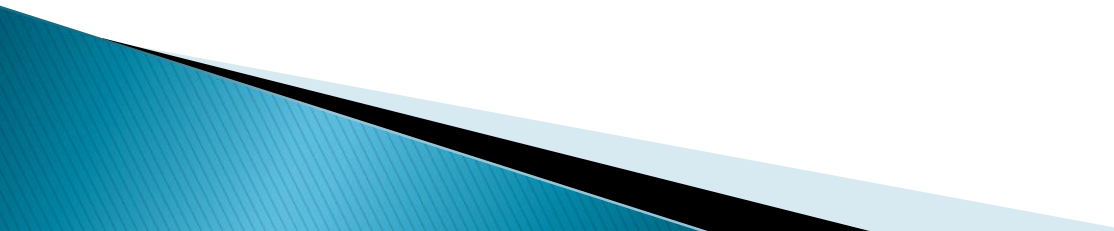


Andrews University
Human Subject Protection Program
Institutional Research Board (IRB)

Mordekai Ongo
Research Integrity & Compliance Officer



Session Goals

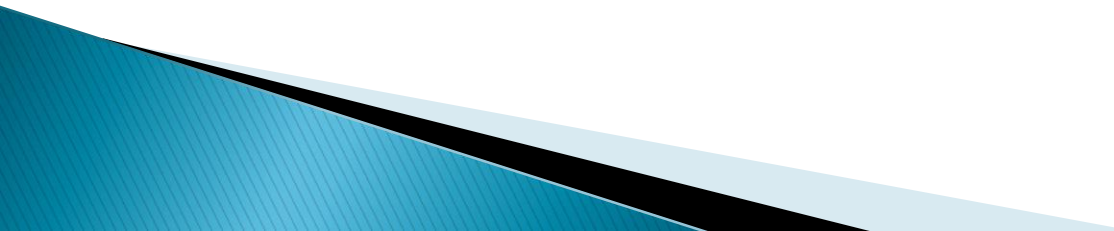
- ▶ Know the DHHS definition of Research.
 - ▶ Know the OHRP definition of human subject.
 - ▶ Know the documents to submit to IRB.
 - ▶ Understand the IRB process.
 - ▶ Know the areas that are frequently problematic in the application process.
- 

Research, Human Subjects, & IRB

IRB approval is **required** before you start your research. All research involving human subjects must be submitted to IRB

Federal regulations require that research projects involving human subjects be reviewed by an Institutional Review Board (IRB).

The IRB must review, approve or determine the project to be exempt prior to the start of any research activities. OR reject a study.

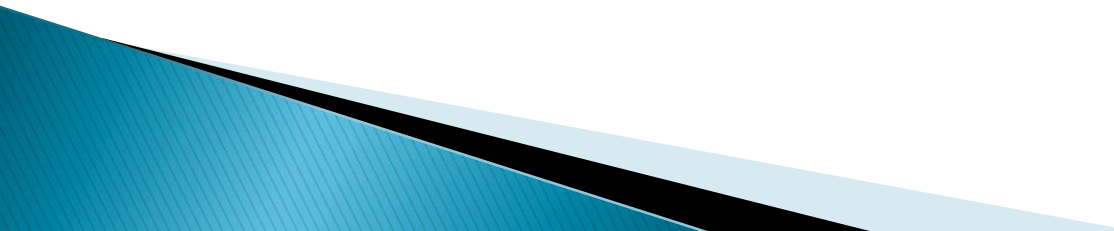


DHHS (OHRP Definition (Research))

Research – a (1) *systematic investigation*, including research development, testing and evaluation, (2) *designed to develop or contribute to generalizable knowledge*.

A 'systematic investigation' involves a plan which incorporates collection of data, either quantitative or qualitative, or specimens; and analysis to answer a question.

Activities '**designed to develop or contribute to generalizable knowledge**' are those activities designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations beyond the specific study population), inform policy, or generalize findings.



DHHS (OHRP Definition (Human Subject))

Human Subject – a *living individual about whom* an investigator (faculty, staff, or student) conducting research obtains (1) *data through intervention or interaction with the individual*, or (2) *identifiable private information*.

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Or designed to change/alter individual or group characteristics or behavior (i.e. bible reading habits, prayer habits after a seminar or workshop presentations, etc.)

Interaction includes communication or interpersonal contact between researcher and subject.

DHHS (OHRP Definition (Human Subject))

Human Subject – a *living individual about whom* an investigator (faculty, staff, or student) conducting research obtains (1) *data through intervention or interaction with the individual*, or (2) *identifiable private information*.

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 information). Private information must be individually identifiable.

Individually identifiable includes where the identity of the subject is or may be ascertained by the researcher or associated with the information.

Documents Submitted to IRB

https://www.andrews.edu/services/research/research_compliance/institutional_review/apply_form.html

- ▶ (1) Application Form
- ▶ (2) Research Protocol
- ▶ (3) Consent/Assent Forms
- ▶ (4) Instruments
- ▶ (5) Recruitment
- ▶ (6) IRB Approvals
- ▶ (7) NIH, RCR Training



Protecting Human Subject Training

https://www.andrews.edu/services/research/research_compliance/institutional_review/training-education.html

Three Ethical Principals



Ethical Principles (Belmont 1979)

- ▶ **Respect for Persons** (*Be Respectful*)
 - Individuals should be treated as autonomous agents
 - Individuals with limited autonomy are entitled to additional protection
- ▶ **Beneficence** (*Be Nice*)
 - Do no harm
 - Minimize risk/maximize benefits
- ▶ **Justice** (*Be Fair*)
 - Fair distribution of risks and benefits of research

Ethical Principles (Belmont 1979)

BENEFICENCE

Experimental Design

Risk/Benefit Analysis

Data Safety

Qualifications of Researchers

JUSTICE

Subject Selection

Inclusion/Exclusion

Recruitment

Fair Distribution

RESPECT FOR PERSONS

Privacy & Confidentiality

Vulnerable Populations

Informed Consent

Surrogate Consent

Parent Permission / Assent

Institutional Review Board (IRB)

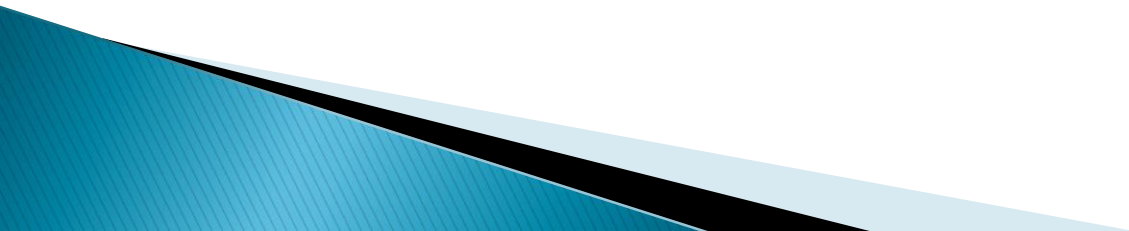
What (and who) is the IRB?

- ▶ IRB at AU has a duty to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of Andrews University



Institutional Review Board (IRB)

Members with sufficient and appropriate expertise to review the research that comes before the committee.



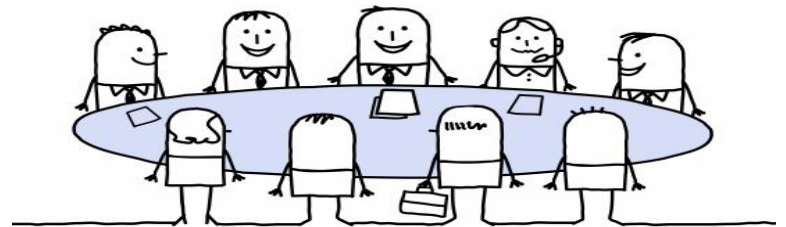
Institutional Review Board (IRB)

What (and who) is the IRB?


The IRB has the authority to:

- Approve; Require modification in, or
- Disapprove

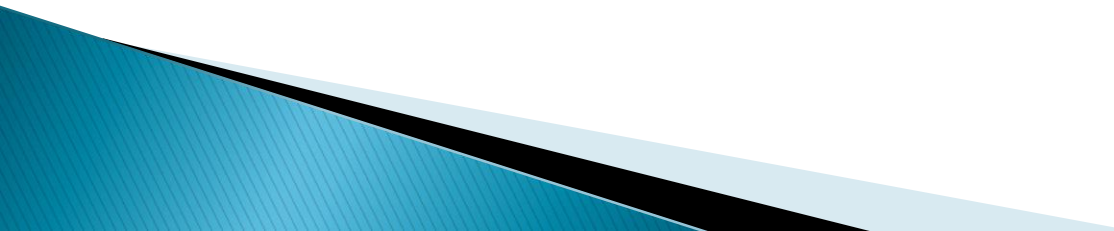
all research activities that fall within its jurisdiction as specified by federal regulations, state law, and institutional policy.



Basic Elements of Research Protocol

- ▶ Purpose of Research
 - ▶ Background and Rationale
 - Summarize and synthesize available research
 - Evaluate prior research for relevance
 - Describe Significance of research
 - ▶ Procedures
 - Research Design should be identified(e.g. experimental, correlational, survey, etc.).
 - ▶ Sample
 - Describe sampling approach to be used.
 - Identify procedures to be used to recruit, screen, and follow subjects.
 - Identify number of subjects to be enrolled
 - Characteristics of subjects to be included in and excluded from the research
- 

Basic Elements of Research Protocol

- ▶ Measurement/Instrumentation
 - Identify variables of interest
 - Justify measurement techniques selected
 - ▶ Detailed study procedures
 - Describe how you secure subject consent
 - Methods of data collection
 - Methods of avoiding/minimizing subject risks
 - Identify how subject confidentiality will be safeguarded.
 - ▶ Internal validity
 - Describe measures taken to avoid study bias
 - ▶ Data Analysis
 - Specify the analytic techniques you will use to answer the study questions.
- 

Informed Consent Process

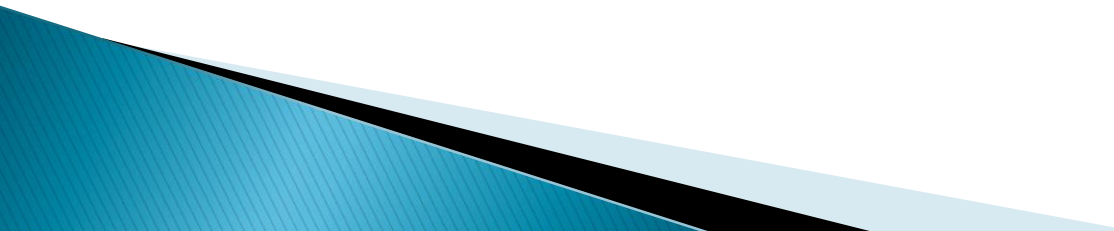
Informed consent is not a single event or just a form to be signed -- rather, it is an educational *process* that takes place between the investigator and the prospective subject.

The basic elements of the consent process include:

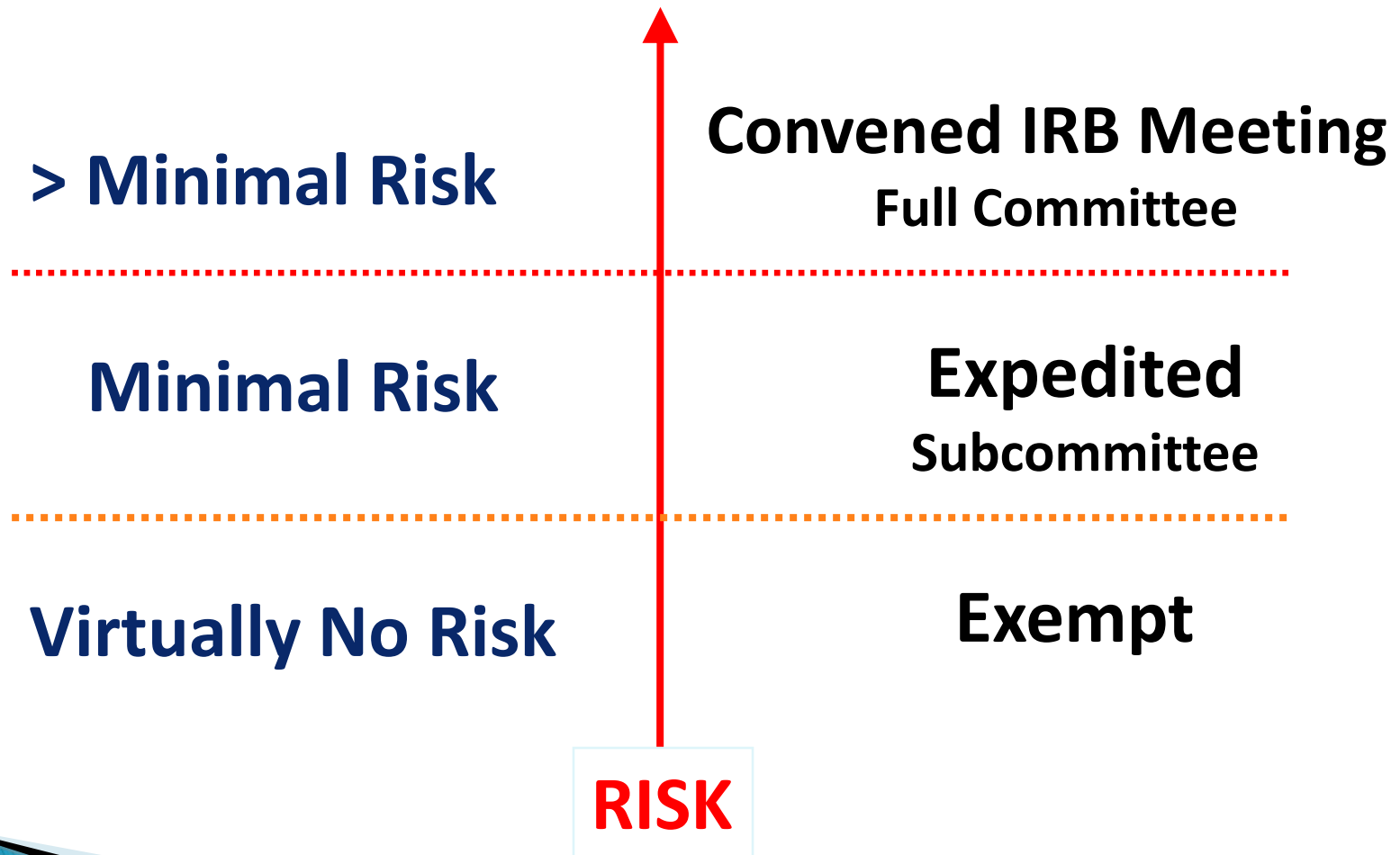
- ▶ **full disclosure** of the nature of the research and the subject's participation,
- ▶ **adequate comprehension** on the part of the potential subjects, and
- ▶ the subject's **voluntary choice** to participate.

Basic Elements of Informed Consent

46.116(b), 50.25(b)

- ▶ Research
 - Duration
 - Procedures
 - Experimental Products
 - ▶ Risks/Discomforts
 - ▶ Benefits
 - ▶ Alternative procedures/treatment, if any
 - ▶ Confidentiality
 - ▶ Compensation for Injury (Full Committee)
 - ▶ Whom to Contact
 - ▶ Voluntary Participation / Right to Refuse or Withdraw at Any Time
- 

Level of Risk Generally Determines Level of Review



Exempt Review

Category 1. School Based Research – research in an educational setting (classroom)

- (a) instructional strategies or
- (b) comparing instructional techniques, curricula or classroom management methods.

Category 2. Interviews, Surveys, Observation of Public Behavior

- (a) Cannot identify subject (anonymous or de-identified), or
- (b) Data is identifiable, but subject is not at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

Category 3. Public Officials – Interviews or observation of public behavior of elected or appointed public officials or candidates for public office

Category 4. Records Review – Collection of *existing* data, recorded such that subjects cannot be identified

Expedited Review

Category 4. Collection of data thru noninvasive means , including studies using cleared medical devices

Category 5. Records Review – involving materials collected for non research purposes that have been collected or *will be* collected (like Exempt #4)

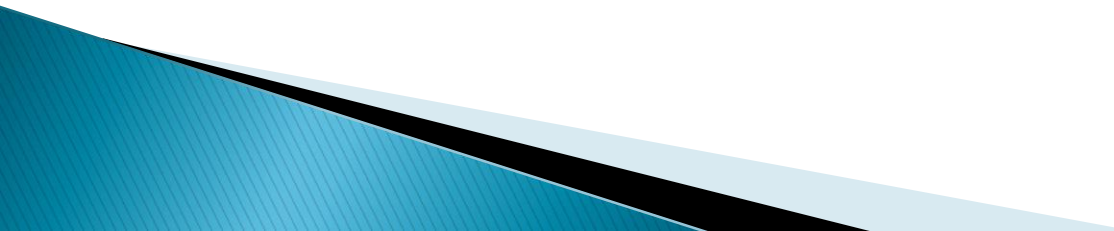
Category 6. Recordings – Video, Digital, Audio, Image (ie, Photos)

Category 7. Interviews, Surveys, Focus Groups – Individual / Group characteristics or behavior (like Exempt #2)

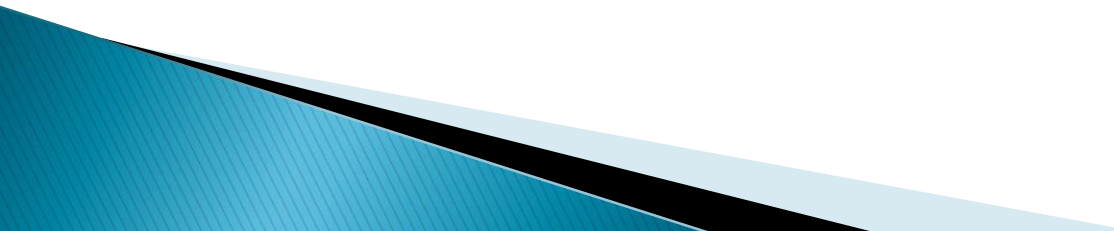
The Application Process?

- ▶ Adviser approval of the proposal
- ▶ Adviser submits proposal to IRB (# assigned)
- ▶ IRB office screens proposal for completeness
- ▶ IRB evaluates the proposal and makes a decision
- ▶ IRB communicates with investigator
 - Exempt from review
 - Approved
 - Deferred for further information or for changes
 - Denied
- ▶ IRB monitors research if not exempt

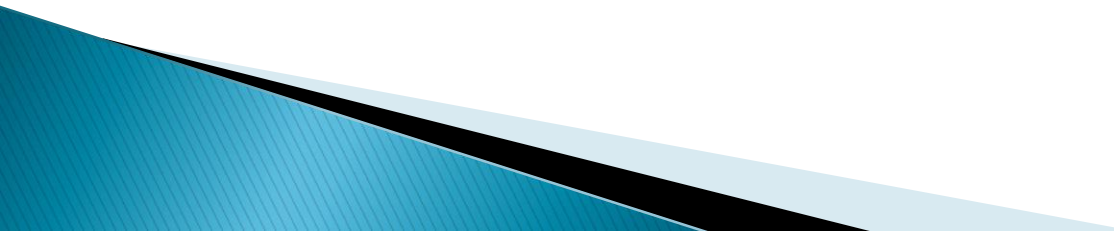
Points To Note

- ▶ IRB does not review applications retrospectively
 - ▶ IRB reviews only complete applications
 - ▶ Allow enough time – at least two weeks for Expedited, one month for Full Review
 - ▶ Faculty advisors must approve proposals before submission
- 

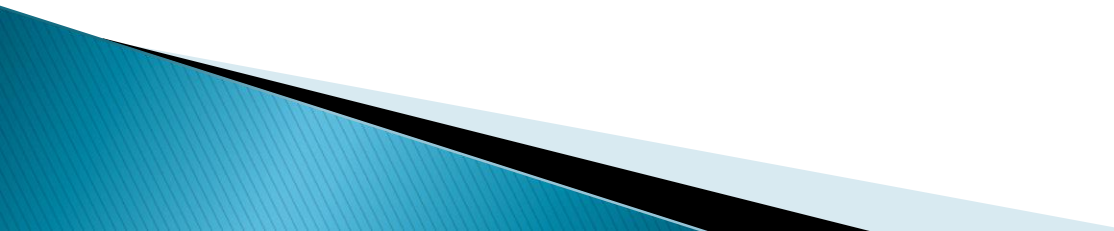
Your Application Will Be “Quickly” Approved if:

- ▶ You clearly explain in detail how you will
 - ✓ Deal with minors or other vulnerable populations appropriately
 - ✓ Not use any undue pressure or coercion to participate
 - ✓ Not use any unnecessary concealment or deception in recruitment
 - ✓ Treat sensitive topics appropriately
- 

Your Application Will Be “Quickly” Approved if:

- ✓ Minimize risk if using physically invasive procedures
 - ✓ Maintain confidentiality of the data
 - ✓ Not expose subjects to undue risk
- 

Contact Information

- ▶ IRB Office
 - ▶ Tel: (269) 471-6361
 - ▶ Email: irb@andrews.edu
 - ▶ Location: BUL Room 234
- 

Questions

THANK YOU!