ITHS
Institute of Translational Health Sciences

Forecasting Regulatory Requirements

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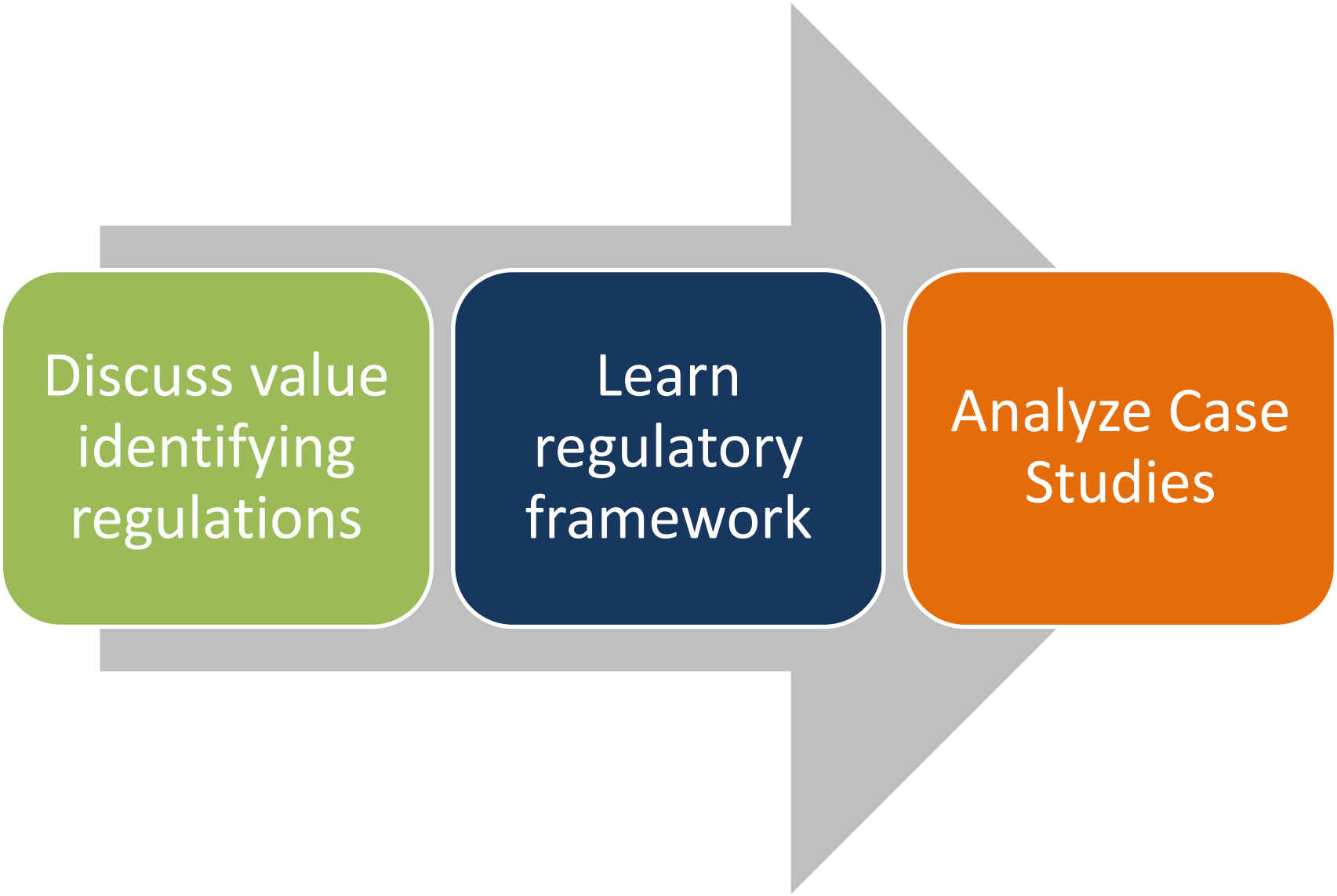
+ Human Subjects Research

Session Goals


Discuss value identifying regulations
Learn regulatory framework
Analyze Case Studies

Why Identify Regulations?

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

Department of Education

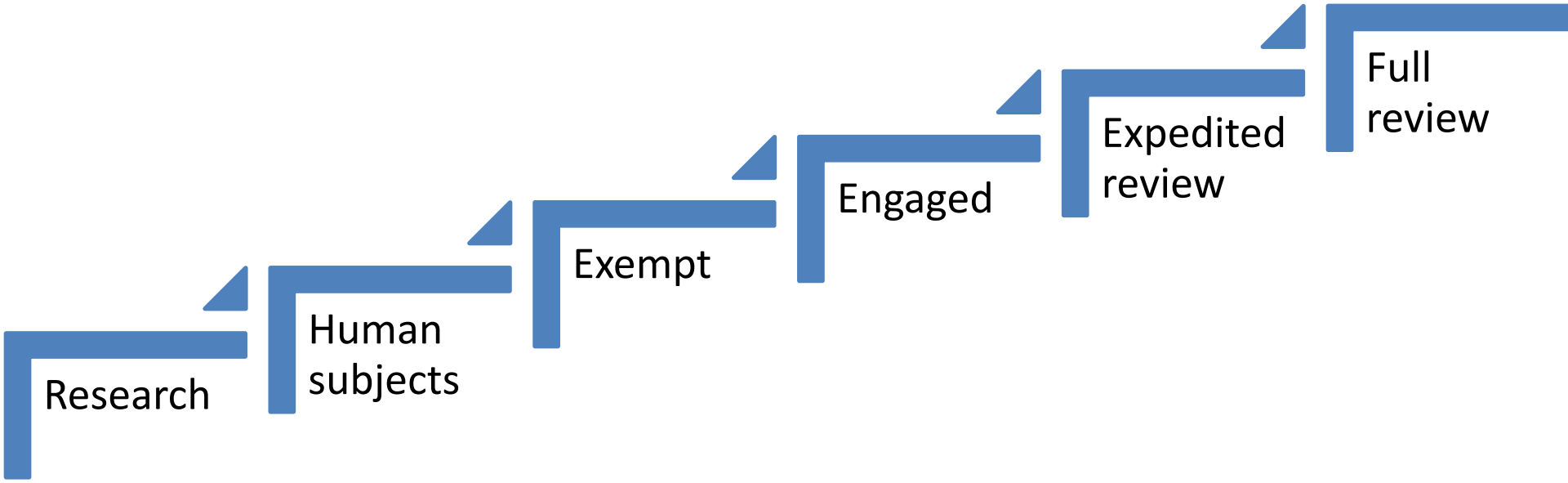
United States Department of Education

Washington State Legislature

Review Framework—OHRP

OHRP regulations at 45 CFR 46

#1. Level of IRB approval required?



Review Framework—OHRP

#2. Federally protected populations?

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

Review Framework—OHRP

#3. How will you document consent?

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

Review Framework—FDA

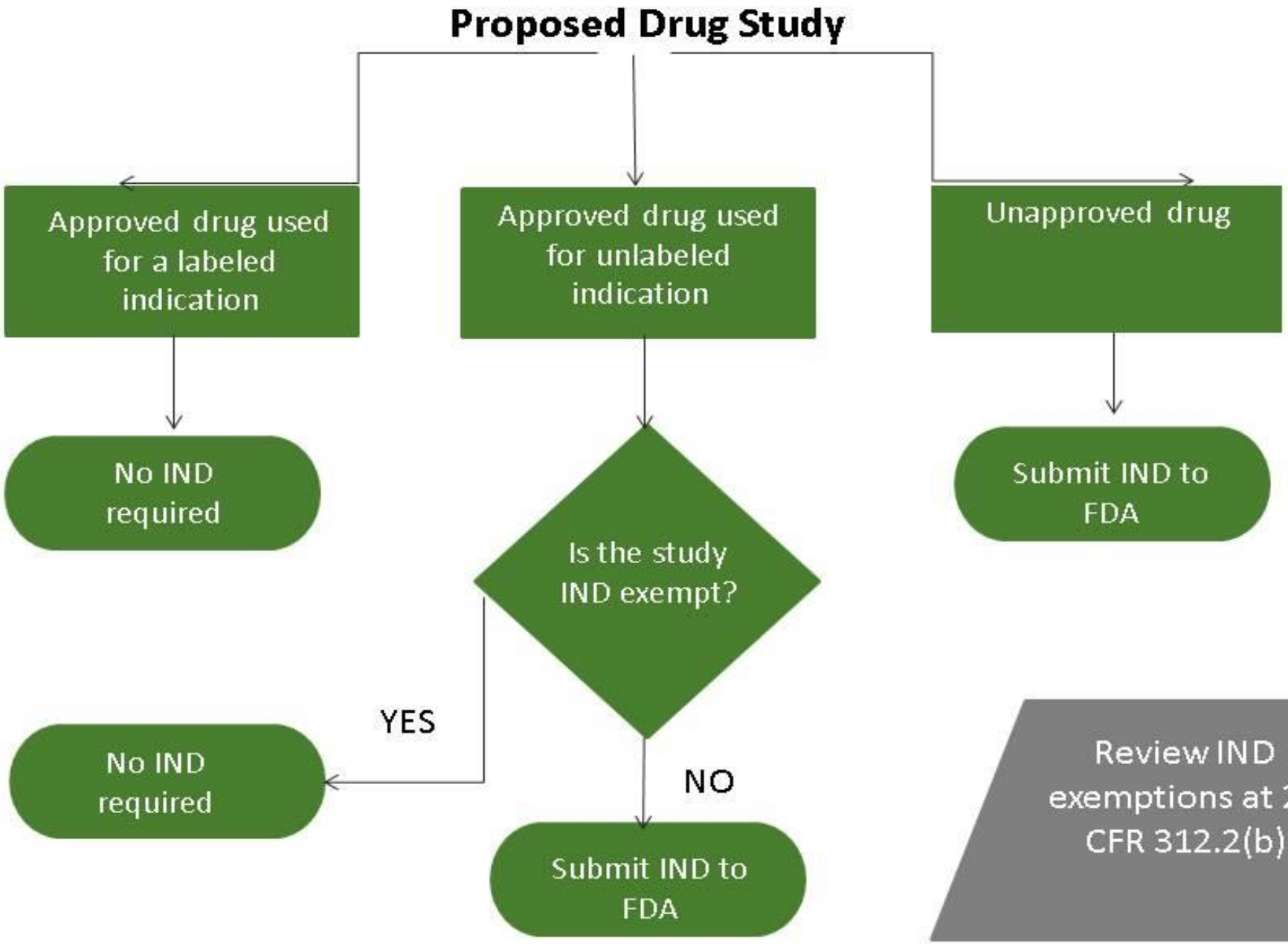
#1. FDA definition of clinical investigation?

Clinical Investigation/Human Subjects research?

Review Framework—FDA

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

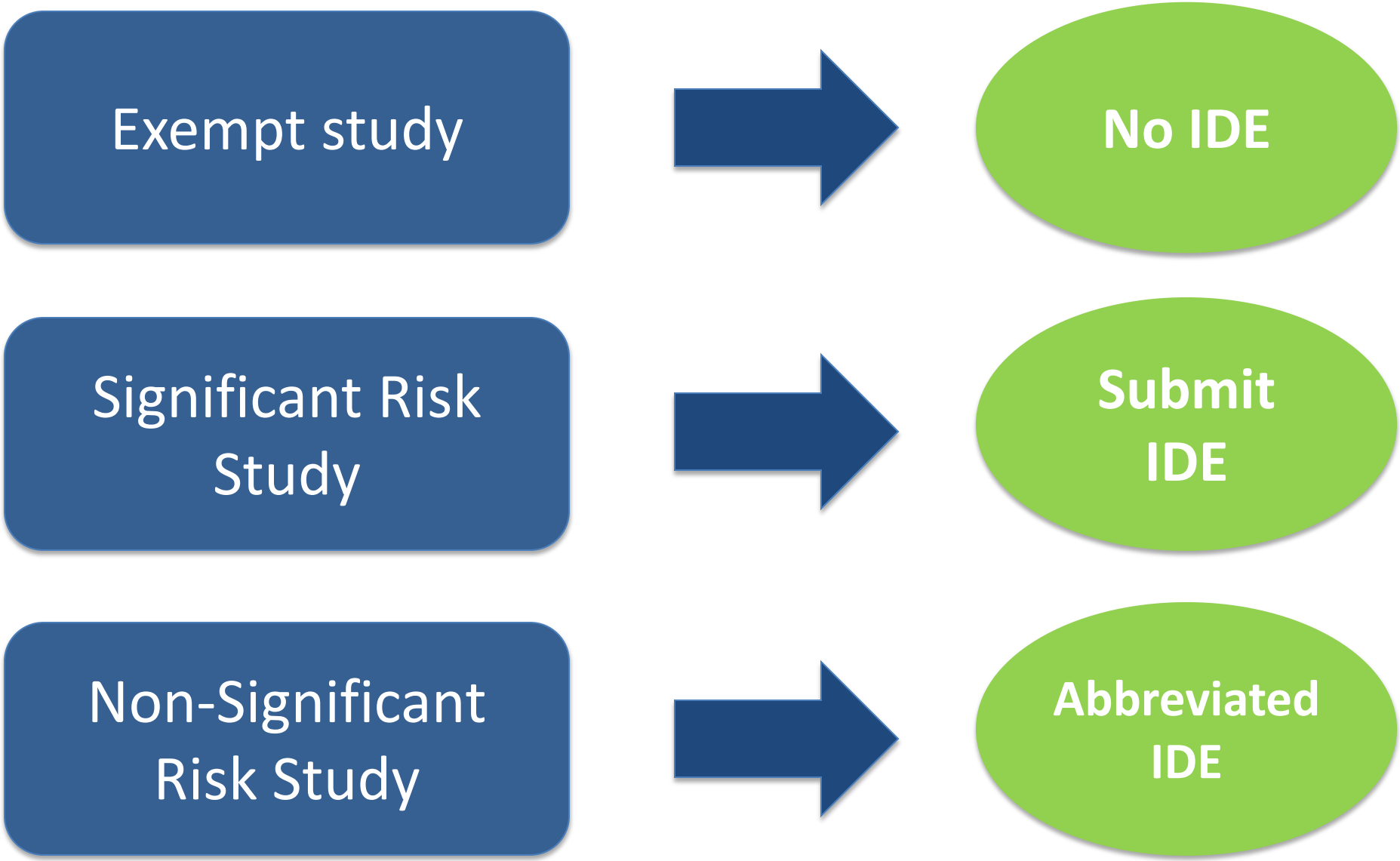
Does an Investigator-Initiated Drug Study Require an IND?



Review Framework—FDA

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

Review Framework—FDA



Review Framework—HIPAA

HIPAA Privacy Rule at 45 CFR 164

#1. Does the study involve PHI?

Review Framework—HIPAA

#2. 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 PHI?

- ❑ Obtain a waiver of authorization
- ❑ Obtain individual authorization from participants

The Gray Zone

Sample Case Study

OHRP

Level of IRB Review

Research ✓

Human subjects ✓

Non-exempt ✓

Institution is engaged in HS research ✓

Study qualifies for expedited review under category 7. ✓

OHRP

Vulnerable populations

Pregnant women, fetuses, or neonates? 

Prisoners 

Children 

OHRP

Document consent

Written documentation of consent 

Waiver of elements of consent 

Waiver of written documentation of consent 

Waiver of consent 

Special consent considerations 

FDA

FDA defined clinical investigation? 

HIPAA Privacy Rule

Obtain, access, or use PHI? 

Limited data set? 

Document permission for the PHI?

HIPAA Authorization form for data collection 

Waiver of HIPAA Authorization for pre-screening 

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
- **ITHS Regulatory tool:** https://redcap.iths.org/surveys/?s=ALYEJEXXYP

YOUR TURN
Analyze Case Studies

Thank you!