.R. 46.305: Minimum Criteria for Approval

(a)(2): Any possible advantages accruing to the prisoner through [their] 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 [their] ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(a)(3): The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(a)(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 IRB 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 particular research project;

45 C.F.R. 46.305: Minimum Criteria for Approval

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

(a)(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 [their] parole; and

(a)(7): Where the IRB 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, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

45 C.F.R. 46.306: Acceptable Categories of Research

Proposed research involving incarcerated individuals must consist of *solely* the following:

- (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;
- (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) 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
- (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.

Utah Juvenile Justice Facilities

Many researchers do not intend to work with juvenile justice facilities, but find themselves in that space. Reference the list of service providers on the [Juvenile Justice & Youth Services website](#) for the best sense of whether your targeted facility is also an incarceration site.

Michael's Slides Begin Here



Resources

- [Text of 45 C.F.R. 46 Subpart C](#)
- [United States Department of Health & Human Services: *Guidance on Approving Research Involving Prisoners* \(2000\)](#)
- [Secretary's Advisory Committee on Human Research Protections *Recommendations: Who Is A Prisoner?*](#)
- [Request a consultation with an expert at the USU Human Research Protections Office](#)



Q

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Thank You!

Please use the feedback link to provide ideas for future IRB training topics.

Mark your calendars for our upcoming training topics & dates!

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