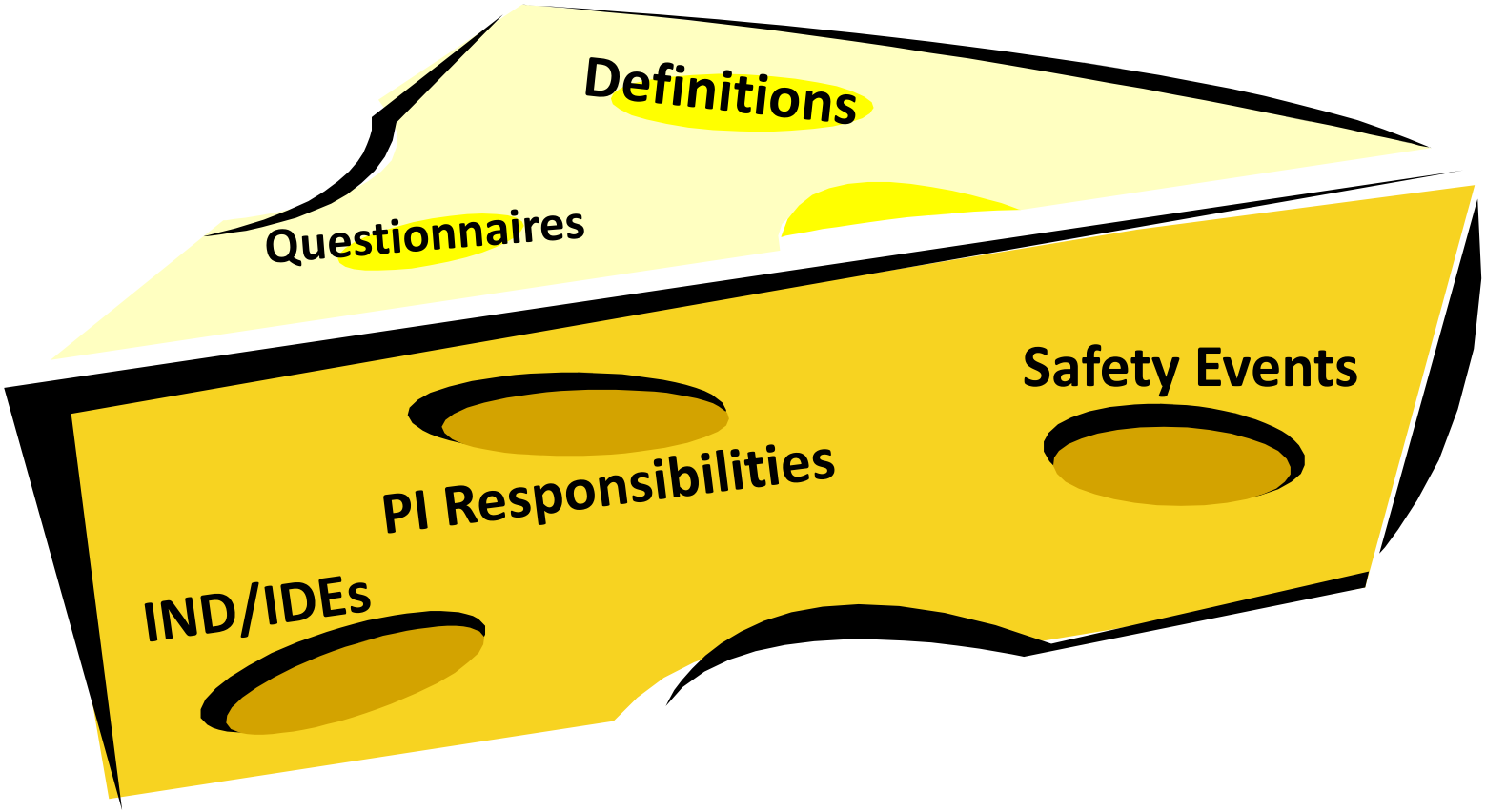
IRB 101 Basics
IRB Meeting Education Topic
March 2020

Basics Refresher—just in case…..



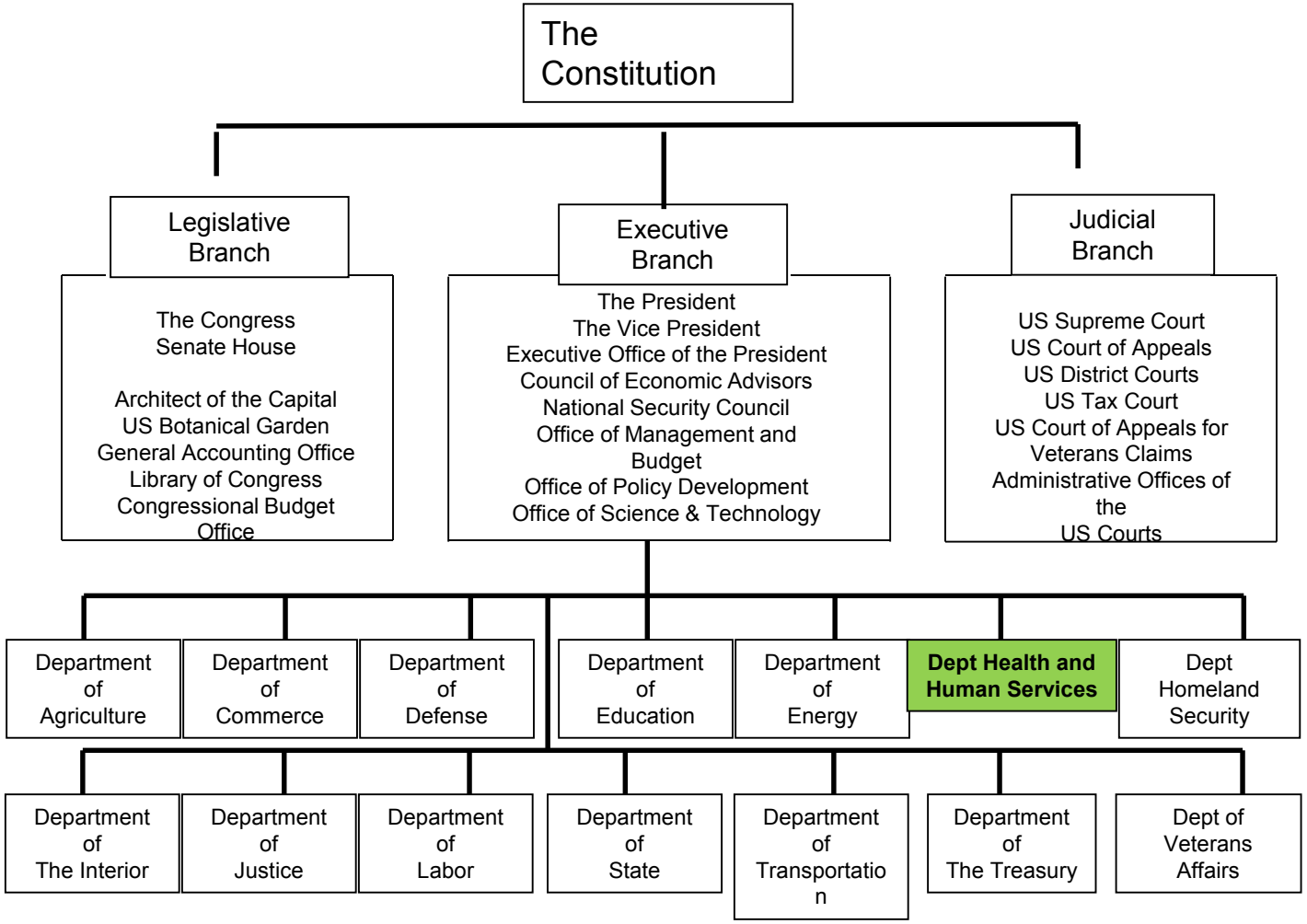
What is an IRB?
(Institutional Review Board)

- A committee **mandated by federal regulations**.
  - If Federal **$$** accepted, then IRB is part of the package if doing human subject research. **NO** choice.

No IRB = ~~$$~~

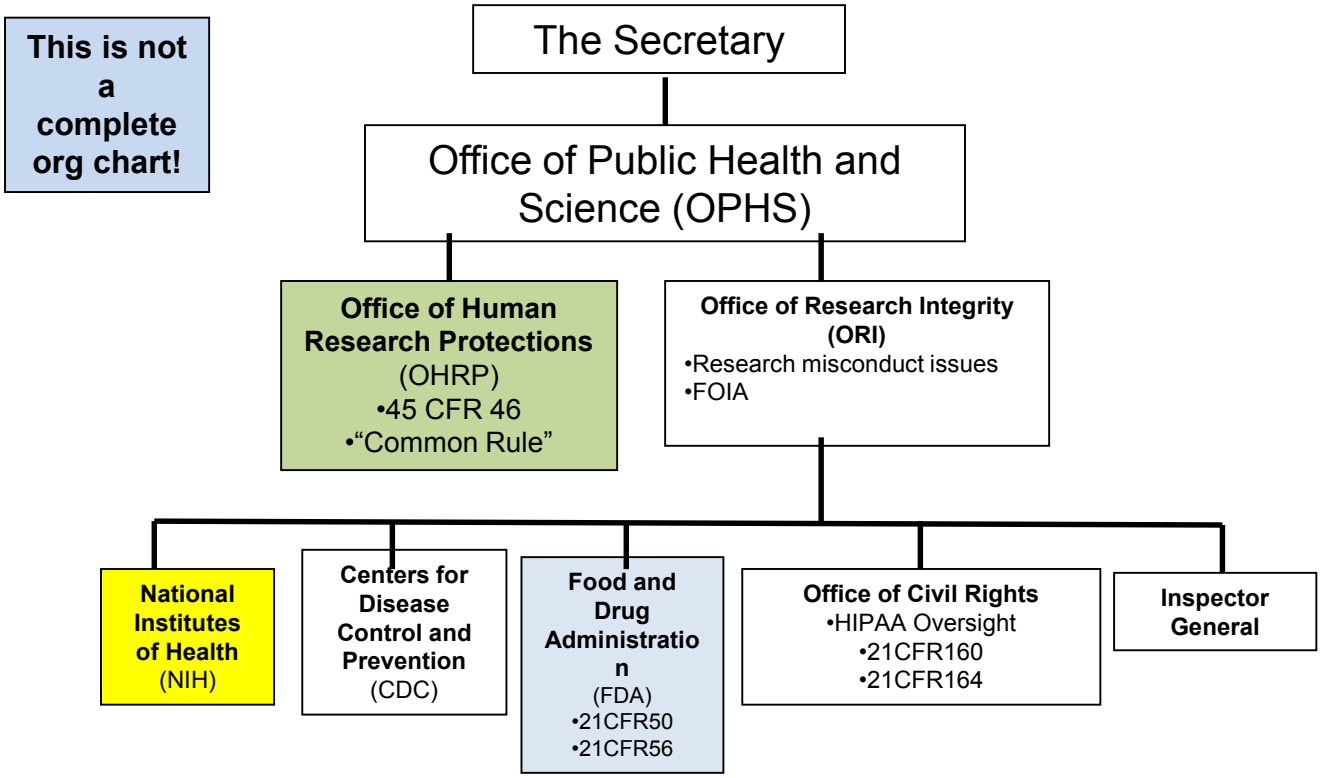
- ***Protects the rights and welfare of human subjects*** in research activities through independent review of proposed research.

Where do the regulations come from?
The Government of the United States



Slide courtesy of Susie Hoffman, UVa

Department of Health & Human Services (DHHS)



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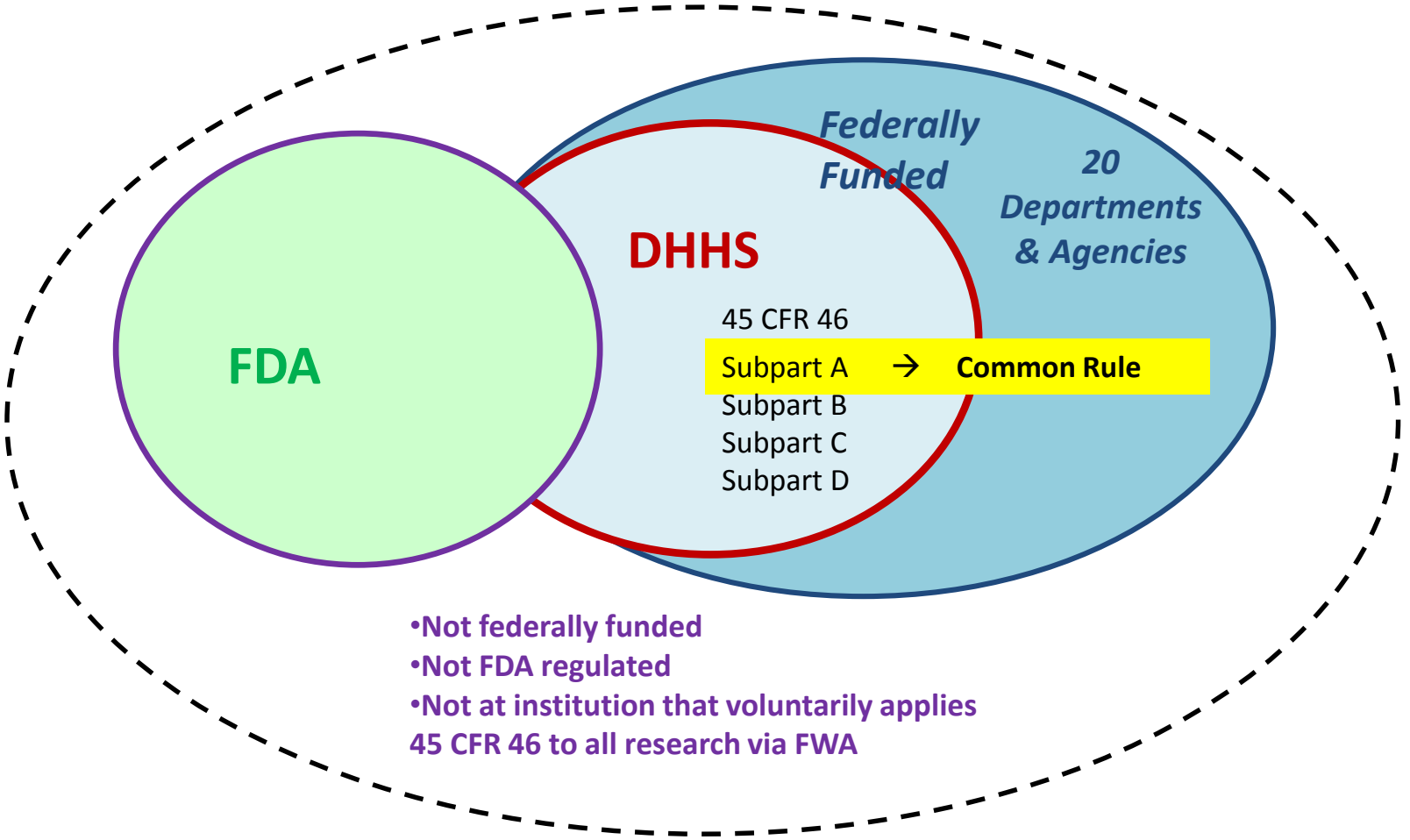
Belmont Report

- Respect for persons:
  - Individual autonomy
  - Protection of individuals with reduced autonomy
- Beneficence:
  - Maximize benefits & minimize harms
- Justice:
  - Equitable distribution of research costs & benefits

Current Regulatory Structure Creates a "Patchwork Quilt" of Protections



Protected Health Information - "PHI"

18 HIPAA Identifiers

1. Name
2. Address (Street, City, Zip except for 1st 3 digits)
1. Dates (all elements directly related to individual; all ages >89)
1. Telephone number
2. FAX number
3. E-mail address
4. Social Security Number
5. Medical Record Number
6. Health Plan Beneficiary Numbers

10. Account Numbers
11. Vehicle identifiers (e.g., serial numbers and license plate numbers)
12. device identifiers and serial numbers
13. URL addresses
14. Biometric identifiers (e.g., finger or voice prints)
15. Full face photographs or comparable images
16. Internet Protocol address numbers
17. Any other unique identifiers
18. Certificate or Professional License Numbers

Bad Behaviors lead to Regulations

- Regulations created after a problem exists
- Rare that laws, regulations, etc. created proactively
- Result:


APRIL 22, 2002
Powell's Mission Impossible
TIME
HOW MEDICAL TESTING HAS TURNED MILLIONS OF US INTO ...
HUMAN GUINEA PIGS
www.time.com AOL Keyword: TIME

The IRBs **ONLY** Job is….

To protect research subjects & minimize study risks.

The IRB functions on the honor system,

Trust but verify!

UNC IRB Review Responsibilities

- Clinical Research
- Social/Behavioral Research
- Safety & Non-Compliance Concerns

Levels of IRB Review

RISK Level

- **FULL COMMITTEE REVIEW** – All studies which do not qualify as exempt or expedited must be reviewed by a full IRB.
- **EXPEDITED REVIEW** – Applies to specific categories of research with no more than minimal risk.
- **EXEMPT** – Applies to specific categories of research, most often with extremely low risk or anonymous data

Note: ***The level of review is determined by IRB, not by the investigator or by the client. The requirements for each level are given in the regulations.***

Risk/Benefit Ratio

"Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."

Institutional Review Board Guidebook, 1993

Types of Risk *per 45 CFR 46.101.b.2.I & ii*

- **Physical** (e.g. pain, drug side effects, or injury)
- **Psychological** (e.g. emotional distress)
- **Social** (e.g. stigmatization)
- **Economic** (e.g. loss of job—breach of confidentiality that relates to stigma, or workplace competency issues)
- **Legal** (requirements to report some illegal activities, whether the focus of the study, or which emerge without prompting)

Clinical Research

1st regs written for this type of research

Clinical Research

- Challenges
  - Not clinical care, What color is the lab coat?
  - Much governed by FDA regulations for drugs or devices
  - Planned emergency research
  - Health research is a foreign language for most subjects, especially when in a crisis

Some studies are also covered by FDA regulations

- Drugs (including nutritional supplements)
- Devices (*including mobile apps, software,* etc.)
- Biologics
- FDA regulations differ from 45 CFR 46 in areas of reporting of adverse events, informed consent waivers, and confidentiality.

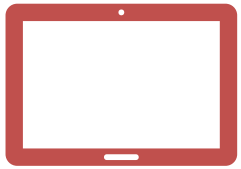
Request IND/IDE From FDA

Investigational New Drug (IND)

Brand new drug or

Off label use of an old drug or

Change in dosing &/or manner of dosing



Investigational Device Exemption (IDE)

New device or

New use of an existing device or

Modification of an existing device

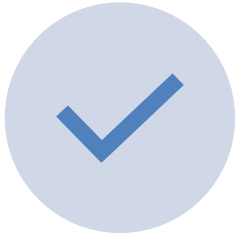
How Does an Idea become a New Drug?

BEGINS WITH A SCIENTIST WHO HAS AN IDEA,

THEN TESTED ON ANIMALS, FROM THERE TO 1ST IN HUMAN STUDIES…

PHASE I (A/B) LOOKING FOR SAFE DOSE, TOLERABILITY, SMALL # OF SUBJECTS

PHASE 2 (A/B) NOW LOOKING FOR DOSE FREQUENCY, SIDE EFFECTS



PHASE 3 LARGER TRIAL, OFTEN MULTI-SITE STUDIES

PHASE 4 POST-APPROVAL SAFETY/EFFECTIVENESS/MARKETING/QUALITY OF LIFE STUDIES

Understanding Clinical Trials
https://www.youtube.com/watch?v=bctaWQTYHJc

Next Step the FDA

The results of all these studies are compiled and submitted to the Food & Drug Administration (FDA) in an application for the approval of a new drug or device and permission to sell it.

Social/Behavioral Research

- Types of studies
  - Interviews, surveys, questionnaires, epidemiology
  - Observational, focus groups,
  - use of mobile devices, apps
- Challenges
  - Subject reactions, prepared to address?
  - Privacy/Confidentiality
  - Are study locations safe?
  - Voting behavior, manipulation, deception
  - Does it cross over into clinical arena?

Revised Common Rule: Activities NOT Considered Research

1. Scholarly & journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research & historical scholarship), including the collection & use of information, that focus directly on the specific individuals about whom the information is collected.

Revised Common Rule: Activities NOT Considered Research

2. Public health surveillance activities, including the collection & testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in disease, or increases in injuries from using consumer products). Such activities include those associated with timely situational awareness & priority setting during the course of an event or crisis that threatens public health (including natural or manmade disasters).

Golden Rule of Consenting

- Everything I need to know I learned in kindergarten or Etiquette class or
- From the Belmont Report and
- If it is not written, it did not happen rule

Additional Considerations

- Who administers consent & where is it done?
- Are they trained?
- What is the back-up?
- Resources when the subjects have questions
- Resources for staff associated with the subject's care when they have to field questions?

Additional Considerations

- On-going &/or periodic communication
- Newsletters, website, letters,
- How are study results shared?

Review of Research Submissions

- Read the consent first,
- Check the protocol
- Check the Investigational Brochure (IB)
- Check inclusion/exclusion criteria
- Any surprises that are missing from the consent?
- Gut check

IRB Member Responsibilities

1. Your mandate is to protect those who volunteer to be research subjects.
   - They are your only priority as an IRB member.
   - This is done by balancing the study risks against potential benefits; remember Beneficence.
2. Recuse yourself if you have a conflict of interest
3. Be prepared
   - Read & review all protocol submissions on the agenda
   - Prepare and upload your Primary or Secondary Review **PRIOR** to the meeting
4. Make a succinct, organized presentation to the IRB Meeting Members.
   - Use the guides for preparing an oral presentation or create your own guide & upload into IRBIS.
5. Allow for other perspectives and viewpoints. Dissention is OK, even encouraged.


At last! An Ethics Committee that will listen to reason..!