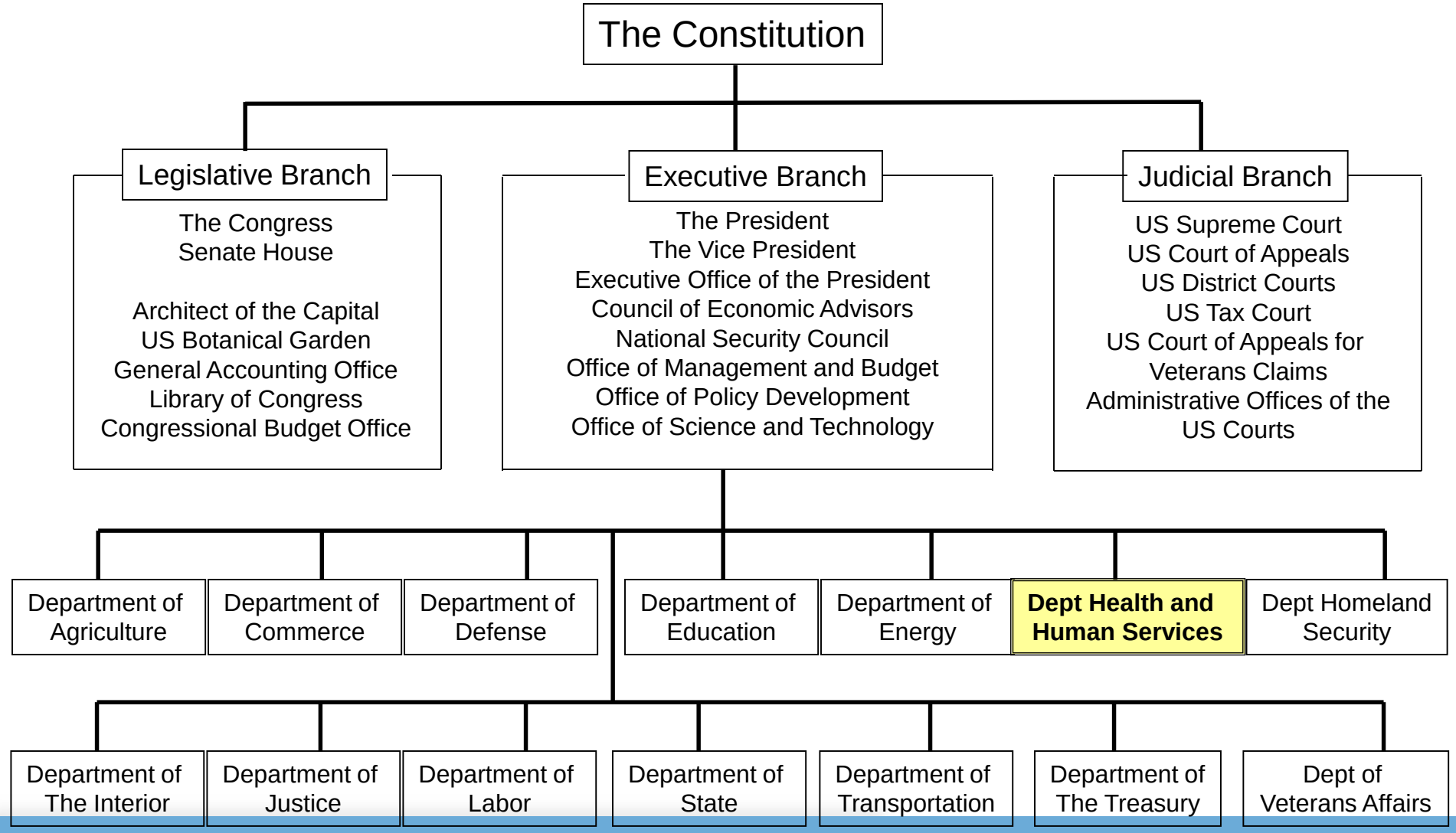
New IRB Member Orientation

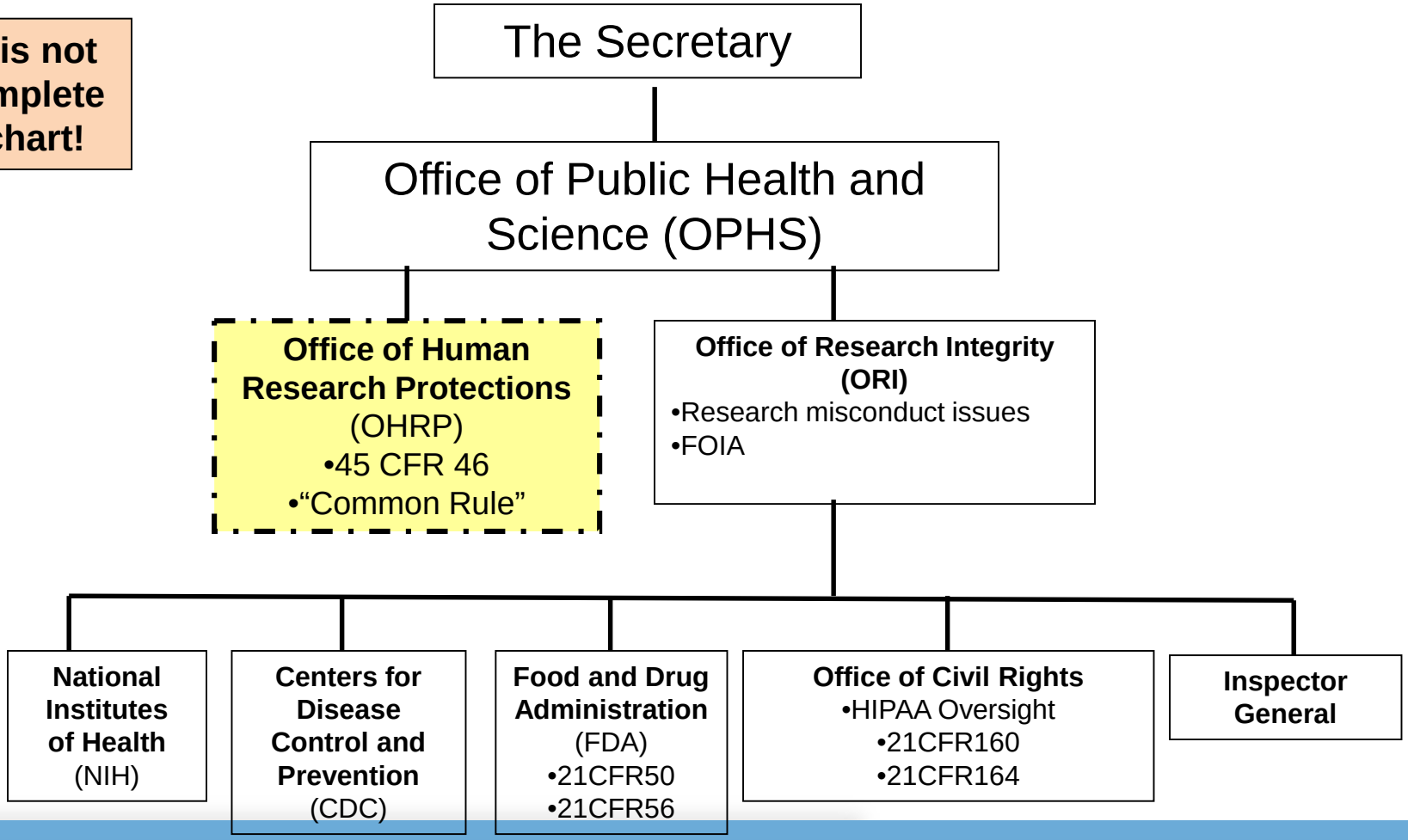
Part III: IRB Regulatory Requirements

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



Department of Health & Human Services

This is not a complete org chart!



Regulatory Requirements

Regulatory Requirements

HHS, NIH regulations: 1974, last update June 23, 2005
http://www.hhs.gov/ohrp/humansubjects/index.html

FDA: 21 CFR 50 & 56
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

Common Rule: 1991—adoption of HHS regulations by 15 Federal Agencies

Office for Human Research Protections (OHRP) moved from NIH to Office of the Secretary of HHS July 2001
http://www.hhs.gov/ohrp/humansubjects/index.html

Code of Federal Regulations: 45 CFR 46

Issued in 1981 by the Dept of Health, Education, and Welfare (DHEW)

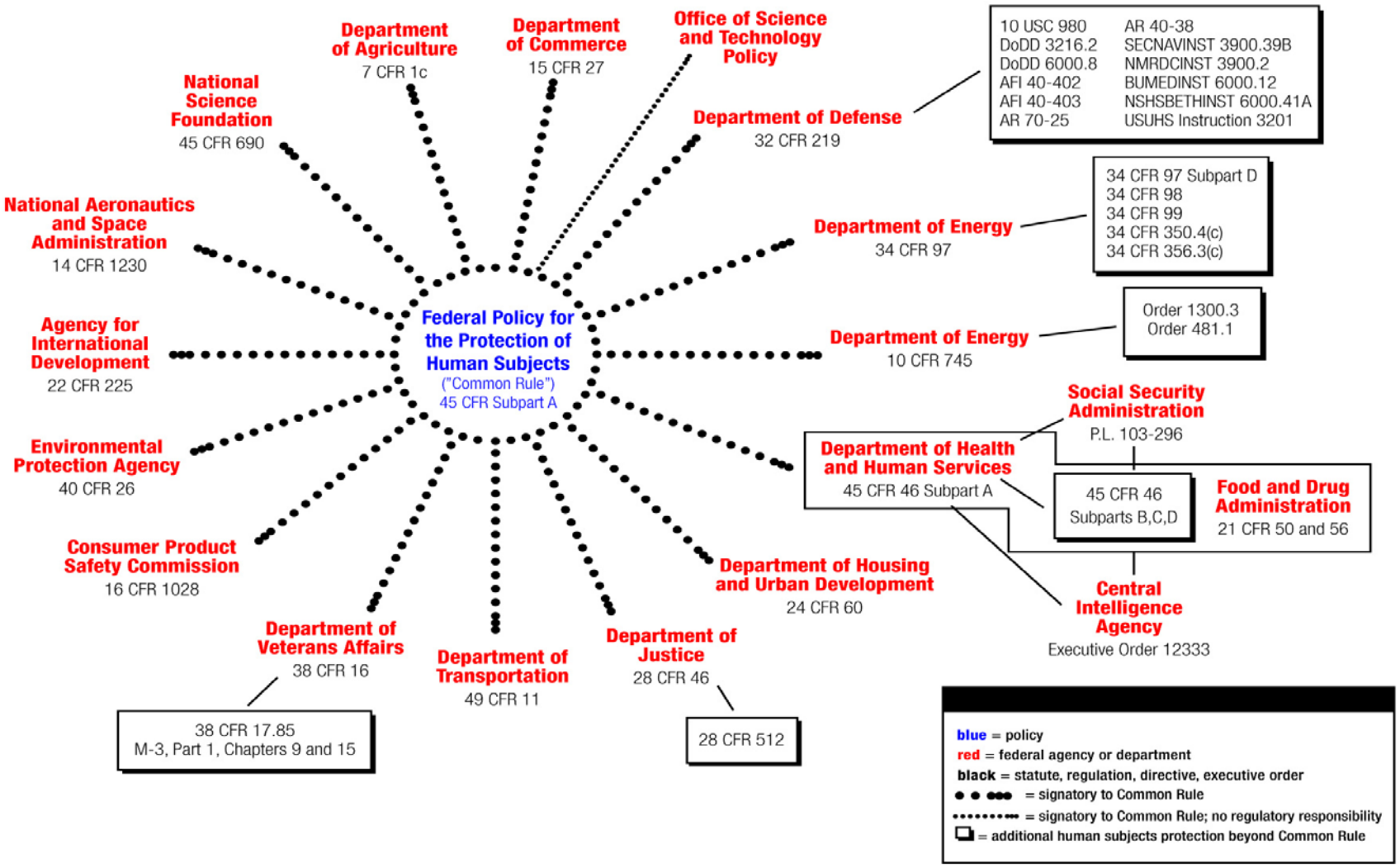
- ✓ Covers all aspects of human subjects protection, including level of review needed, IRB composition, informed consent requirements, and added protections for special populations
- ✓ In 1991, 16 other Federal agencies agreed to abide by these regulations for their human research studies → subsequently became known as the "Common Rule"

Code of Federal Regulations: 45 CFR 46

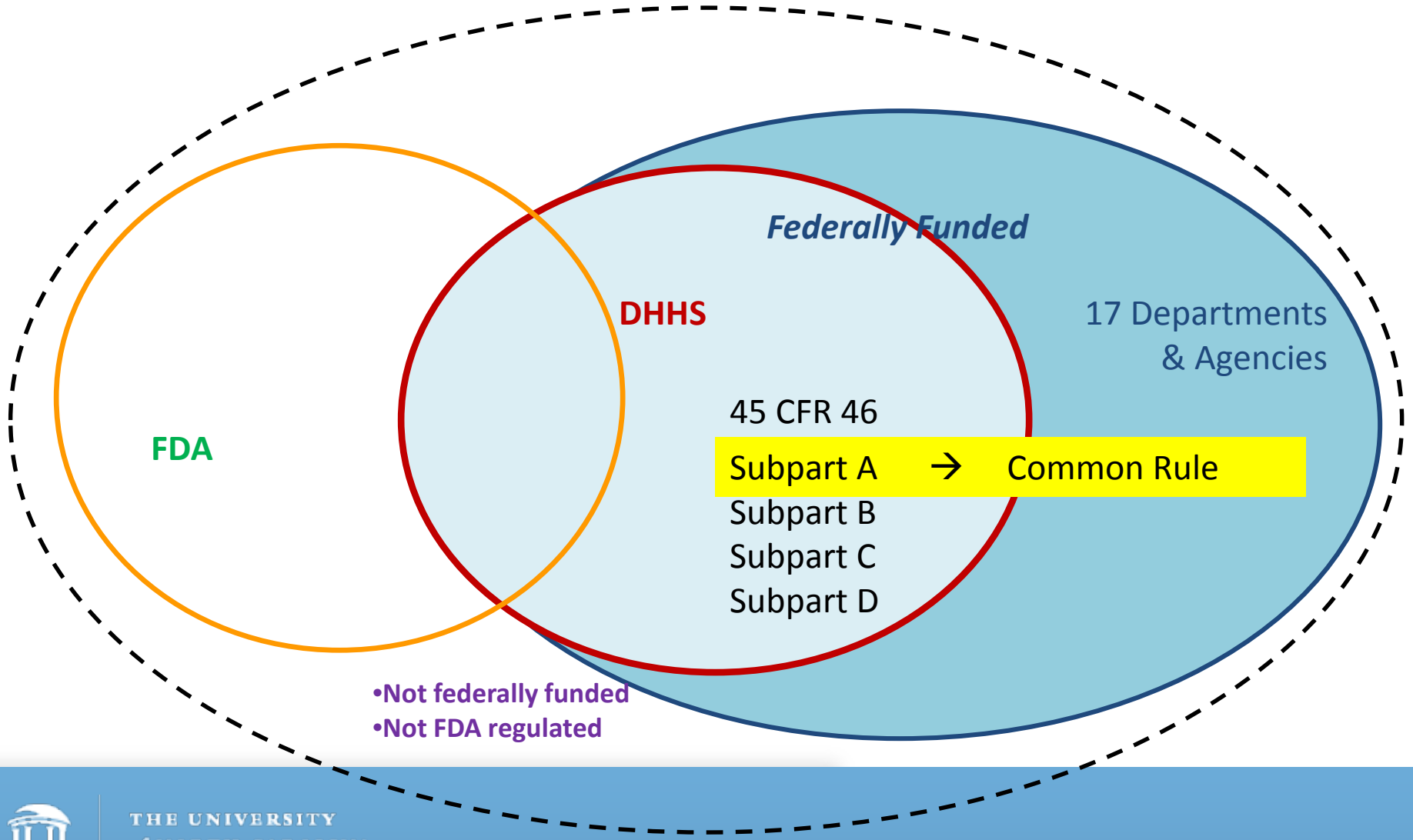
Subpart A applies to all research. Subparts B, C, and D cover selected special populations

- ✓ **Subpart A**: Basic Regulations
- ✓ **Subpart B**: Pregnant Women, Human Fetuses, and Neonates
- ✓ **Subpart C**: Prisoners
- ✓ **Subpart D**: Children
- ✓ Diminished Capacity: Subpart coming

Current Federal Regulatory Structure



Current Regulatory Structure Creates a "Patchwork Quilt" of Protections



Office for Human Research Protections (OHRP)

Responsible for monitoring compliance with 45 CFR 46 Regulations

- ✓ Formerly the Office for Protection from Research Risks (OPRR), name changed to OHRP in 2000 following shutdown of several major programs and moved into the Secretary's Office from NIH
- ✓ Located within the Office of the Secretary, Department of Health and Human Services (DHHS), reports directly to the Secretary of Health -- increased visibility over OPRR
- ✓ Issues assurances to institutions to allow them to conduct human subjects research

Definitions

- Research: a systematic investigation designed to develop or contribute to generalizable knowledge
- Human subject: a (*living*)* individual about whom an investigator conducting research obtains:
  - Data through intervention or interaction with the individual,

    or

  - Identifiable private information

* HIPAA (Health Insurance Portability & Accountability Act of 1996) Change

Definitions (continued)

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

45 CFR 46.102(f)

FDA Definition

- 21 CFR 56.102 (c)
  - Research involving a drug, device or biologic and all research involving data that will be submitted to or held for inspection by the FDA

45 CFR 46.101.b.2.I & ii

ii any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation."

Types of Review

1. Review by Convened Board

2. Expedited Review by a Chair or designee

3. Exempt Review by a Chair or designee

Levels of IRB Review

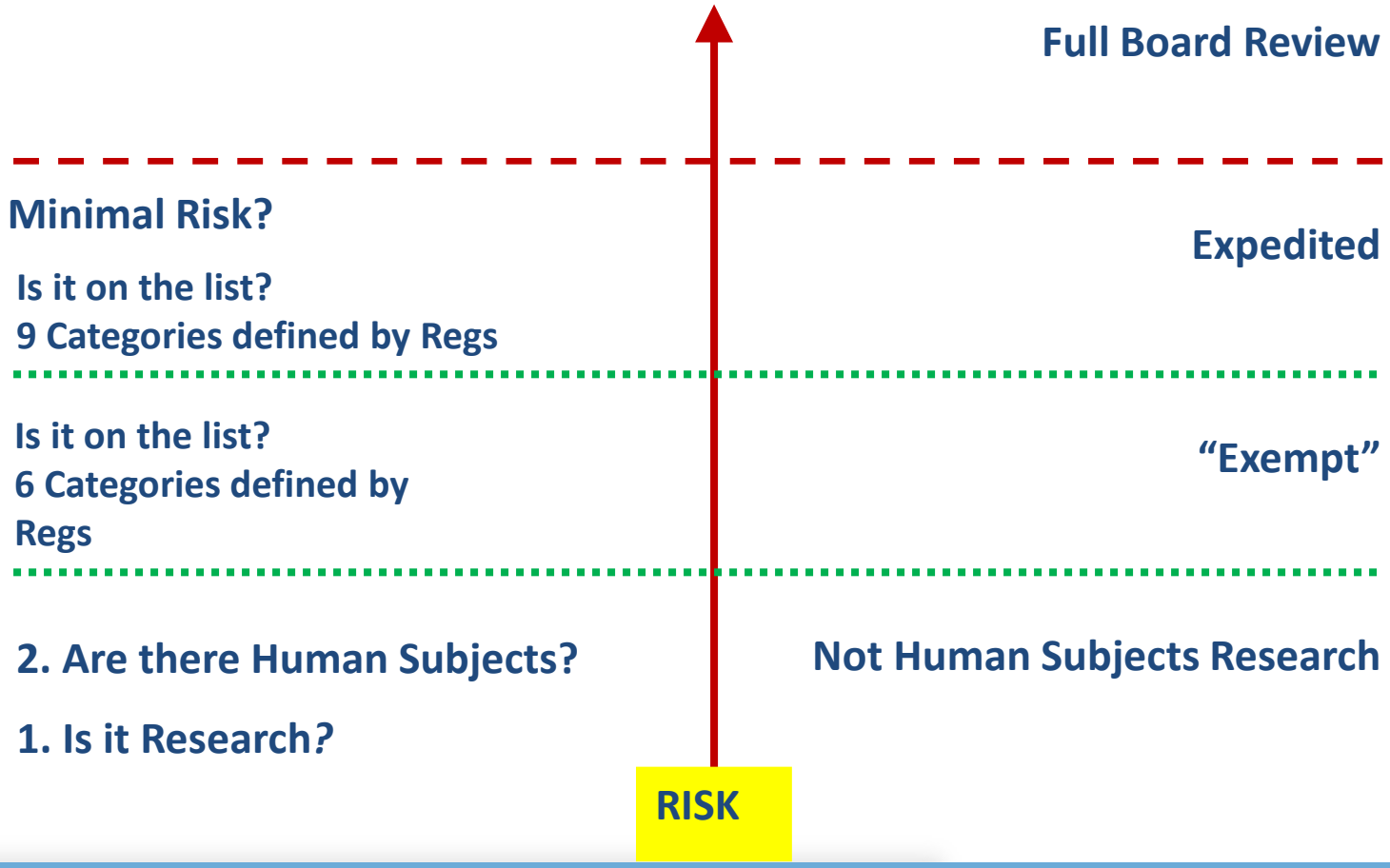
- **EXEMPT** – Applies to specific categories of research, most often with extremely low risk or anonymous data

- **EXPEDITED REVIEW** – Applies to specific categories of research with no more than minimal risk.

- **FULL COMMITTEE REVIEW** – All studies which do not qualify as exempt or expedited must be reviewed by a full IRB.

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.***

Level of Risk Generally Determines Level of IRB Review



Criteria for IRB Approval

45 CFR 46.111 & 21 CFR 56.111

OHRE SOP 24.0

1. Risks minimized
2. Favorable risk : benefit ratio
3. Equitable selection of subjects
4. Informed consent sought
5. Informed consent documented
6. Monitoring plan for safety
7. Privacy and confidentiality protected
8. Additional safeguards for vulnerable populations

Elements of an IRB Submission

1. Protocol Summary
2. Purpose of the Study
3. Design & Procedures
4. Risk/Benefit Assessment
5. Subject identification, recruitment & Compensation

Elements of an IRB Submission

6. Subject competency

7. Costs to the Subject

8 Data analysis & monitoring

9. Data Storage & confidentiality

IRB Approval is limited to …

An IRB Approved Protocol--
Good for 1 year max!

- Valid for *no more than 1 year* and not 5 seconds longer,
- Authorized to do ONLY what is in the protocol as approved by the IRB,
- ALL changes MUST be submitted to the IRB for review and approval **PRIOR** to implementation of the change(s)