# Forecasting Regulatory Requirements

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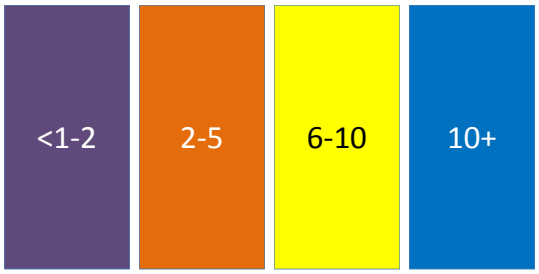
# Who are you?

## Years in research?



ITHS

Make a Diverse Group
(n=4-5)

ITHS


+ Human Subjects Research

# Session Goals

ITHS

Why Identify?

Review Framework

Analyze Case Studies

Why is it important to identify regulatory requirements?

## Why Identify Regulations?

Save Time

## Why Identify Regulations?

Regulations Interact

## Why Identify Regulations?

Understand Responsibilities


## Why Identify Regulations?

No one will do it for you

## Why Identify Regulations?

Professional Growth

## Review Regulatory Framework

## Regulatory Environment

OHRP
Office for Human Research Protections

FDA

HIPAA

Department of Defense
United States of America

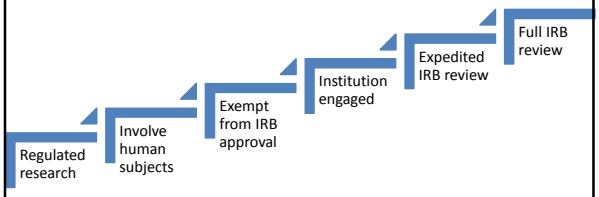
Washington State Legislature

United States Department of Education

## Review Framework—HHS

HHS regulations at 45 CFR 46

**#1. Level of IRB approval required?**




## Review Framework—HHS

**#2. Federally protected populations?**

- Pregnant women, fetuses, neonates (Subpart B)
- Prisoners (Subpart C applies)
- Children (Subpart D applies)

## Review Framework—HHS

**#3. How will you obtain consent?**

- Waiver of consent?
- Waiver of elements of consent?
- Waiver of written documentation of consent?
- Special considerations?

## Review Framework—FDA

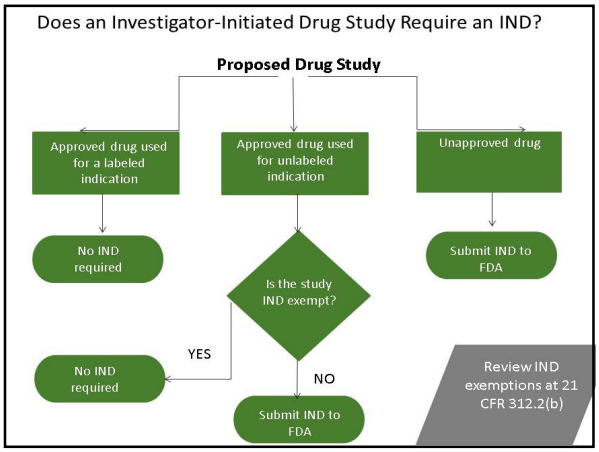
FDA Regulations at 21 CFR parts 50, 54, 56, 312, 812

**#1. FDA definition of human subjects research?**

Human subjects research/Clinical Investigation?

## Review Framework—FDA

**#2. Require Investigational New Drug application (IND) from the FDA?**



## Review Framework—FDA

**#3. Subject to Investigational Device Exemption (IDE) requirements?**

## Review Framework—FDA

| | | |
|---|---|---|
| Exempt study | → | No IDE |
| Significant Risk Study | → | Submit IDE |
| Non-Significant Risk Study | → | Abbreviated IDE |

## Review Framework—HIPAA

HIPAA Privacy Rule at 45 CFR 164

**#1. Does the study involve PHI from a covered entity?**

## Review Framework—HIPAA

**#2. Will you receive or release ONLY a limited data set of PHI?**

**Limited health information**
- Dates
- Geocodes (except street address)
- Ages

**Data Use Agreement (DUA)**

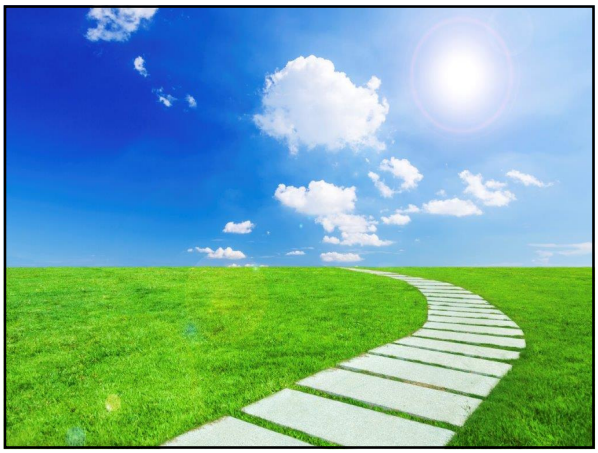
## Review Framework—HIPAA

**#3. How will you document permission for the PHI?**

❑Obtain a waiver of authorization

❑Obtain individual authorization from participants

## The Gray Zone



Analyze Case Studies

Thank you!

## Resources

- **OHRP Decision charts:** http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html
- **OHRP Engagement of Institutions:** http://www.hhs.gov/ohrp/policy/engage08.html
- **FDA Guidance on INDs:** http://www.fda.gov/downloads/Drugs/Guidances/UCM229175.pdf
- **UC Davis article on INDs:** http://www.ucdmc.ucdavis.edu/clinicaltrials/ind/ind_documents/journalofinvestigativemedicineaugust2009.pdf
- **FDA Guidance on IDEs:** http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279107.pdf
- **Article on sponsor-investigator IDEs:** http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3448842/
- **HIPAA Guidance:** http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/index.html