



THE OHIO STATE UNIVERSITY

Office of Responsible Research Practices
Human Subjects Research
EHE IRB Workshop

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Objectives

- Types of Research & Review Process
- Research Examples
- PI Responsibilities
 - Education, Training, and Delegation
 - Research Monitoring
 - Record Management
 - Reporting Requirements
- Compliance Considerations



Is it *research* according to DHHS regulations?

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Questions to ask-

- Is it systematic?
- Is it designed to develop or contribute to generalizable knowledge?
- What is the purpose of the project?
- How will the data be used?



Does it involve *human subjects* according to DHHS regulations?

A living individual about whom an investigator (whether professional or student) conducting research obtains

(1) data through intervention or interaction with the individual, or

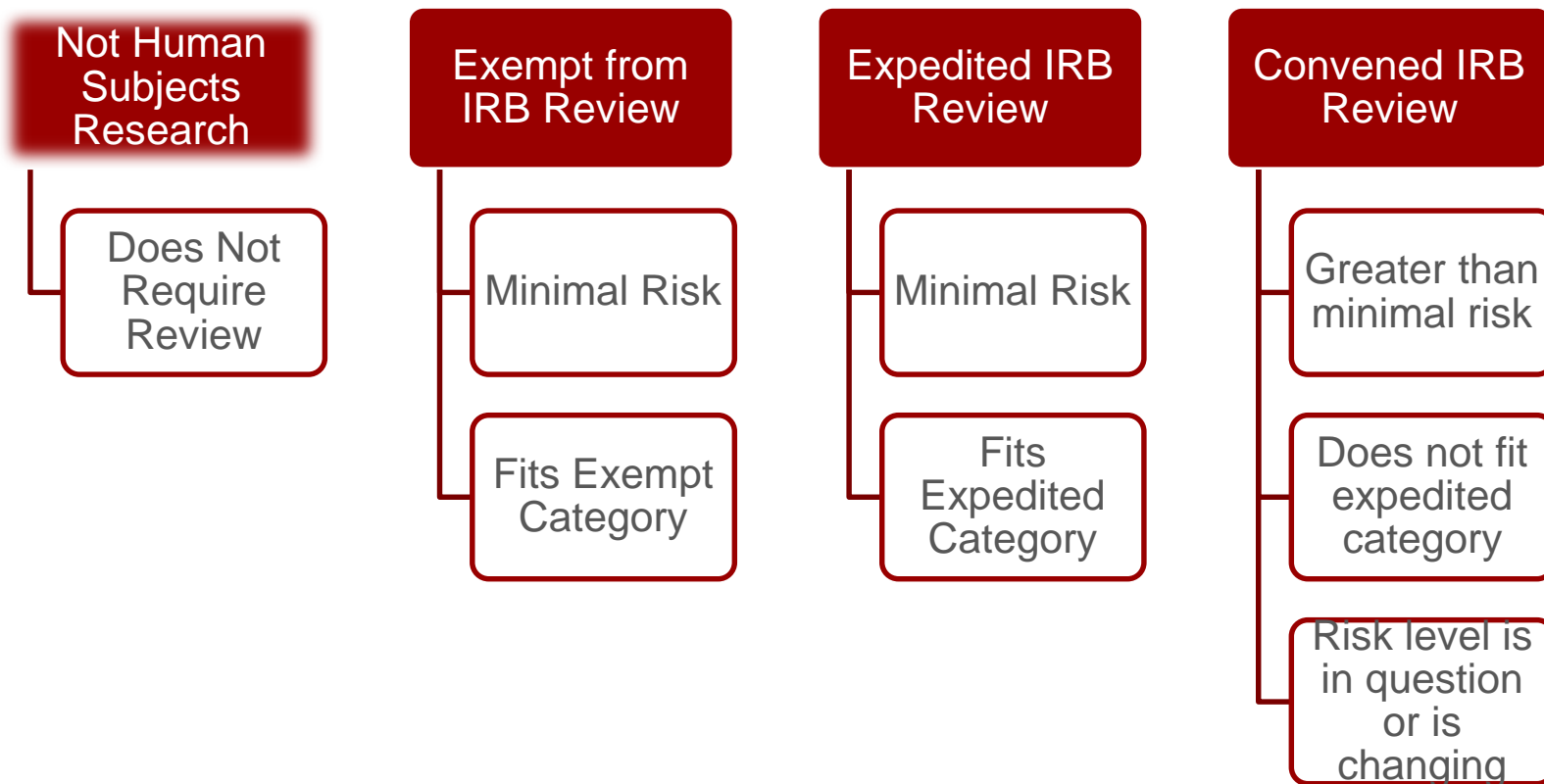
(2) identifiable private information.

Questions to ask-

- Is information about a living individual being obtained?
- Is there any interaction or intervention with the individual?
- Is it identifiable?
- Is the data public or private?



The Continuum of Review





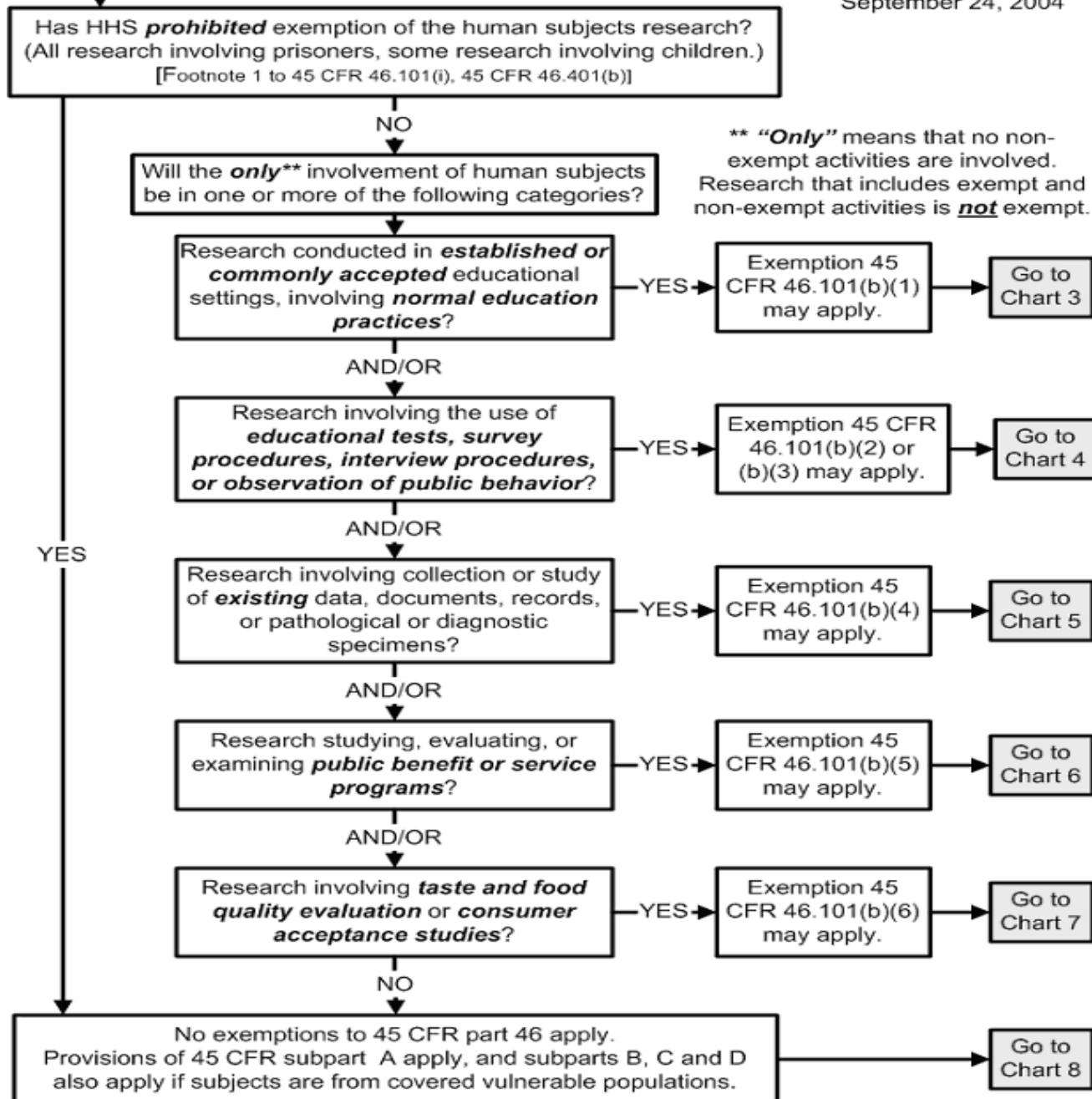
Does my research qualify for exemption?

- Category 1: Classroom research
- Category 2: Surveys, Observational studies, interviews, focus groups
- Category 3: Similar to Category 2 with elected officials
- Category 4: Existing data/materials
- Category 5: Federal Agency initiated programs
- Category 6: Food quality and taste

Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

From Chart 1

September 24, 2004





Institutional Review Boards and Safety Committees

WIRB

Biomedical

Cancer

Behavioral &
Social Sciences

Other

CCC Clinical
Scientific Review
Committee

Institutional
BioSafety
Committee

University
Radiation Safety
Committee

Maternal-Fetal
Welfare Committee

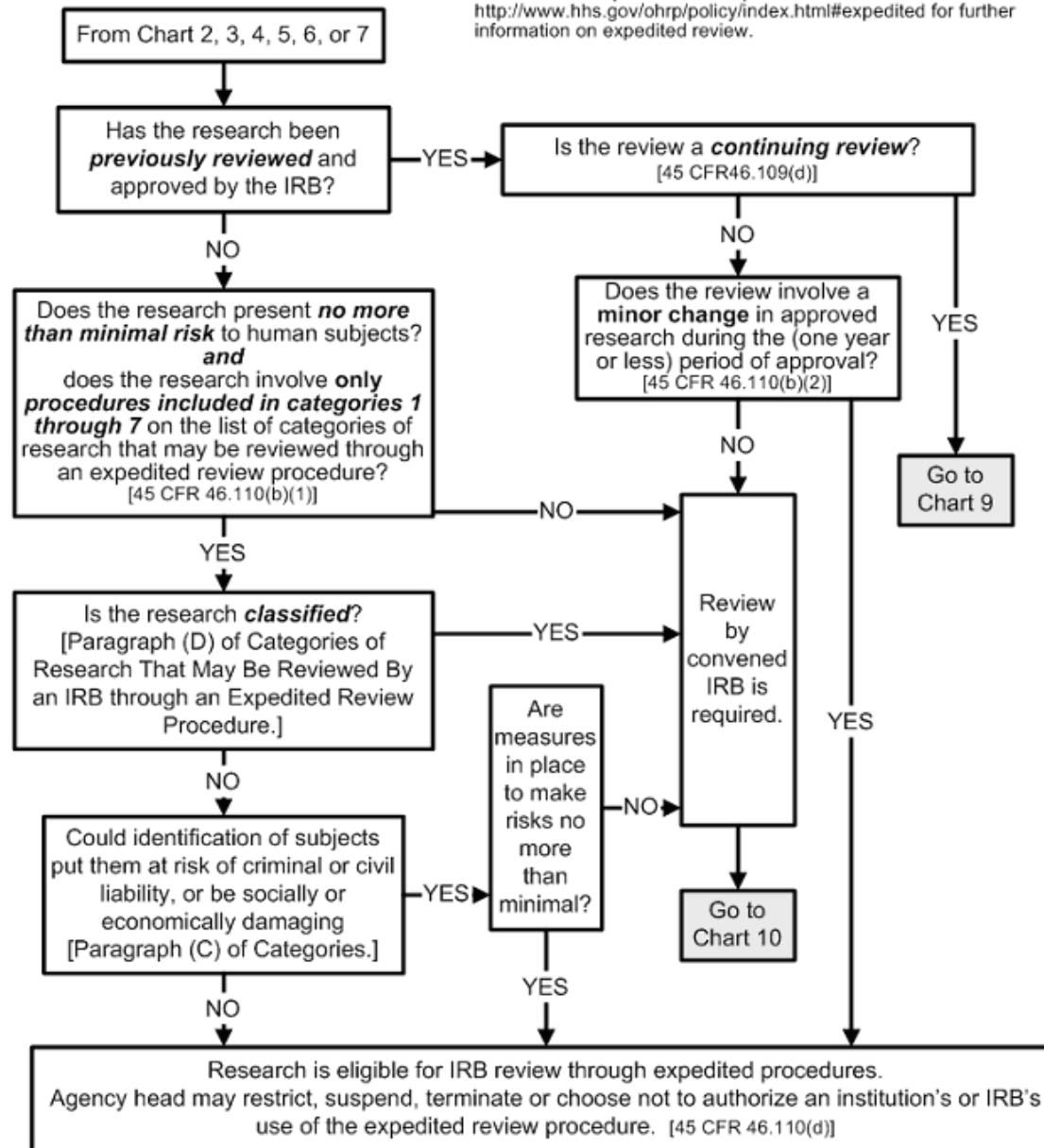


Does it qualify for expedited IRB review?

- Category 1: Marketed drugs/devices
- Category 2: Blood draws
- Category 3: Non-invasive specimen collection
- Category 4: Non-invasive clinical data collection
- Category 5: Secondary use of non-research data
- Category 6: Audio and video recordings
- Category 7: Investigations into characteristics of specific populations

Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

* Note: See expedited review categories and OHRP guidance on the use of expedited review procedures at <http://www.hhs.gov/ohrp/policy/index.html#expedited> for further information on expedited review.





Case 1



Case 1

- MFA graduate student received an award from the Ohio Arts Council. She intends to interview people about their experiences related to race and identity.
- She will conduct audio-recorded interviews with individuals from both rural and urban areas Ohio.
- She intends to ask some basic demographic questions as well as open-ended questions about ethnicity, family, religion, defining experiences related to race (both good and bad).
- The information she gathers will be used to create a vignette-based, fictional performance piece for the theater that reflects on the nature of race and the self. The interview data will not be used for any other purposes.



The order of the questions matters:

Definitions	Yes	No
Is the project <i>research</i> according to the applicable regulations (DHHS, FDA, etc.)?	continue	stop
Does the project involve <i>human subjects</i> according to the applicable regulations (DHHS, FDA, etc.)?	continue	stop
Is our institution <i>engaged</i> in the research involving human subjects?	continue	stop



Is it *research* according to DHHS regulations?

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Questions to ask-

- Is it systematic?
- Is it designed to develop or contribute to generalizable knowledge?
- What is the purpose of the project?
- How will the data be used?



Not Research

At Ohio State, we would determine that this project is not *research*, as the purpose of the project is to create a work of art (a fictional performance piece)—therefore the project is not intended to create, develop, or contribute to generalizable knowledge.



Case 2



Case 2

- A geography faculty member wishes to conduct a federally-funded study to describe, compare, categorize, and analyze the tobacco use policies/restrictions of the most heavily used public transportation systems in several countries and correlate results to local tobacco use rates.
- The goal is to develop or contribute to generalizable knowledge and results will be published/presented.
- Data will be collected from existing datasets, websites, policies, and from transit authority personnel (phone/email questionnaires).
- It has already been determined that the project involves *research* according to DHHS regulations.



Does it involve *human subjects* according to DHHS regulations?

A living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) data through intervention or interaction with the individual, or
- (2) identifiable private information.

Questions to ask-

- Is information about living individuals collected?
- Exactly what data is being collected? From where/who? How?
- Are the sources public or private?
- Ask for a copy of the questionnaire.



Additional information provided:

- The investigator will contact transit authority personnel in order to request a written copy of any tobacco-related policies (or to confirm that no policies exists), and to obtain factual information about how the policies are communicated.
- An email questionnaire will be sent first, followed by a phone call if no response.
- Only factual information about the policies/organizations will be collected, no opinions from (or personal information about) individuals will be obtained.



Not Human Subjects

No *human subjects* (as defined by DHHS regulations) are involved.

- For the questionnaires/interviews: the “about whom” of the DHHS human subject definition is not met.
- The questionnaire does not collect information about living individuals. All information is factual information about the organization’s policies and procedures.
- For the existing, non-policy data: all is aggregate and publicly available. No personally identifiable, private information.
- The policies do not contain private information about an individual.



What if:

- The investigator wanted to include questions where personal opinions on the policies/procedures were elicited, or additional personal data about the respondents and policy makers was collected
- Then it would be determined that data about living individuals was being collected, and the research would include *Human Subjects*.
- Collecting information *from* an individual does not necessarily equal collecting information *about* an individual.

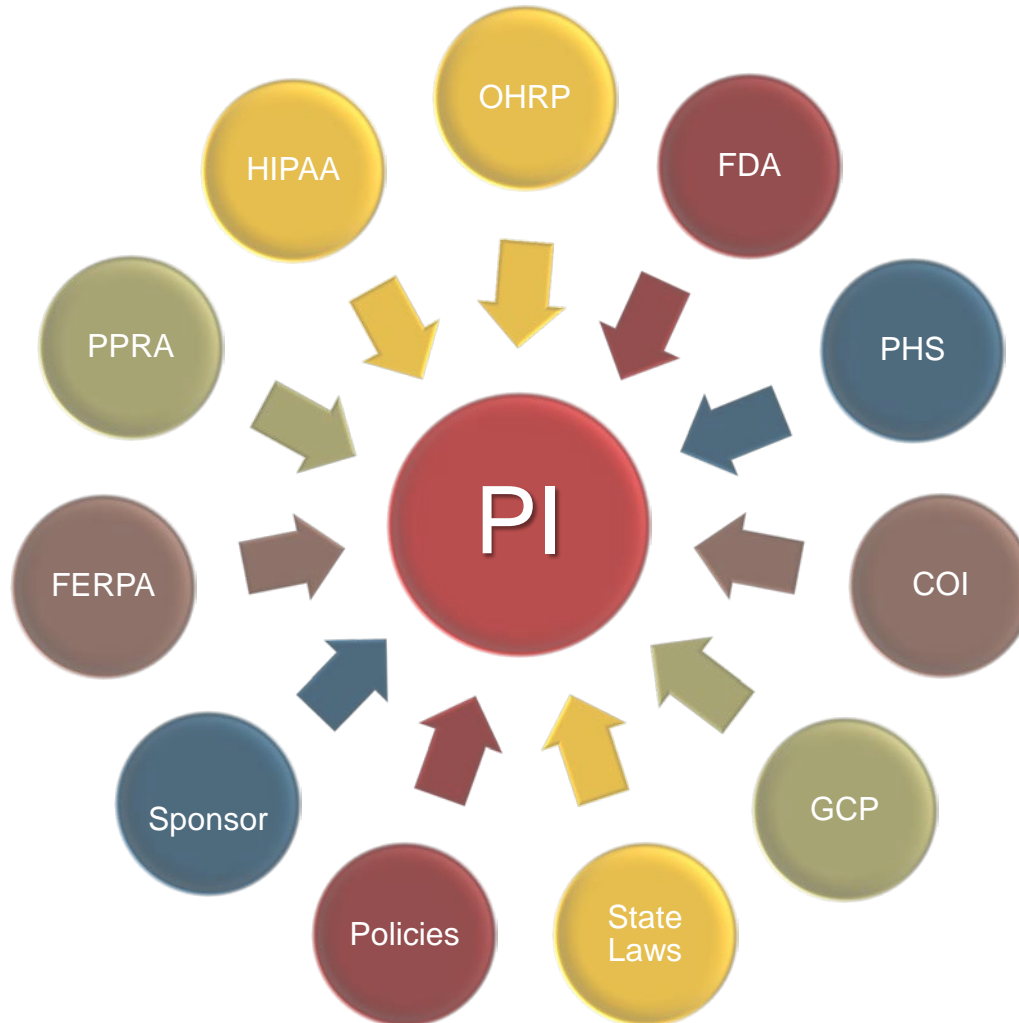


Award Considerations: Ohio State engaged in human subjects research (DHHS) requiring review

- Ohio State receives a federal award for work that involves non-exempt human subjects research automatically engages us in human subjects research requiring review (DHHS definitions).
- Ohio State IRB review is required.
- In limited circumstances, we may have the opportunity to cede IRB review to one of the other participating institutions, but this is done through a formal process facilitated by ORRP.



Regulations, Policies, & Standards





Principal Investigator

- Scientific and/or scholarly training and expertise to assume direct responsibility for the ethical conduct of a study involving human subjects
- Technical and administrative oversight of the research
- Responsible leader of the team, makes important study-related decisions

Research Team

An **individual** (or **organization**) becomes “engaged” in human subjects research when for non-exempt research, the following are obtained:

- Data about research participants through intervention or interaction
- Identifiable private information about research participants
- Informed consent of research participants



Principal Investigator Responsibilities

Ultimately responsible for the ethical conduct of human subjects research and for compliance with federal regulations, applicable state and local laws, and university policies

Education
Delegation
Training
Communication
Monitoring
Data Management
Recordkeeping
Reporting



Education, Delegation, & Training

Qualified Research Team Members

- CVs, job descriptions, COI

Defined Roles and Responsibilities

- IRB approval of personnel, delegation of tasks

Human Subjects Training

- CITI, RCR, GCP, Other

External Personnel

- Investigator Agreements

Research Specific Training

- Protocol, SOPs, training checklist



Communication and Monitoring

Communication Plan:

- Various communication vehicles
- Research meetings
- IRB, sponsor, and regulatory entities
- Participants

Monitoring Plan:

- Consent process and documentation
- Participant enrollment
- Eligibility
- Randomization assignment
- Event reporting
- Protocol compliance
- Investigational product accountability



Document!



Data Management & Record Keeping

Data Management Plan

- Responsibilities, format, access

Data Collection Tools

- Paper, electronic, recordings

Data Integrity & Validity

Security and Privacy (PPI and PHI)

Confidentiality

Record Maintenance

Data Retention





Privacy, Confidentiality, Security

Privacy:

- The state of being free from the observation, intrusion, or attention of others.
- **concerns are about the people involved in the research**
- Personally identifiable records: IRBs evaluate whether disclosure of the information could be embarrassing or damaging to the participants' reputation, financial standing, employability or insurability, or place participants at risk of criminal or civil liability

<http://orpp.osu.edu/files/2012/02/Privacy-and-Confidentiality.pdf>



Privacy, Confidentiality, Security

Confidentiality:

- The condition that results when data are maintained in a way that prevents inadvertent or inappropriate disclosure of participants' identifiable information.
- **Issues are those associated with the data obtained for research purposes.**
- Refers to the investigator's agreement with participants, when applicable (i.e., through participants' informed consent), about how their identifiable private information will be handled, managed, and disseminated.

<http://orpr.osu.edu/files/2012/02/Privacy-and-Confidentiality.pdf>



Confidentiality & Security Considerations:

- Codes for participant identifiers
- Limited access
- Locked cabinets

OCIO University Policy: Institutional Data

Medical Center Policies & Security Tools

- Storage devices
- Encryption
- Restricted data



Research Records Retention

ORRP: Responsibilities of Principal Investigators, Co-Investigators and Key Personnel

- Maintain records in a manner that protects the validity of research and integrity of data collected while protecting data confidentiality and privacy of participants
- Research related records (study protocol, consent forms, instruments, IRB correspondence, “source” documents)
- Retain for audit and inspection for a period of at least 3 years after research has ended (or longer according to sponsor, publication or federal requirements such as FDA)



Research Data Retention

Office of Research: Research Data Policy

- Research data should be archived for a minimum of five years* after the final project closeout, with primary data retained
 - Sponsored Agreements, Intellectual Property, Federal Requirements, State Laws, Compliance Concerns
- Accuracy, authenticity, primacy, and compliance with laws and regulations governing the conduct of the research
- PI or Co-I request to transfer data:
 - Consent language?, Identifiable?, Primary or Copy?, etc...
 - Approval: Chair, Dean, VP of Research and Med Center
 - Data Use Agreement



Routine Reporting to the IRB

- Continuing review
 - Annual Review (Convened or Expedited)
 - Annual Status Report (Live 1/15/2016)
- Change in research
 - Prior to implementing changes unless to eliminate immediate harm to participants
- Change in supportive funding
 - 45 CFR 46.103 (f) Requires that each application or proposal for HHS-supported human subject research be reviewed and approved by the IRB
 - Research described in the application or proposal is entirely consistent with any corresponding protocol(s) submitted to the IRB
- Change in personnel
 - Prior to engagement in research
- Final study report



Event Reporting

UPIRSO (Unanticipated Problem Involving Risks to Subjects or Others)- Related and Unexpected

- SAEs
- Not following the approved protocol
- Use of incorrect version of consent form/script
- Lack of consent or authorization
- Individuals working on protocol without prior IRB approval
- Enacting amendments without prior IRB approval
- Use of unapproved documents
- Participant complaints
- Change in risk level
- Other (loss of study data or forms, breach of confidentiality)



Noncompliance: Failure (intentional or unintentional) to comply with applicable federal regulations, state or local law, the requirements or determinations of the IRB, or university policy regarding research involving human subjects.

- ~ Can result from action or omission
- ~ May be non-serious (minor) or serious
- ~ May be continuing



Human Subjects Noncompliance

Non-serious or Minor Noncompliance: Does not increase risk to research participants, compromise participants' rights or welfare or affect the integrity of the research/data

- Lapse in Continuing Review, minor deviations from the protocol

Serious Noncompliance: Potential to increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data

- Conducting research without prior approval, failure to report serious adverse events, inappropriate oversight of research

Continuing Noncompliance: (serious or non-serious) that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of human subjects protection requirements that may affect research participants or the validity of the research and suggest the potential for future noncompliance without intervention.



Corrective Action Examples

- Modification of the protocol, consent process
- Monitoring of the consent process
- PI and/or staff education or mentoring
- Modification of the continuing review cycle
- Requiring additional resources to support investigator's research activities
- Placing limitations on investigator's activities (PI privileges)
- Placing limitation on use of research data
- Study suspension or termination



Reporting

- Internal Reporting
 - Institutional Official, Dean, Vice Dean for Research, Chair, Co-Investigators
 - Other: OSP, TCO, HIPAA Privacy Officer, Legal Affairs, Office of Research Compliance
- External Reporting
 - Funding Agency, Collaborating Institutions, OHRP, FDA, Participants, Other



The Human Research Protection Program (HRPP)

Protect the rights, dignity, welfare, and privacy of the human subjects in all research conducted on behalf of the university in accordance with:

- Belmont Report
- Department of Health and Human Services (DHHS)
- Food and Drug Administration (FDA)

Maintain Federalwide Assurance (FWA)

- Agreement with DHHS Office for Human Research Protections to review and approve federally-sponsored human subjects research

Maintain Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)



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Protecting Human Subjects in Research at Ohio State



Human Subjects

The Human Research Protection Program is responsible for all Ohio State research involving human subjects. The HRPP's primary responsibility is to protect the rights and welfare of human research subjects, in accordance with Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations.

NEWS

[Spring 2015 IRB Newsletter now available](#)

POSTED: MARCH 26, 2015

[New System for IRB and Exempt Submissions](#)