NCURA Life Cycle of the Award Series

Compliance

Day 1

Why Compliance Matters

Why Compliance Matters

Why compliance matters

- Potential loss of funding
- Financial risk (fines and penalties)
- Risks of harm to animals, humans, the environment
- Reputational risk (investigator, institution)
- Public trust

Trust and Accountability

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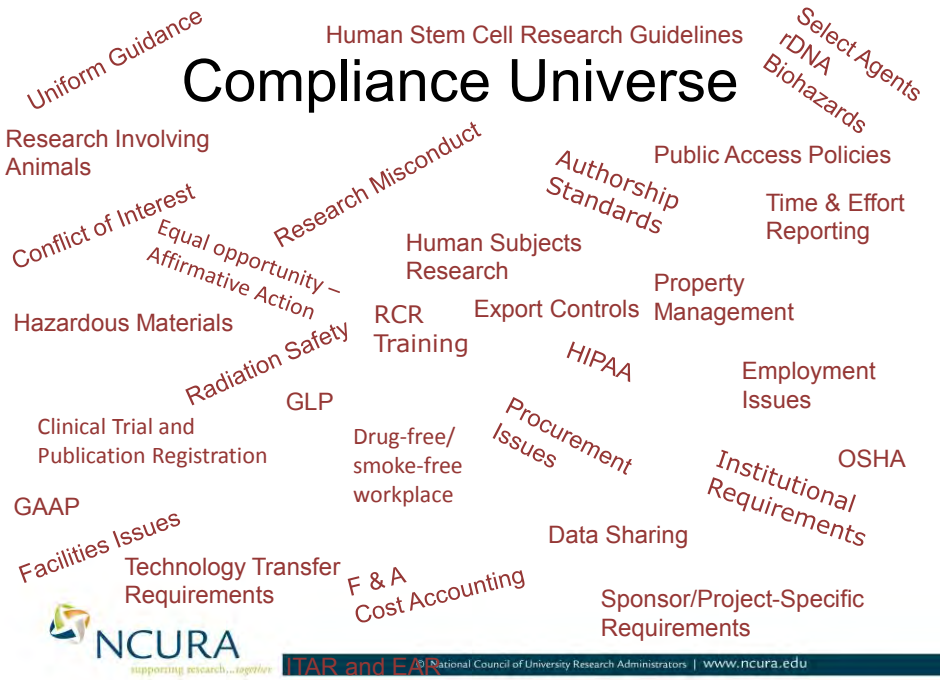
Compliance Universe



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Research Compliance Roles

Research Integrity

Truth or Consequences

Objectives

Why is it Important?

- Identifies best practice
- Establishes the university expectation
- Expands individual and group understanding
- Enhances ability to make fair judgement calls
- Promotes ethical behavior
- Sets local cultural standards
- Promotes public confidence in research

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Trust and Honesty

Cornerstones of scientific integrity

"For a scientist, integrity embodies above all the individual's commitment to intellectual honesty and personal responsibility…."

Integrity in Scientific Research,

National Academy of Sciences

Public Expectation

It is intended to ensure:

- Objectivity
- Clarity
- Reproducibility
- Utility

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Public Confidence

Scientific Integrity is important because demonstrates that the research is free from:

- Bias
- Falsification
- Outside interference and Censorship
- Fabrication
- Plagiarism

Basic Precepts of Research Ethics

- Honesty
- Objectivity
- Integrity
- Stewardship
- Collegiality
- Justice Openness

- Slide attributed to Katrina A. Bramstedt and Amir Darr, Cleveland Clinic

Federal Requirements

In 2000, the White House Office of Science and Technology Policy published the Federal Research Misconduct Policy which required all federal agencies or departments supporting intramural or extramural research to implement within one year either through policies or regulations.

Research Misconduct – What is it?

(1) fabrication, falsification, plagiarism or other serious deviation from accepted practices in proposing, carrying out, or reporting results from research or other scholarly activities; or (2) material failure to comply with applicable federal requirements for protection of researchers, human subjects, or the public, or for ensuring the welfare of laboratory animals; or

Research Misconduct – What is it?

- **Fabrication** means making up data or results and recording or reporting them.
- **Falsification** means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- **Plagiarism** means appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Other deviations may include action such as performing research without obtaining the appropriate approvals.

What is it (continued)

Example of Other –

-Failure to disclose real or perceived significant financial business interests

-Failure to comply with other applicable legal requirements governing research or other scholarly activities

What it is not

It does not include:

- – disputes of authorship
- – honest error, or
- – differences in interpretations or judgments of data

The Misconduct Scale

- Surprising Sloppiness - misconduct of the lazy kind
- Innocent Ignorance - misconduct of the uninformed kind
- Intentional Deception - misconduct of the sleazy kind

The Misconduct Scale – Surprising Sloppiness

Noncompliance is due to inaction, inattention to detail, inadequate staff, lack of supervision. The act itself may be intentional or unintentional and is usually repeated.

Examples Include:

- Consent forms inadvertently not obtained from subjects
- Blood pressures rounded to the nearest 5mm
- Data estimated rather than actually measured
- Data inaccurately transcribed as recorded
- Protocol ignored or shortcuts taken

The Misconduct Scale – Innocent Ignorance

Noncompliance is based on lack of understanding the regulatory consequences of an action. The act itself is usually intentional but the noncompliance is unintentional, not usually done to deliberately deceive

Examples Include:

- Backdating the subject's signature on a consent form
- Discarding source documents after accurate transcription and reporting transcribed data as original.
- Using Case Report Forms as only source document

The Misconduct Scale – Intentional Deception

- Creating data that were never obtained
- Altering data that were obtained by substituting different data
- Recording or obtaining data from a specimen, sample or test whose origin is not accurately described or in a way that does not accurately reflect the data
- Omitting data that were obtained and ordinarily would be recorded
- Using of another person's ideas, processes, results, or words without giving appropriate credit.
- Other deviations may include action such as performing research with human or animal subjects without obtaining the appropriate approvals.

The Misconduct Scale – Intentional Deception

Usually noncompliance is due to deliberate action to deceive or mislead: **Falsification, Fabrication, or Plagiarism.**

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Policies

Sample policies and links are provided in the workbook materials.

An Allegation Has Been Made Now What?

- Assessment
- Inquiry
- Investigation
- Adjudication

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Consequences

Research Misconduct

Federal Consequences &Internal Consequences

- Debarment form receive of federal funding
- Suspension & Certification for future research
- Prison
- Termination
- Formal Reprimand

Consequences (continued)

Research Misconduct

Federal Consequences & Internal Consequences

- Formal apology
- Mandatory ethical training
- Loss of reputation

Truth or Consequences

A faculty member is reviewing data from a series of experiments in preparation for a publication. Data from one set of experiments appears to be outliers and presents statistical significance. The Investigator decides to eliminate that data from the analysis with the assumption that there was a technical problem for that set without explaining.

Is the an example of Research Misconduct?

1. Yes 2. No

Truth or Consequences

A graduate student is in the midst of writing her dissertation discovers that her note taking over the years has been sloppy and disorganized. Her notes, including those used in her dissertation proposal, contain substantial paragraphs of text that contain important concepts and ideas placed in quotation marks as well as short unique phrases conveying important concepts that she knows intuitively were not her own. Some of notes have a name written by them and other list a book or article title with page numbers but many do not.

Truth or Consequences

With the knowledge that she has already used the material in her proposal and that none of her committee members raised any issues, the student reasons that there is no harm in doing the same in her dissertation. She reasons that, if she paraphrases the quoted material, it will not be a direct quotation and therefore she does not need to use quotation marks or cite the source.

Is this an example of Research Misconduct?

1. Yes 2. No

What else is it?

It is also about conducting research responsibility - otherwise know as the Responsible Conduct of Research (RCR)

Responsible Conduct of Research

NSF Requirements – USA Competes Act

HHS Requirements – ORI Introduction

Responsible Conduct of Research

- Responsible authorship & publication
- Data integrity
- Collegial collaborative research
- Research mentoring
- Responsible peer review

Responsible Conduct of Research

- Conflict of interest disclosure
- Ethical conduct of research with humans or animals
- Fiscal responsibility
- Safe Laboratory Practices

Awareness and Training

- Formal RCR Training Requirements
- Seminars and Symposia
- Published Materials
- Institutional Expectations

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Implementation Examples

ASU

University of Maryland

University of Texas - Austin

Conclusions and Questions

Acknowledgments

Tony Onofrietti, Director of Research Education University of Utah www.education.reseach.utah.edu.

Shiela Garrity, Director, Research Integrity, Johns Hopkins University, Online Audio Presentation: Recognizing, Reporting and Avoiding Research Misconduct .

University of New Hampshire Responsible Conduct of Research on line study guide http://www.unh.edu/rcr/.

Wikipedia, the free encyclopedia.

University of Sheffield, Department of Marketing & Communication.

BBC Homepage Science and Nature: TV & Radio Follow-up.

Roger Highfield, Editor of 'New Scientist' ; Marc Hauser: monkeying with the truth .

Edyta Zielinska,Top Science Scandals of 2012, The Scientist, News and Opinions.

Peter H. Abbrecht, M.D., Ph.D. from the Office of Research integrity (ORI), from PowerPoint presentation: "Comprehending Research Misconduct and Malfeasance".

Avoiding Being Penalized: Research Misconduct, Office for the Protection of Research Subjects (OPRS), *Dalar Shahnazarian, MSW Candidate, IRB Student Mentor; Susan L. Rose, Ph.D.; Jennifer Hagemann, MS; Monica Aburto.*

Research Integrity, 2010 Patricia Kerby, MPA, Office of Research Compliance, University of Tennessee Heath Sciences Center

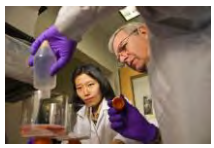
Export Controls

U.S. Export Control Regulations

- Designed to advance the national security, foreign policy and economic interests of the United States
- Govern the export of strategic technologies, equipment, hardware, software or providing technical assistance to Foreign Persons.

Do academic institutions export?

Global Collaborations



Foreign nationals on campus

Foreign travel

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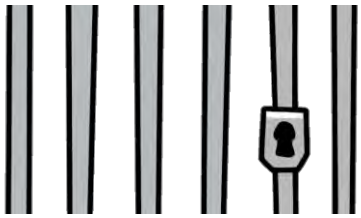
Export means:

Use or application of **controlled** technology on behalf of, or for the benefit of, any **foreign person** or entity, **either in U.S. or abroad**

- Dissemination of research data and information
- Transmission of material goods

Use or application of **controlled** technology on behalf of, or for the benefit of, any **foreign person** or entity, **either in U.S. or abroad**



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Deemed Export

- Export without crossing borders
- Transfer of a controlled item or controlled information is "deemed" to be an export to the home country or countries of the foreign person

How do we know what is controlled?

The devil is in the details

- **Legal analysis** of the regulations determines whether an exemption, exclusion or authorization is available for the transaction
- **Scientific analysis** of the regulations determines whether the item under review meets the detailed specifications for control

Three U.S. agencies
Three sets of regulations

Treasury	Commerce	State
Office of Foreign Assets Control (OFAC)	Bureau of Industry and Security (BIS)	Directorate of Defense Trade Controls (DDTC)
Foreign Assets Control Regulations (31 CFR §§500-599)	Export Administration Regulations (EAR) (15 CFR §§734-774)	International Traffic in Arms Regulations (ITAR) (22 CFR §§120-130)
	Commerce Control List (CCL)	United States Munitions List (USML)
Addresses transactions with sanctioned or embargoed countries, entities and persons	Covers dual-use (civil and military) items, software, equipment and technology	Controls defense articles and defense services; covers inherently military technologies

What is NOT export controlled?

- Information in the public domain
- Educational information disclosed to enrolled students
- Basic marketing and general system descriptions
- Certain disclosures to bona fide full-time employees (ITAR)
- **Information excluded as "fundamental research"**

Fundamental Research Exclusion (FRE)

- Fundamental Research:
  - basic/applied research that is ordinarily **published and shared broadly** within the scientific community
  - not subject to the EAR or ITAR (see regulations for exact definitions)
- Campuses that are not "Fundamental Research Institutions" usually have controls including secure facilities for classified research

"Fundamental Research" Institutions cannot ignore export controls

- Restricted entities and individuals
- OFAC regulations always apply
- EAR and ITAR country prohibitions
- FRE applies to research, not services
- FRE does not cover
  - Shipping materials/equipment out of the U.S.
  - International travel
  - Overseas research

Restricted parties

- Lists
- Valid match

ICE058000	CHEN, Hong AKA CHEN, Evan
MWC000028	CHEN, Hong
PIS044135	YU, Chao Qun AKA YEE, Charles AKA LIN, Xiang AKA CHEN, Jie
SDN005084	WONG, Moon Chi AKA WU, Chaisu AKA HU, Chishu AKA WONG, Kamkong AKA CHEN, Shusheng AKA CHEN, Bing Shen AKA HUANG, Man Chi AKA CHEN, Bingshen AKA WU, Chai Su AKA "Chi Bang" AKA WONG, Mun Chi AKA WONG, Munchi AKA HU, Chi Shu AKA WONG, Kam Kong AKA CHEN, Shu Sheng AKA ZHANG, Jiang Ping AKA CHAN, Shu Sang AKA CHAN, Shusang AKA WONG, Moonchi AKA ZHANG, Jiangping AKA DU, Yurong AKA DU, Yu Rong AKA HUANG, Manchi Hong Kong China

OFAC Sanctions

Sanctions Program:	Program Last Updated:
Balkans-Related Sanctions	07/09/2015
Belarus Sanctions	10/29/2015
Burma Sanctions	12/07/2015
Burundi-Related Sanctions	02/03/2016
Central African Republic Sanctions	12/18/2015
Cote d'Ivoire (Ivory Coast)-Related Sanctions	07/30/2015
Counter Narcotics Trafficking Sanctions	02/03/2016
Counter Terrorism Sanctions	02/11/2016
Cuba Sanctions	01/26/2016

Examples:

Campus Visitor

Subaward

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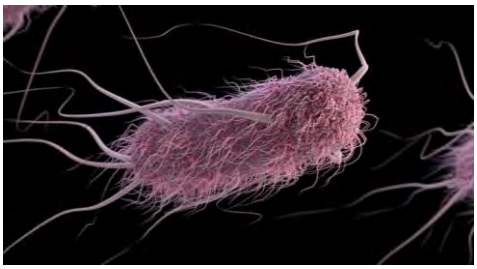
Export Administration Regulation (Dept of Commerce)



Export Administration Regulation (Dept of Commerce)

- Is the item/technology subject to EAR?
- If your item or activity is subject to the EAR
  - Classify the export (specifications/details)
  - Is there a general prohibition?
  - Is a license exception available?
  - Work with Export Control Office or General Counsel to apply for a license; comply with it; keep records

Example

- Doppler Velocity Log will be hand-carried in personal luggage for overseas field research
- Manufacturer lists ECCN (EAR classification number) as 6A001 or 6A991 depending on instrument accuracy/precision

International Traffic in Arms Regulations (Department of State)

International Traffic in Arms Regulations (Department of State)

- Is the item/technology subject to ITAR?
- If the item or activity is subject to the ITAR
  - Classify the export (specifications/details)
    - Review the general characteristics of your item. This will usually guide you to the appropriate category on the U.S. Munitions List.
    - Then match the particular characteristics and functions of your article to a specific entry within the appropriate category.
  - Work with Export Control Office or General Counsel to apply for a license and meet other requirements

Example 1

Category XIV—Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment

(h) Medical countermeasures, to include pre- and post-treatments, vaccines, antidotes and medical diagnostics, specifically designed or modified for use with the chemical agents listed in paragraph (a) of this category and vaccines with the sole purpose of protecting against biological agents identified in paragraph (b) of this category. Examples include: barrier creams specifically designed to be applied to skin and personal equipment to protect against vesicant agents controlled in paragraph (a) of this category; atropine auto injectors specifically designed to counter nerve agent poisoning.

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Example 2

Category XV— Spacecraft and Related Articles

(a) Spacecraft, including satellites and space vehicles, whether designated developmental, experimental, research, or scientific, or having a commercial, civil, or military end-use, that:

*(1) Are specially designed to mitigate effects (e.g., scintillation) of or for detection of a nuclear detonation;

*(2) Autonomously track ground, airborne, missile, or space objects in real-time using imaging, infrared, radar, or laser systems;

(etc.)

The asterisk means the enumerated defense article is deemed to be "Significant Military Equipment" to the extent specified in §120.7 of this subchapter.

Risk Assessment

Where do you focus your energies?

- How does YOUR campus export?
- Which faculty and what departments have controlled items and/or significant international collaboration?

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Typical Procedures

- Foreign national employees – I-129 certification
- Campus visitors
- Subawards and collaborations
- Travel
- Shipping
- Overseas field research and other activities
- Classified/restricted research, controlled items/information
  - Secure facilities
  - Technology control plans

Licensing

- Work with export control officer and/or general counsel
- PI input is critical
- Agency review process can be very long (weeks to months)
- Review authorization or license carefully
- Maintain records of determinations, requests, authorizations, licenses, reports, shipping documents, etc, for 5 years after completion of the activity

Penalties for Violation

- Denial of export privileges
- Seizure and forfeiture of goods
- Suspension; debarment
- Negative publicity
- May apply to the individual(s) involved and/or the university
- Federal penalties applied may be criminal and/or civil
- Institutional disciplinary actions up to termination and dismissal

University-related compliance cases

Good practices

- Centralize export compliance oversight, but involve relevant campus offices
- Implement a clear institutional policy
- Partner with PIs
- If there is controlled research on your campus, keep it separate with limited access (secure facilities)
- Maintain FRE: prohibit sponsor restrictions on publication and access to/dissemination of results
- Promote compliance with awareness training
- Create and use checklists

Questions?

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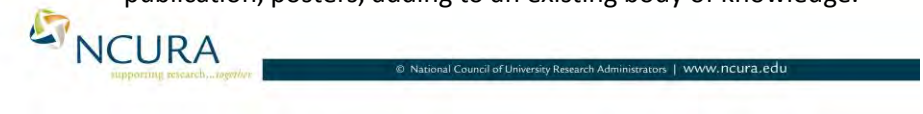
Human Participants:
Human Research Protections

What Is Human Subjects Research?

Human Subjects Research

- **Human Subject:**
  - A human subject is a living individual about whom an investigator obtains either
    - data through interaction or intervention with the individual
    - private, identifiable information (medical record; student record, blood samples, etc.)
- **Research:**
  - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
    - The definition of "generalizable knowledge" can vary. Examples: publication, posters, adding to an existing body of knowledge.



Why do we have rules about human subjects research?

BRIEF HISTORY LESSON

Brief History Lesson

- WWII: Nuremburg Code
  - Voluntary Consent
  - Experiments should yield fruitful results
  - Avoid unnecessary risk
  - Adequate resources and training to conduct study
  - Participation is entirely voluntary
- 1964 Declaration of Helsinki
  - Every participant must receive best known treatment
- 1974 National Research Act
  - Formed in the aftermath of the Tuskegee Syphilis Study to develop guidelines for human subject research

Brief History Lesson (cont.)

- **Tuskegee Syphilis Study**
  - A clinical trial conducted between 1932 and 1972 in Tuskegee, Alabama by the U.S. Public Health Service. Investigators recruited 399 poor, mostly illiterate, African-American sharecroppers with syphilis for research related to the natural progression of the untreated disease
  - ***Advertised*** treatment for "***bad blood***," a local term used to describe several ailments, including syphilis, anemia, and fatigue. In exchange for participating, the men received free medical exams, free meals, and burial insurance.
  - Researchers ***failed to treat*** patients appropriately after the 1940s validation of penicillin as a cure for the disease

Brief History Lesson (cont.)

- **Sexually Transmitted Diseases (STD) Inoculation Study (Guatemala: 1946-1948)**
  - **Intent:** to look for new ways to prevent STDs. Experiments involved infecting female commercial sex workers with gonorrhea or syphilis and then allowing them to have unprotected sex with soldiers, prison inmates and mental hospital patients. Some individuals were directly inoculated with gonorrhea or syphilis.
    - About ***1500 study subjects*** were involved. Once individuals were infected, most received treatment with injections of penicillin.
    - The study subjects were ***not informed*** of the purpose of the study and ***did not provide consent***.
  - Ethical Violations: ***1)*** use of study subjects who were members of highly vulnerable populations, ***2)*** research without valid informed consent, and ***3)*** deliberate exposure of subjects to known serious health threats.

Belmont Report

- ***1979 Belmont Report***
  - Identifies the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects:
    - **Respect for Persons**
      - Individuals are autonomous (Voluntary Consent)
      - Protect those w/reduced autonomy (adequate protections)
    - **Beneficence**
      - Do not harm (Risk : benefit ratio)
      - Minimize potential risks
    - **Justice**
      - Distribute risks and benefits equally among those who may benefit. (Equitable subject selection)

What is the researcher required to do to comply with applicable laws and policies?

REQUIREMENTS/ASSURANCES

Federalwide Assurance (FWA)

- All human subjects research activities will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution.
- These terms apply whenever the Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the Common Rule (45CFR46)

Engagement & Authorization Agreements

- **Engaged in Human Subject Research**
  - An institution becomes "engaged" in human subjects research when its agents (employees/faculty/staff):
    - (i) intervene or interact with living individuals for research purposes or,
    - (ii) obtain individually identifiable private information for research purposes
- **Authorization Agreements**
  - If two or more institutions will be engaged in human subjects research
  - Allows one institution to be the ***IRB of Record for the life of the study***.
  - Varies from institution to institution – be sure to check before beginning the process.
  - **Benefits**
    - Reduces administrative burden
    - Helps to eliminate confusion
    - Institutional review occurs with appropriate expertise present

Funding Requirements

- Grants Involving Human Subject Research
  - Must submit a protocol
  - A protocol may have more than one funding source
- Grants Not Involving Human Subject Research
  - Do not require IRB Review
  - If unsure, contact IRB to discuss
    - ***Better to be safe than sorry!***
    - ***There is no retroactive IRB Approval!***
  - Complete Request for Human Subjects Research Determination Form for official documentation

Funding Requirements

- **<u>Federal Funding</u>**
  - Grant application must be uploaded with Initial Protocol Submission.
  - The information in the Grant must be consistent with what human subject research activities will be conducted.
  - New or change in funding source after initial IRB Approval must be added to the protocol via an Amendment application.

What do I need to know when planning to submit an application? Review Paths, Turnaround Times, Who can be a PI, Continuing Review.

PREPARING FOR THE APPLICATION PROCESS

Institutional Review Board

- The IRB is a committee designated by an institution to help assure the protection of the rights and welfare of human subjects.
  - Guided by **OHRP, FDA, State and Local Laws, Institutional Policies**
  - Membership includes: **scientists, non-scientists, unaffiliated member**
- The IRB makes an ***independent determination*** whether to approve or disapprove the protocol based upon whether or not human subjects are adequately protected, which includes determination of a ***favorable risk*** : ***benefit analysis*** of the research.
- The IRB ***approves the initiation of*** and ***continuing reviews of*** research involving human subjects.
- ***Investigators are responsible for the conduct of the study and protection of human participants.***
  - ***Investigator may be student or faculty. If student, the faculty advisor must be on the project***

Review Paths

- **EXEMPT** (45CFR46.101) – 6 Categories
  - Exempt from requirements of 45CFR46
  - IRB makes this determination, not the PI
    - PI can suggest an Exempt Category
- **EXPEDITED**(45CFR46.110) – 9 Categories
  - Does not mean "***Fast***"
  - Minimal Risk transactions
    - Addenda to Greater than Minimal Risk protocols can be Expedited.
- **FULL BOARD**
  - Research presenting greater than minimal risk to participants

Protocol Review

Vulnerable Populations

- *Are there appropriate protections in place for the group or groups you are recruiting?*
  - *Prisoners*
  - *Children*
  - *Pregnant woman and Fetus*
  - *Cognitively impaired*
  - *Students*

HIPAA - Health Insurance Portability and Accountability Act

- *Is PHI involved (designated record set)?*
- *Plans to protect PHI*
- *Authorization to collect PHI? (HIPAA Authorization)*
- *Who will have access to identifiers?*
- *Will the data be coded?*
- *Where will the data be stored?*

Timeline for Review

- **Quality of Protocol Applications**
  - Turnaround time likely to be shorter when protocol is written well and requires little to no modification
  - Student may be PI, as long as Faculty Advisor is on the project and signs. ***FA bears responsibility for the quality of the application!***
- **Continuing Review (Annual Renewal)**
  - To avoid Protocol Expiration or Administrative Closure, submit Continuing Reviews ***at least 45 days in advance of Expiration date.***
  - ***IRB Office should send you reminders!***

Submitting an Application to the IRB

- ***Complete Required Forms***
  - ***New Project Applications Require:***
    - ***Initial Application – lay summary***
    - ***Full Protocol – technical summary (if investigator-initiated)***
    - ***Awarded Grant portion containing human subject research activities***
    - ***Supplemental Project Documentation (Recruitment Materials, Consent Forms, Interview Scripts, Questionnaires, etc.)***
    - ***Department Liaison Signature***
    - ***Faculty Advisor's Signature***
    - ***Principal Investigator's Signature***
    - ***Training records for all investigators involved in the HSR portion of the project***

Good Ads for Human Subjects…

- Answers who, what, when, where, and how
  - Who – eligibility criteria
  - What – description of what research is
  - When – gives duration of project
  - Where – logistics
- Ad is the first step in informed consent
  - Should be vetted by IRB committee

Online study of young children's daily emotions and behaviors

Are you a parent of a child between the ages of 3 and 5 years old?

Researchers at UMD are investigating a number of phenomena related to children's emotional and behavioral development from early childhood through adulthood.

Participants will be asked to complete online surveys each evening for 14 days.

Parent must be the primary caregiver and read and speak English. Children must not have major medical or developmental disabilities. One child per family can participate.

Compensation: $50

Research possible through Federal award.

Project Expiration

- Continuing Reviews may only be approved within **30 days prior to the expiration date.** [OHRP Guidance]
- Expiration: w/o Continuing Review Submitted
  - ***All human subject research activity must cease***. New protocol application must be submitted if PI wishes to continue
- Expiration: w/Continuing Review Submitted
  - ***Human subject research activity must cease until submitted Continuing Review is IRB Approved***
  - ***Continuing Review applications submitted after Expiration will not be considered***

What Now?

Know Your Responsibilities

- Educate others.
- Be Accountable (PI, Student Investigator, Research Staff).
- Utilize your resources.
- Be sure your protocol is in good shape prior to being submitted to the IRB. The less mods that are sent back, means a quicker turn around time for approval.
- Contact the IRB Office with any questions.

Questions?