
To IRB, or Not to IRB...

PTS STAFF MEETING
OCTOBER 15, 2013

To be, or not to be: that is the question. - Hamlet

Who is the IRB?

- **Staff**
 - Jennifer McGaughey
 - Serrena Slaton
 - Sarah Marie Huban
- **Compliance**
 - Emily Smotherman
- **Members**
 - Scientists
 - Non Scientists
 - Community Representatives

Who is it that can tell me who I am? – King Lear

Where is the IRB?

Externally:

- Choa.org
- Pedsresearch.org

Internally:

- Careforce

Really:

- 1687 Tullie

O Romeo, Romeo! wherefore art thou Romeo? – Romeo and Juliet

What is the IRB?

- A committee charged with the review of human subject research to assure that the rights and welfare of human participants are adequately protected.
- IRB's are required to have a diverse mix of scientific, non-scientific, and community members.

In time we hate that which we often fear. – Antony and Cleopatra

Regulations and Ethical Principles

- DHHS
- FDA
- OHRP
- Nuremberg Code
- Belmont Report

Let me be that I am and seek not to alter me. – Much Ado About Nothing

Nuremberg Code

Set of research ethics principles for human experimentation as a result of Nuremberg Trials.

- Voluntary Consent is Essential
- Yield Fruitful Results
- Designed and Based on Animal Experiments and Knowledge
- Avoid Unnecessary Physical and Mental Suffering and Injury
- No experiments where there is reason to believe death or disabling injury will occur
- Degree of risk should not exceed humanitarian importance
- Preparations and adequate facilities to protect subject against injury, disability or death
- Conducted by scientifically qualified persons
- Subject has the right to withdraw at any time
- Terminate the study at any stage if there is probable cause the experiment is likely to result in injury, disability or death

Belmont Report

Summarizes the basic ethical principles that should underlie the conduct of research.

Respect for Persons

- Informed Consent

Beneficence

- Risk Benefit Ratio

Justice

- Selection of Subjects

How do I know if my project needs IRB review?

- Is it research?
- Is it research with human subjects?

I am not bound to please thee with my answer. – The Merchant of Venice

Is it Research?

DHHS: Research is a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**

- A **systematic investigation** is a project that is planned in advance and that uses data collection and analysis to answer a question
- **Generalizable knowledge** is information that expands the knowledge base of a scientific discipline or other scholarly field of study.

FDA: Any experiment in which a drug, biologic, or significant risk device is administered or dispensed for use involving one or more human subjects

Though this be madness, yet there is method in't. – Hamlet

Is it Research?

Probably NOT research if:

- Designed and implemented for Children's purposes, and
- Is not designed to produce information that expands the knowledge base of a scientific discipline or other scholarly field.

Is it Research?

IS research if:

- Meets the definition of research
- Funded or supported as research
- Clinical investigations as defined under Food and Drug Administration (FDA) regulations.

Is it Research?

Common Research Project Design Characteristics:

- Double blinding, Placebo, Matched Pairs
- Assessment of a new intervention that is not standard of care
- Comparison of two or more interventions
- Collection of clinical information that is not medically necessary
- Interventions not designed for direct patient benefit

Is it Research with Human Subjects?

DHHS: Human subject means a living individual **about whom** an investigator conducting research obtains:

- (1) data through intervention or interaction, OR
- (2) identifiable private information

FDA: Recipient of a test article

Goats and Monkeys! - Othello

Is it Research with Human Subjects?

- ***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.

Non-Human Subjects Determination Form

What happens when a study gets to the IRB?

- Triaging
 - NHR
 - Exempt
 - Expedited
 - Full Board
- Pre-screening
 - Expedited
 - Full Board
- Review
- Re-review (if necessary)

There is nothing either good or bad, but thinking makes it so. - Hamlet

How long does it take?

Type of Review	Turnaround Time (days)
NHSR Determination	3
Exempt	3
Expedited	10
Full Board	30
<i>Wisely and slow; they stumble that run fast. – Romeo and Juliet</i>	

Contacting your IRB

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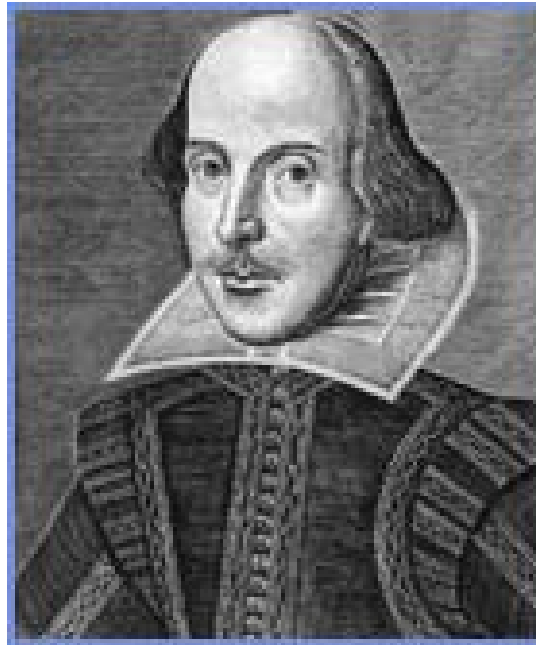
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*Though she be but little, she is fierce! – A
Midsummer Night's Dream*



QUESTIONS



Et tu, Brute? – Julius Caesar