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ACCELERATING RESEARCH. IMPROVING HEALTH.
NED 2020
Networking to Enhance Development
A Conference By and For Research Coordinators
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Regulatory Year in Review

Karen Moe, Director
UW Human Subjects Division

Learning Objectives

1. Identify key regulatory changes this past year
2. Explain how key regulatory changes affect certain types of research
3. Recognize how to apply those changes to your clinical research
4. Review the resources available for managing regulatory aspects of clinical research

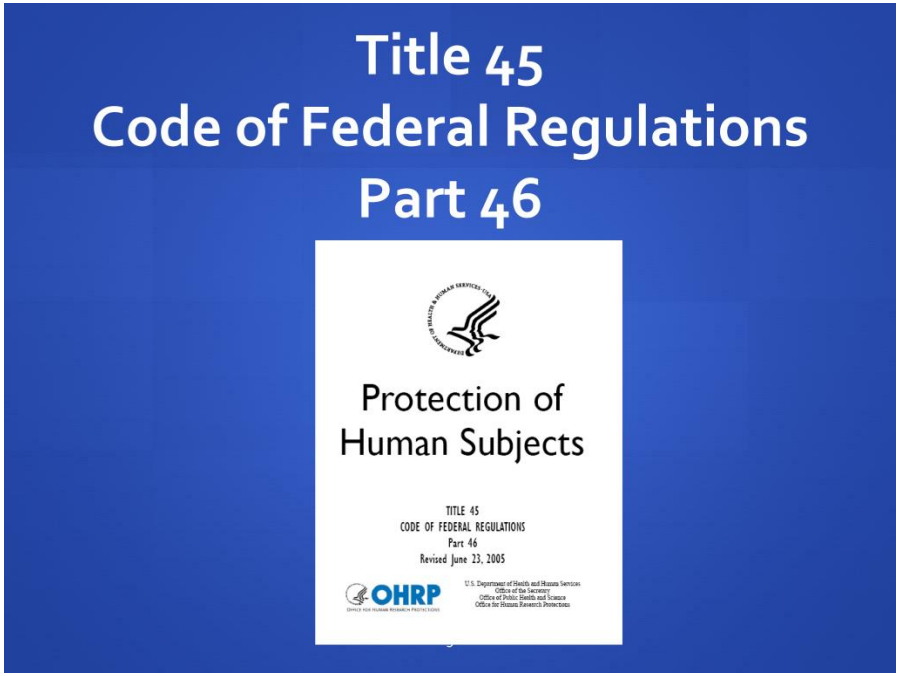
Regulatory changes

Common Rule	FDA	NIH	Washington State	Univ of Washington
				
Which research? *Federally-funded*	***Which research?*** *FDA-regulated*	***Which research?*** *NIH-funded*	***Which research?*** *Located in WA, & some WA records*	***Which research?*** *Conducted by UW PI*

Some changes make research easier, some add new requirements

The Common Rule

The human subjects regulations that 18 federal agencies have in common



The Common Rule

How do you know if it applies to your research?

Look at your funding. It applies to human subjects research funded by virtually all federal agencies.

CDC Centers for Disease Control and Prevention

VA U.S. Department of Veterans Affairs

AHRQ Agency for Healthcare Research and Quality

Department of Defense United States of America

NSF National Science Foundation

NIH

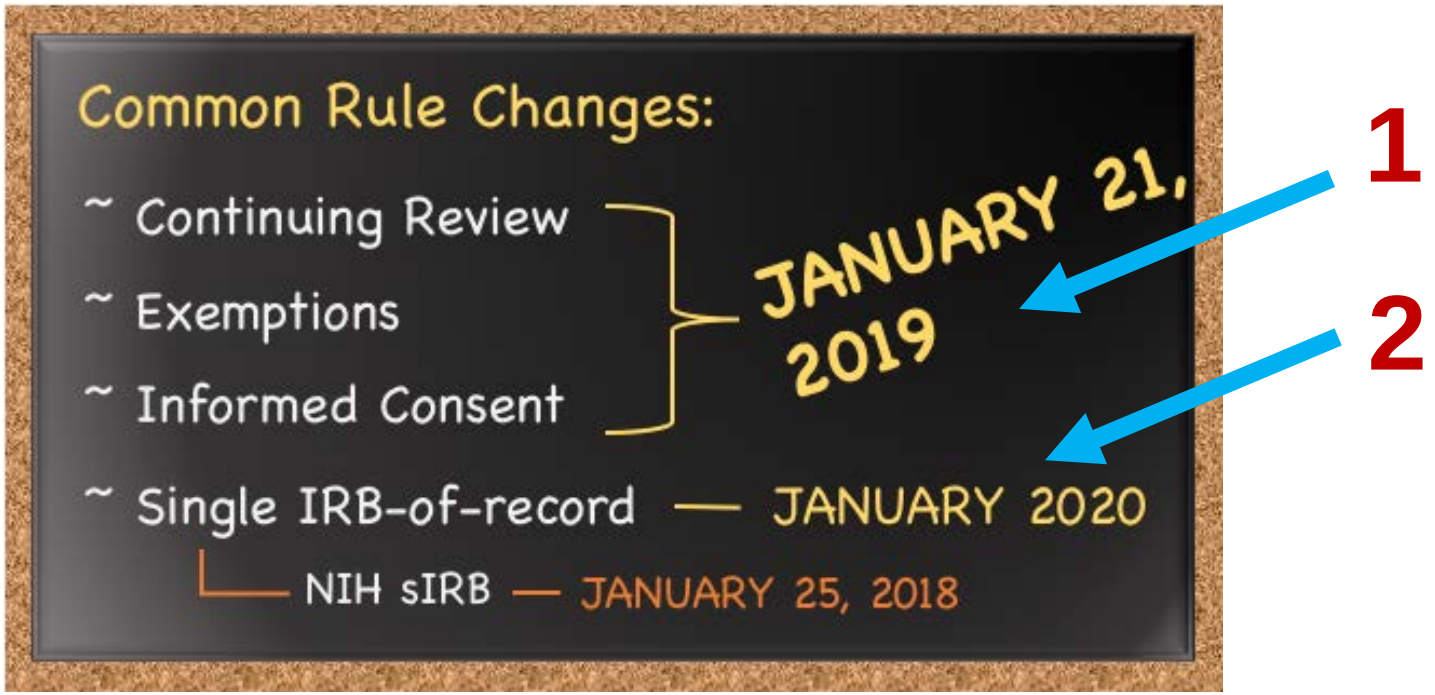
The Common Rule

How do you know if it applies to your research?

Most academic and research IRBs routinely apply most of it to all studies, even if there is no federal funding

Revised Common Rule

FIRST REVISION IN DECADES: TWO PARTS



Why change the Common Rule?

Address evolving research methods & designs

Reduce regulatory burden for less risky studies

Improve participant protections

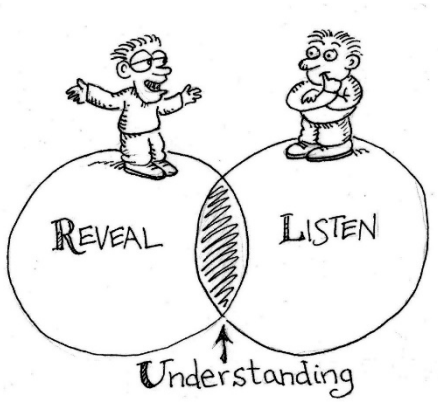
Lengthy, repeated public consultation about need for changes

Revised Common Rule

Reduced regulatory work for less risky studies

- ***No IRB review required**: Some public health research*
- ***More research qualifies for exempt status**, which means no further interaction with the IRB*
  - *Medical records reviews*
  - *Benign behavioural interactions*
- ***No continuing review for low-risk research***
- ***Consent or consent form waivers** possible in more situations*

Revised Common Rule



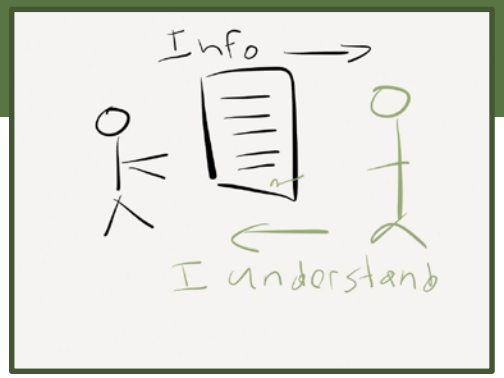
<u>New protection requirements</u>:

Consent forms must quickly and clearly capture the study

- ***New specific elements****: Secondary research; genetic analysis; return of results; commercial profit*
- ***New required characteristics***

New Required Characteristics of Consent

- **Key Information** must be presented at the beginning
- **Reasonable person standard** for what information is provided
- **Sufficient detail** is provided
- **Organized & presented** so as to facilitate understanding
- **Opportunity for discussion**



Key Information

What does this mean?

Key Information section *at the beginning of informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.*

Important for participants, but…

These are “squishy” requirements

Federal agencies have provided very little guidance

Each IRB may have its own interpretation

What should you do?

- Consent form template
- SOP Consent

Look at resources from your IRB

- What information would they want?
- What information would influence their decision?

Think about someone you know

- UW: hsdinfo@uw.edu, or contact the HSD team that works with your department

Contact your IRB staff

What about the second part of the revision?

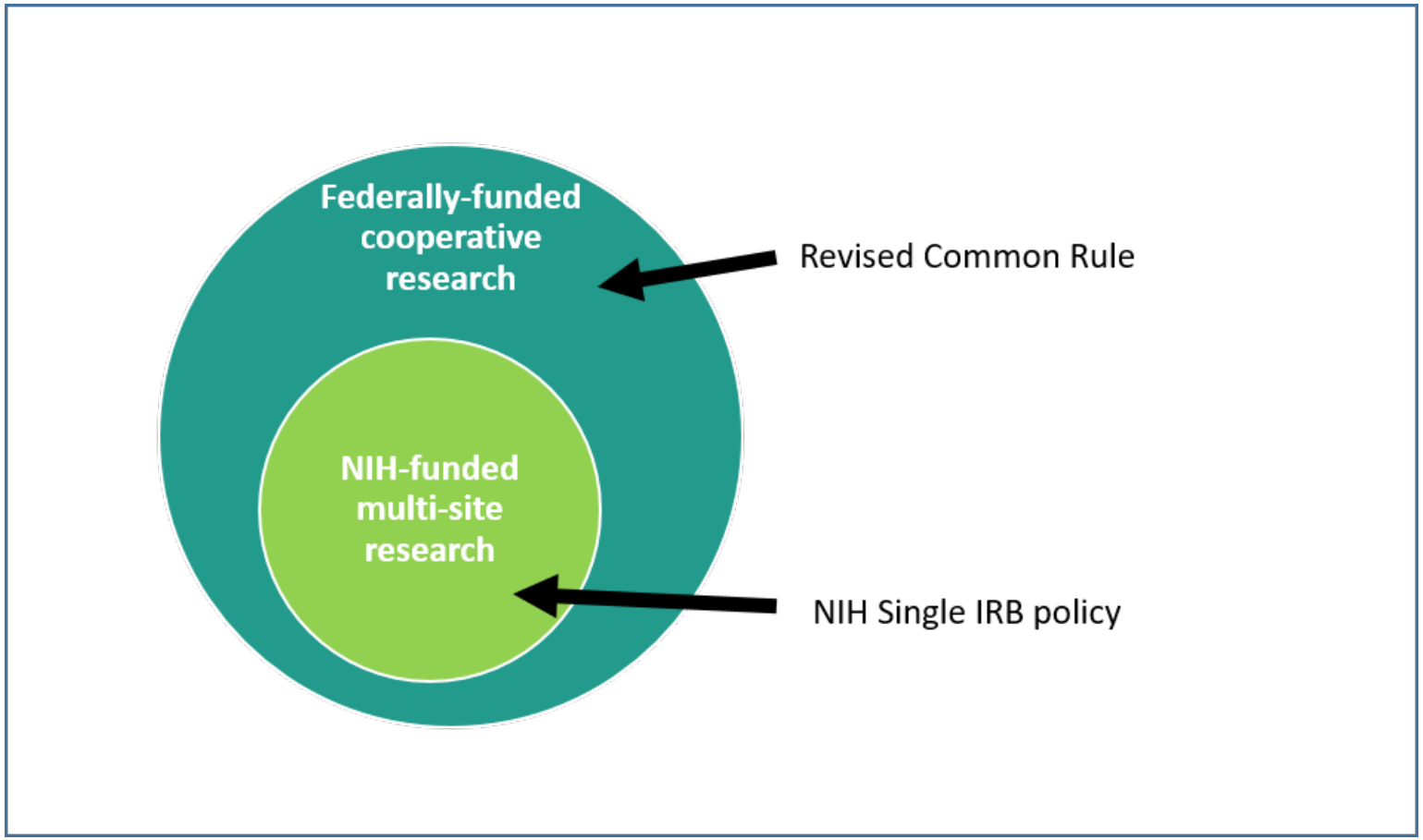
JANUARY 21, 2020

2

A **Single IRB** must do the review for all domestic institutions participating in any federally-funded study

Supersedes and greatly expands the NIH Single IRB Policy

All federally-funded studies, not just NIH
Collaborative AND classic multi-site studies



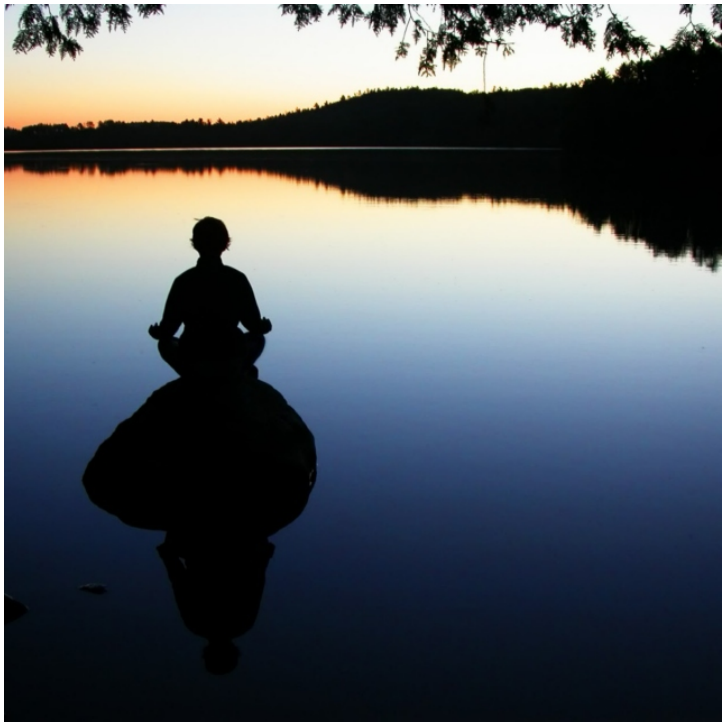
Huge impact on multi-institutional research!

See Breakout session 1B
“Single IRB: The Promise and the Reality”

Human Subjects Division Single IRB website
https://www.washington.edu/research/hsd/single-irb/

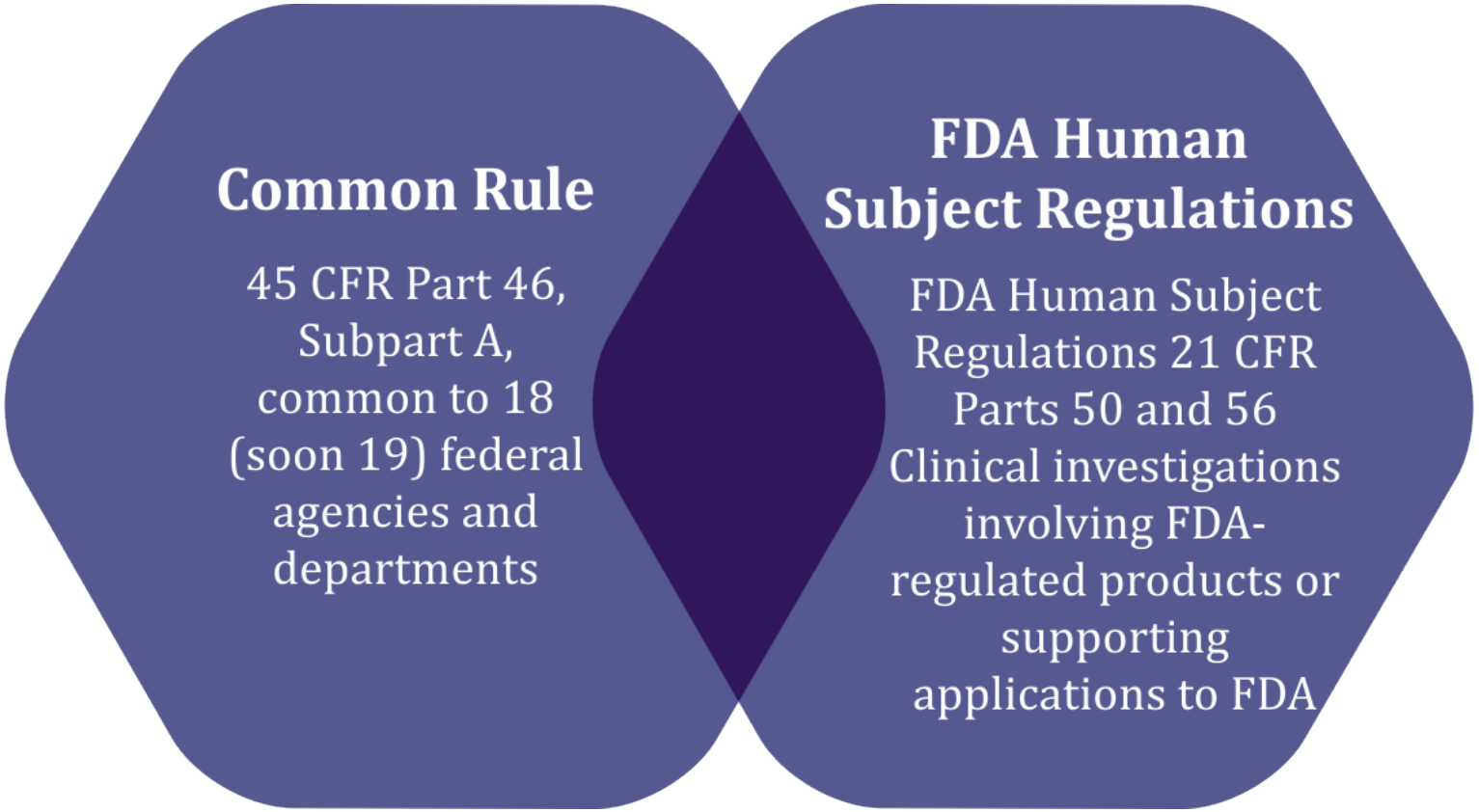

FDA

FDA: A quiet year



- No regulatory changes
- Many new draft or final guidance documents, but aimed at industry (not investigators or IRBs)

In the works: Harmonization

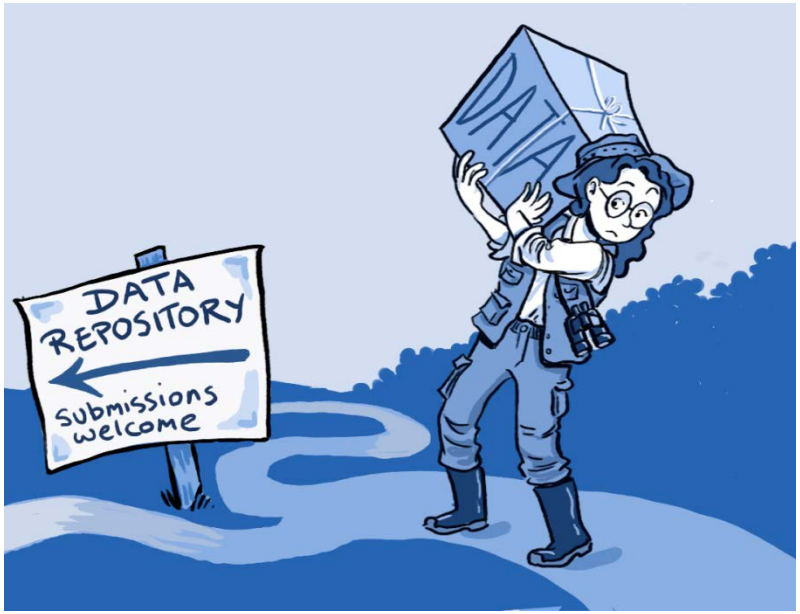


New policy that affects **all** NIH-funded clinical research

New policy that affects a **very specific type** of NIH-funded research

DRAFT Data Sharing and Management Policy

A BIG CHANGE FROM THE OLD POLICY

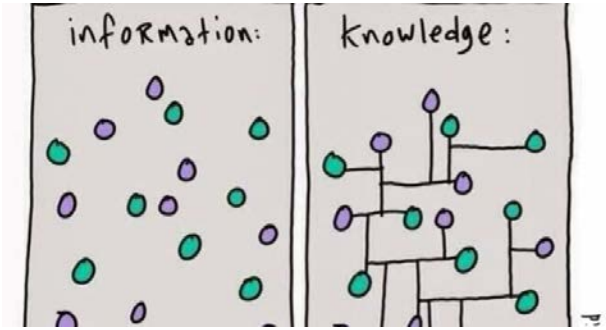


- **All** NIH-funded research
- **Mandatory sharing** with colleague (including **individual-level data**)
- **Mandatory detailed data sharing plan**, which must include steps to protect participant privacy

What this means for Clinical Research Management

ADDITIONAL RESPONSIBILITIES, PLANNING, AND RESOURCES

- Which data to share
- Storage and security
- Protection of participant privacy; what to tell them
- Request process, who handles it
- Data Use Agreements (content, who signs)
- Costs to put in the grant
- How to keep this going after the grant is over



A hot topic
NIH is eager to move forward

Part of good stewardship & accountability initiatives

Clinical research managers should start thinking about how they would do this

Best source of information: NIH website

https://osp.od.nih.gov/scientific-sharing/nih-data-management-and-sharing-activities-related-to-public-access-and-open-science/

Research involving the use of Human Fetal Tissue from elective abortions

- Tissue, cells, cell cultures, derivative products, xenografts, extra-embryonic cells and tissue (e.g., umbilical cord, cord blood)
- Some stem cell research

New requirements for study team

NIH notice::
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html
Human Subjects Division news announcement
https://www.washington.edu/research/announcements/nih-human-fetal-tissue-research-clarifications-and-faqs-published/

WASHINGTON STATE

Two helpful changes

2019 Washington Legislative session

Confidentiality Agreement no longer required for state college & university records, including UW Medicine records. *All other laws still apply (e.g., HIPAA)*

Extended family members and close friends can now be **surrogate health care decision makers** – includes research.

Where to find out more

Human Subjects Division GUIDANCE: Legally Authorized Representative

https://www.washington.edu/research/policies/guidance-legally-authorized-representative/

Research by the University of Washington

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UW Policy APS 10.13: Research Involving Minors

Which UW research?

Has primary goal of interactions with, or observations of, minors located anywhere (in-person or virtual)

Does IRB status matter?

No. This policy applies to all activities, even if the IRB says it is "not research" or is "exempt"

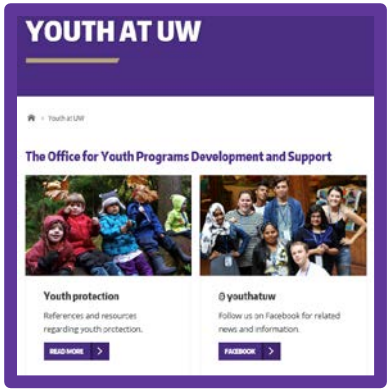
What are the requirements?

Registration; background checks and training for some personnel

UW Youth Programs Development & Support

Youth Policy Resource Website

https://www.washington.edu/youth/policy/protecting-youth-at-uw-aps-10-13/



FAQ about research and the policy

https://www.washington.edu/youth/policy/protecting-youth-at-uw-aps-10-13/aps-10-13-info-for-researchers/

Complete checklist of requirements

https://s3-us-west-2.amazonaws.com/uw-s3-cdn/wp-content/uploads/sites/129/2019/06/16200119/Policy-Quick-Reference-Checklist-9-2019-1.pdf

Summary of the 2019 regulatory changes

Common Rule	FDA	NIH	Washington State	Univ of Washington
				
Fewer requirements for low risk research; major new consent requirements	*Stay tuned for harmonization with the Common Rule*	*Pending Data Sharing Requirements; human fetal tissue*	*No more Confidentiality Agreements; expanded surrogate decision makers*	*UW Minors Policy: registration, background checks, training*

General Resources

Your IRB office staff

Your IRB's website

UW Human Subjects Division

Email hsdinfo@uw.edu

Website https://www.washington.edu/research/hsd/

Monthly eNewsletter subscribe at https://www.washington.edu/research/manage-your-office-of-research-subscriptions/#hsd-newsletter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Questions?


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Thank You


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