

# The Institutional Review Board

# What is an IRB?

- An IRB is committee set up by an institution to review, approve, and regulate research conducted under its jurisdiction.
- The National Research Act of 1974 directed all institutions receiving federal support research to establish IRBs.

# Purpose of the IRB

- To protect the rights of human subjects in research
- To ensure human subjects are informed of their rights as participants and understand the consequences of the research
- The IRB is not charged with evaluating or modifying the science of a research project beyond protecting the rights of human subjects

# Who are the members?

- UMKC faculty and staff (scientists and non-scientists) from various academic disciplines (11 schools or departments represented) and Truman Medical Center (legal and medical) employees.
- Three individuals not affiliated with UMKC who represents the concerns of the community and vulnerable populations

# Legal structure

- IRBs are governed by - OHRP (Code of Federal Regulations Title 45, Part 46) and FDA (21 CFR 50 & 56)
  - This covers **all** institutions receiving funding from or operating on behalf of the Federal government
  - In practice, **all** research involving human subjects is reviewed by the IRB, whether it is federally funded or not

# Governing Principles

- The IRB's authority is founded in and guided by many sources, including regulatory statutes, institutional policies, ethical canons, and members' own perceptions of community and professional standards.

# Types of IRB Review

Exempt	Expedited	Full Board	Does not need IRB Review
Research on two different teaching strategies	Research where disclosure of the participant's identity might result in negative legal, financial, economic or social consequences	Research that might put participants at risk, such as research on domestic violence or illegal drug use	Activities with no hypothesis-driven methodologies and no research protocol
Analyzing census data about aging or housing	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds.	Research using sensitive information (e.g., information that reasonable persons would not want disclosed)	Course-related activities designed specifically for educational or teaching purposes,
Data that comes from sources that are publicly available	Research that involves combining de identified data sets in a way that may make some data individually identifiable.	Research studies on human subjects that involve greater than minimal risk	Literature review addresses previous research in a field and supports the researcher's purpose or research question
Observing adult and child interactions at a sports game	Interviews or surveys on sensitive topics where the subject can be identified		Surveys issued or completed by University personnel for the intent and purposes of improving services and programs
Surveys or interviews of non-vulnerable adults about non-sensitive topics	Linguistic and ethnographic studies, or studies involving focus groups		
	Almost all research involving minors		
	Studies of existing data or pathological specimens that include identifying information		
	Analyses of data collected via recordings		

# Criteria for IRB Approval

- (1) Risks to subjects are minimized
- (2) Risks to subjects are reasonable in relation to anticipated
- (3) Selection of subjects is equitable.
- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [§46.116](#).
- (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by [§46.117](#).
- (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.



# Consequences of IRB failures

## Universities and Hospitals shut down by FDA and/or OHRP

- Mar 1999 West Los Angeles Veterans Administration Medical Center
- May 1999 Duke University Medical Center
- Aug 1999 University of Illinois
- Sep 1999 University of Colorado
- Sep 1999 University of Pennsylvania
- Jan 2000 Virginia Commonwealth University
- Jan 2000 University of Alabama at Birmingham
- Jun 2000 University of Oklahoma – Tulsa
- Jun 2001 Johns Hopkins Medical University
- August 2008 – Indiana University voluntarily moves IRB reviews to Indianapolis campus

# Consequences of IRB failures

- Duke
  - Routine site visit in December, 1998 uncovered 22 administrative deficiencies (including inadequate documentation)
  - All NIH-funded activities were suspended until the deficiencies were addressed
- Texas Applied Biomedical Services
  - FDA audit in 2012 identified 5 significant violations resulting in the suspension of all ongoing trials

# Consequences of IRB failures

- University of Colorado – Denver
  - FDA and OHRP ordered the suspension of thousands of human research studies
  - According to the school, the cost to revamp research guidelines, strengthen its internal review board and hire consultants was \$3 million.

# eProtocol IRB Submission

- UMKC Research Compliance Office launched eProtocol in 2012, resulting in
  - A database of research submission records forever available to Investigators
    - Previous submissions, approval letters, consent forms, data collection tools
  - Improved IRB ability to respond
  - More efficient IRB administrative process

# IRB Submissions

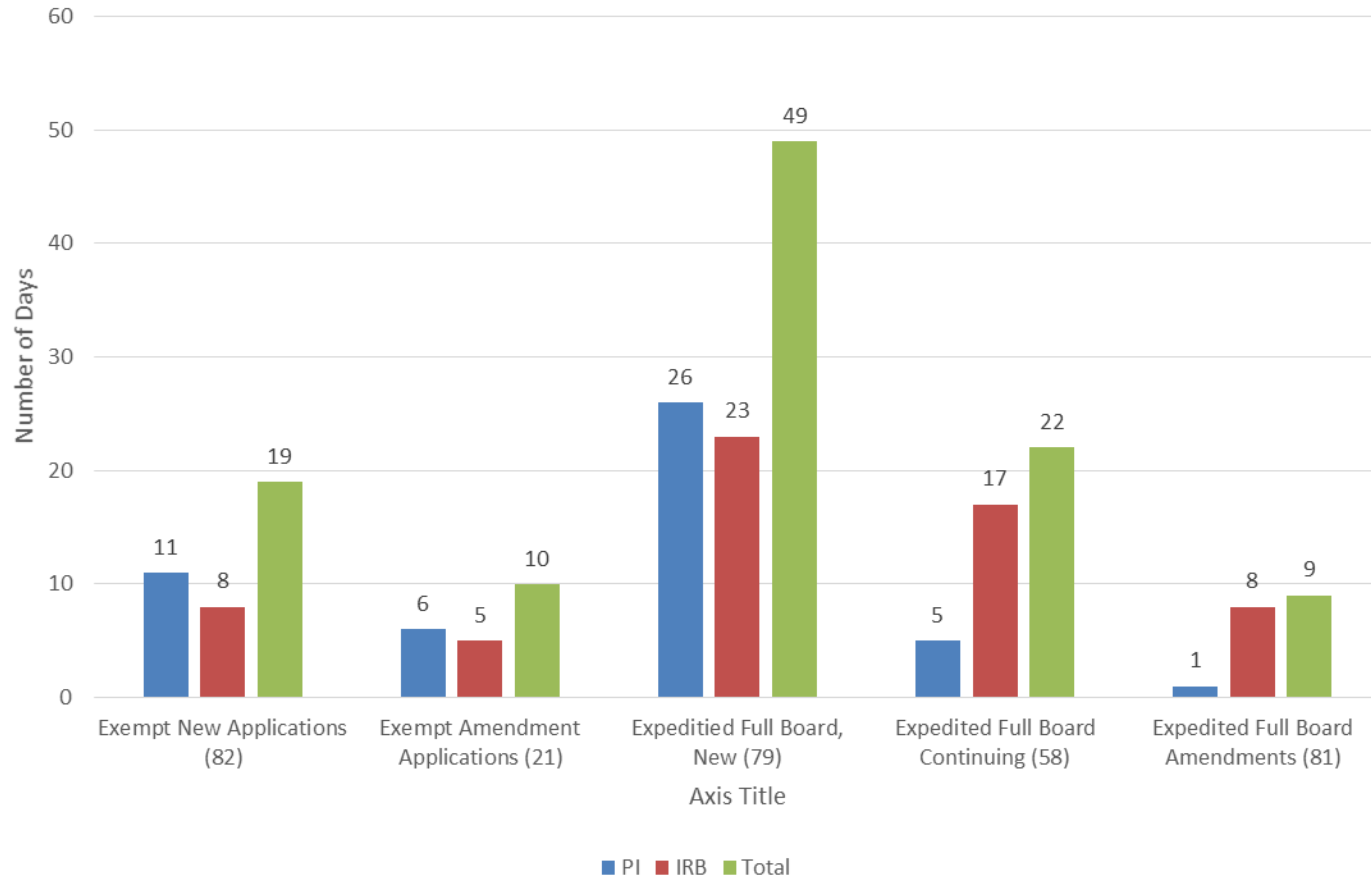
- 2009 - 286
- 2010 - 265
- 2011 - 303
- 2012 - 290
- 2013 - 297
- 2014 - 272 (as of 11/1/2014)

# IRB Turn Around Time

## All 3 types of review

- In 2011 the average review time was 55 Days
- In 2014 the average review time is 31 Days

# 2013



# 2014

