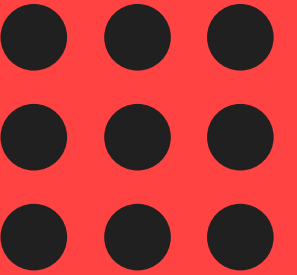


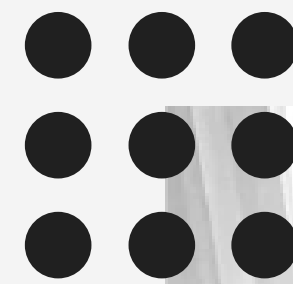
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# RESEARCH WITH PRISONERS

Regulations, ethical considerations, and best practices



# Nyssa Towsley



## EDUCATION

MS - Research Administration - Johns Hopkins

BA - Poli Sci - University of Minnesota, Twin Cities

## EXPERIENCE

HRPP Manager, UNLV HRPP

Education & Outreach Manager, VCU HRPP

IRB Analyst, VCU HRPP

Clinical Research Coordinator, VCU Health

Regular national conference presenter

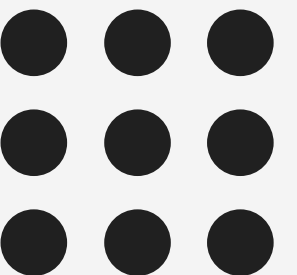
Certified IRB Professional (CIP)






# Learning Objectives

- Define "prisoner" and other key definitions relating to research with prisoners and justice-involved individuals
- Articulate the requirements of Subpart C, the portion of the regulations dedicated to protection of prisoner subjects
- Discuss other considerations and best practices for working with prisoners or other justice-involved individuals





# Research with Prisoners: Overview

## Subpart C

Subpart C of 45 CFR 46 contains the additional regulatory requirements for research that involves prisoners

# Prisoner Research: Review Level Requirements

## NO EXEMPTION

Research involving prisoners cannot be exempt (unless **not specifically targeting prisoners**, and prisoners are only **incidentally** included)

## FULL BOARD REVIEW

Almost always, research involving prisoners is reviewed by the convened IRB (AKA "full board" review)

# SUBPART C (45 CFR 46) OVERVIEW

## DEFINITIONS

- Definition of "prisoner"
- Special definition of "minimal risk"

## ADDITIONAL FINDINGS

- 7 additional regulatory findings required to be made by IRB
- Defines "categories (types) of research allowable under regs"

## IRB COMPOSITION REQUIREMENTS

- Special board membership requirements

## SECRETARIAL CERTIFICATION

- DHHS-supported studies require certification with OHRP Secretary



# Research with Prisoners: Subpart C Details

## Subpart C

Subpart C of 45 CFR 46 contains the additional regulatory requirements for research that involves prisoners

# When Does Subpart C Apply?

## TRIGGER POINT

Subpart C is triggered whenever there are research interactions/interventions with someone who meets the definition of “prisoner.”

## TWO POTENTIAL SCENARIOS

- Initial review with subpart C – when anticipating prisoner population
- Modification review with subpart C – when not anticipating prisoner population, but one or more subjects become incarcerated/meet the definition of “prisoner” while ON STUDY



# Definition of "Prisoner"

45 CFR 46.303(C)

"Prisoner" means any individual **involuntarily confined or detained** in a penal institution

## INCLUDING:

- Sentenced 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 (i.e.: court-ordered residential treatment centers), and
- Individuals **detained** pending arraignment, trial, or sentencing

# Definition of "Prisoner" (cont)

## DEFINITION TYPICALLY DOES NOT INCLUDE:

- Court-adjudicated to attend **non-residential** treatment programs as alternative to incarceration **while living in the community**
- Voluntarily entered treatment
- Released from prison to halfway house
- Civilly committed due to danger to self or others
- Handcuffed
- Electronic monitoring (generally)

## GUIDANCE

See [Prisoner FAQs on OHRP website](#)

# Definition of "Minimal Risk"

## **SUBPART A DEFINES MINIMAL RISK AS:**

"the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests"

## **SUBPART C DEFINES MINIMAL RISK AS:**

"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."

## **WHY DIFFERENT DEFINITIONS?**

This definition is more specific, and pushes researchers/IRBs towards a "general population" standard for understanding minimal risk

# IRB Composition Requirements

## INSTITUTIONAL AFFILIATION

A majority of the IRB must have no association with the prison where research is taking place

## PRISONER REPRESENTATIVE

At least one member of the IRB must be a “prisoner representative”

- Someone familiar with the context of operating in prisons and/or working with incarcerated/justice-involved individuals
- i.e.: prison social worker, chaplain, former prisoner, etc.
- **Lean on your prisoner rep!** They are there to provide logistical and cultural insight regarding working in a prison context. If you don't know if or how something will work in the prison context, talk to them!
- Prisoner rep **REQUIRED** when research is subject to Subpart C. Prisoner rep **RECOMMENDED** for consult when subjects are not strictly prisoners, but are still justice-involved (i.e.: on parole)



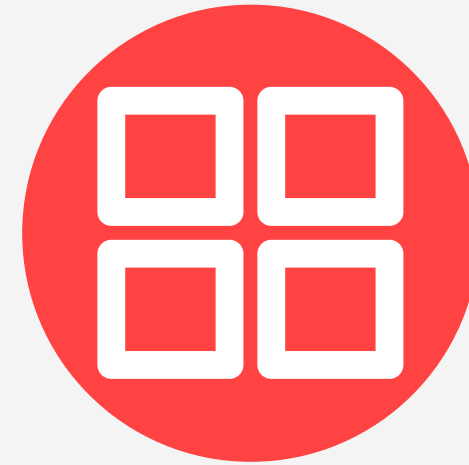
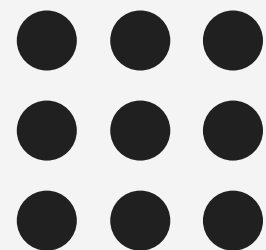
# Research with Prisoners: Additional Findings

## Subpart C

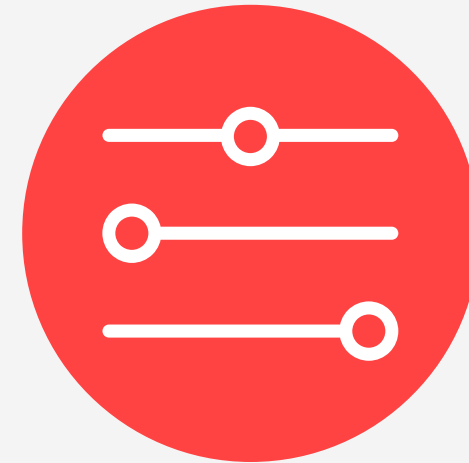
Subpart C of 45 CFR 46 includes **7 additional findings** the IRB must make in order to approve prisoner research; these are made **in addition to** the 8 criteria for approval outlined in Subpart A

# Additional Findings

The IRB must find and document that the following conditions are met before approving prisoner research



The research must fit into one of the **permissible categories** of prisoner research



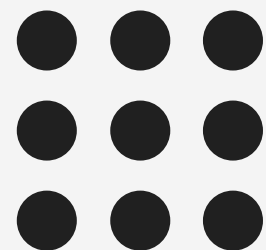
**Any possible advantages** accruing to the prisoner through their participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, **are not of such a magnitude that their ability to weigh the risks of the research against the value of such advantages ... is impaired**



The **risks** involved in the research **are commensurate** with risks that would be accepted by nonprisoner volunteers

# Additional Findings (cont)

The IRB must find and document that the following conditions are met before approving prisoner research



**Selection of subjects** within the prison is fair and **immune from arbitrary intervention** by prison authorities or prisoners



Assurance exists that **parole boards will not consider research participation** in parole decisions; **prisoners are informed in advance** that participation in the research will not affect parole



Adequate provision has been made for **follow-up care**



The information is **presented in language** which is **understandable to the subject population**



# Research with Prisoners: Literacy Considerations

## Reading Level

Subparts A and C require that consent information be in a language understandable to subjects. What does this mean in a practical sense?



# "Language Understandable to Subjects"

## DOUBLE REQUIREMENT

Both the criteria for approval in Subpart A and the additional findings required by Subpart C stipulate that study information must be in a language understandable by subjects. This means both utilizing native language AND using lay language.

## AVERAGE AMERICAN READING LEVEL

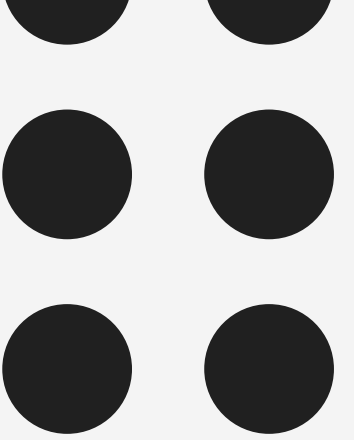
The average American reads between a 7th and 8th grade reading level. Over 70% of inmates in America's prisons **cannot read above a fourth grade level** (Early Literacy Foundation).

## WHY IS THIS SO IMPORTANT?

It is vastly preferable to meet subjects where they are at with their reading skills, over risking enrolling a subject without their full informed consent.

## What do different reading levels look like?

What kind of texts are at different reading levels?



## Let's play a game!

Guess the Flesch-Kincaid Reading Level for 5 different texts!

Texts and reading levels for this activity pulled from University of Southern Florida's [Lit 2 Go website](#)

# Readability and Plain Language


## READABILITY VS. CONTENT

Many of the books in the activity are at lower reading levels than one would think. But we think of them as more difficult books because the **content** of the text may not match the readability level. The activity shows that complex content can indeed be conveyed in relatively simple language.

## READABILITY RESOURCES

Learn more about how to enhance readability and how to write in "plain language" with these resources:

- [5 steps to plain language](#), Center for Plain Language
- [How to check reading level in MS Word](#)
- [NIH Training on plain language](#)
- [Plain language for science writing \(YouTube\)](#)
- [Plain language training \(Program for Readability in Science & Medicine \[PRISM\]\)](#)
- [PRISM readability toolkit \(PDF\)](#)



# Research with Prisoners: Compensation

## Subpart C

The additional findings required in Subpart C for prisoner research address advantages accruing to participants, such as compensation.

# Compensation Considerations

## **SUBPART C REQUIREMENTS**

Subpart C stipulates that advantages accruing to participants from the research, such as compensation, must not be of such high value that the prisoners' decision-making may be unduly influenced.

## **WHAT DOES THIS MEAN?**

It doesn't mean you can't compensate participants, but it does mean compensation amount and format must be appropriately calibrated to the prison context. This is a great place to consult with your prisoner rep.

## **DOC CONSIDERATIONS**

Approval from Oregon Dept. of Corrections may be required in addition to IRB approval, particularly around the topic of compensation. WOU IRB approval must come first, but consult with contacts at the DOC early and often.



# Research with Prisoners: Permissible Categories

## Subpart C

Subpart C outlines 5 categories of types of research that are allowed to include prisoners as subjects. Otherwise, prisoners are not allowed to be included as research subjects.

# Permissible Categories

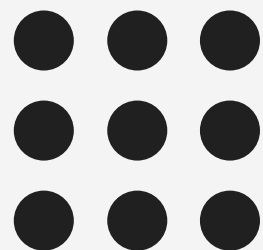
The entirety of the research project must fall into one of these allowable categories of types of research.



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

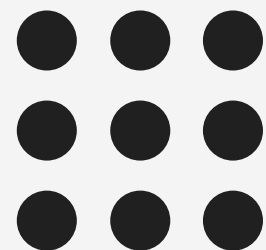


Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study **presents no more than minimal risk and no more than inconvenience** to the subjects



# Permissible Categories

The entirety of the research project must fall into one of these allowable categories of types of research.



Research on **conditions particularly affecting prisoners as a class** ... 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**



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 ... 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 his intent to approve such research**

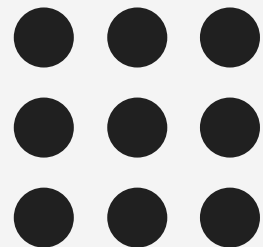



# Permissible Categories

The entirety of the research project must fall into one of these allowable categories of types of research.



Epidemiological “waiver” – The research must have **as its sole purpose** (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease. **The institution still must review the research under subpart C and certify to OHRP** that an appropriately constituted IRB has reviewed the proposal and made all other required findings under HHS regulations at 45 CFR 46.305(a) **and receive OHRP authorization prior to initiating any research involving prisoners**





# Research with Prisoners: DHHS Secretarial Certification

## Subpart C

Certain types of prisoner research require consultation and/or certification from the Secretary of DHHS

# SECRETARIAL CERTIFICATION

## ● **HHS-conducted or -supported**

The requirement for certification applies only to those studies conducted or supported (i.e.: through funding) by DHHS

Certification involves affirming that the IRB reviewed the research according to Subpart C and made the 7 additional required findings

Research not conducted or supported by DHHS does not require certification

## ● **Budget time for the process**

The certification process may involve the Secretary publishing the intent to approve the study, prior to approving it.

WOU IRB would be notified of approval or disapproval by secretary

Budget time for this process! It may take several months



# Additional Considerations

## **Ethical and Logistical Concerns**

These additional considerations may apply even when working with subjects who do not meet the definition of prisoner, but who are still justice-involved and are therefore subject to vulnerability



# LIMITATIONS ON PRIVACY/CONFIDENTIALITY

- **Prison Control**

Prisoners have very little control over communications with people outside the prison. Often times these communications are monitored

- **Group Settings**

Conducting consent or study activities in group settings can be problematic for privacy and confidentiality

- **Mandatory Reporting**

Some things require mandatory reporting, such as certain communicable diseases

- **Inform Subjects**

Be realistic about the limitations on your ability to provide confidentiality and privacy, and communicate these with subjects

# Certificates of Confidentiality

## WHAT ARE THEY?

CoCs allow researchers to resist legal demands for identifiable information collected during a research study. **They require additional language to be present in the consent form** describing the CoC, its protections, and its limitations.

## HOW DO I GET ONE?

CoCs are automatically issued to NIH-funded research. CoCs can be applied for from the NIH (or from a few other agencies) for non-NIH-funded research. Learn more on the [NIH CoC website](#), including sample informed consent language.

## WHEN DO I NEED ONE?

CoCs are highly recommended for research that collects information about illegal or illicit activities, regardless of whether subjects are prisoners under Subpart C

# Dept of Justice Requirements

## DIFFERENT REGS

The DoJ has its own regulations for conducting human subjects research ([28 CFR 46](#)), that may differ slightly from the regulations under DHHS ([45 CFR 46](#)).

## PRIVACY CERTIFICATE

One requirement under DoJ regs is a privacy certificate. Get guidance on what a privacy certificate is and how to complete one on the [DoJ Privacy Certificate website](#).

# Documentation of Consent

## CONSIDER A WAIVER OF DOCUMENTATION

For minimal risk research, IRBs can waive the requirement to document consent with a signature. This may be desirable for research with justice-involved individuals as an additional privacy protection





# Double Trouble: Research on Justice- Involved Juveniles

## Two Subparts

Research on minors (under 18) who are justice-involved will invoke both Subpart C and Subpart D (protections for children)

# Subpart D Considerations

## **PARENTAL PERMISSION**

In almost all cases, parental permission must be obtained, either from one or both parents (depending on the nature of the research). This will be a logistical challenge. State law may impact who is able to provide permission.

## **CHILD ASSENT**

Subpart D requires researchers to obtain assent (affirmative agreement) from children before enrolling them in a study. Assent requirements are much more flexible than consent; verbal/non-written processes are acceptable.

## **WAIVER OF PARENTAL PERMISSION**

45 CFR 46.408(c) allows for an IRB to waive the requirement for parental permission, for a population for whom that is not reasonable requirement to protect the subjects (for example, neglected or abused children). However, alternative mechanisms for protection must be in place.

**THE BURDEN OF PROTECTING PRISONERS IN RESEARCH SHOULD REST NOT ONLY ON THE IRB, BUT ALSO ON INVESTIGATORS, WHO BECAUSE OF THEIR PRESENCE IN THE CORRECTIONAL SETTINGS WILL HAVE MORE AWARENESS OF ACTUAL CIRCUMSTANCES THAN AN IRB.**

...

**WHILE IRBS MAY BE A CHECK ON THE SYSTEM OF RESEARCH PROTECTIONS, EACH INVESTIGATOR HAS A DUTY TO ASSURE THAT RESEARCH IN CORRECTIONAL SETTINGS IS DONE IN AN ETHICAL MANNER AND THAT INFORMED CONSENT AND PARTICIPATION BY PRISONERS ARE VOLUNTARY.**

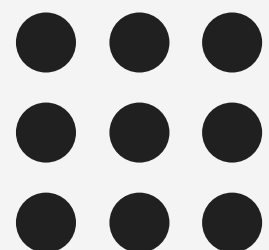
-SECRETARY'S ADVISORY COMMITTEE ON HUMAN RESEARCH PROTECTIONS (SACHRP), APRIL 18, 2005.



Thank you!

## RESOURCES

- [OHRP Research with Prisoners FAQ](#)
- [OHRP Research with Children FAQ](#)
- [OHRP Guidance on Prisoner Involvement in Research](#)
- [OHRP Educational Videos on Prisoner Research](#)
- Article: [Guidelines for Conducting Meaningful Research in Jails](#)
- Article: [A Scoping Review of Qualitative Research Methods Used With People in Prison](#)
- Article: [Ethical monitoring: conducting research in a prison setting](#)
- Article: [Conducting Research in Corrections: Challenges and Solutions](#)
- Article: [Conducting Research with Incarcerated Populations](#)
- PDF: [Conducting Participatory Research in Prisons](#)



# Questions?