HUMAN SUBJECTS PROTECTION

National Sponsored Programs Administrators Alliance for HBCUs Technical Assistance Workshop

June 6-9, 2023

Presented by: Dr. Mildred Huff Ofosu

AGENDA

- What is a Human Subject?/ Human Subject Research?/ What is Research and a Research Participant?
- Examples of Non-research activities?
- Historic and Ethical Events & Milestones
- Common Rule of 1991 (45 CFR 46A)
- Revised Common Rule Regulations, Jan. 21, 2019
- Single IRB of Record
- Exemption Categories under Revised Common Rule Regulations
- Sensitive Issues with Children
- IRB Membership and Functions
- Categories in IRB Review Progress
  - Expedited Review Process
  - Exempt Categories
- Suspension or Termination of IRB Approvals
- Human Subjects Ethic Training
  - Collaborative Institutional Training Initiative (CITI)

What is a Human Subject?

- A human subject is "a living individual about whom an investigator (whether professional or student) conducting research does the following:
  - Obtains information or biospecimens through intervention or interaction with the individual

  AND
  - uses, studies, or analyzes the information or biospecimens; OR
  - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Reference: 45 CFR 46.102

Human Subject is **about whom** an investigator conducting research does……

The phrase **'about whom'** is important.

- A human subject is the person that the information is about, not necessarily the person providing the information.
- In the case of biospecimens, the human subject is the person from whom the specimen was taken.

What is Human Subjects Research?

- It is research on people - on a living individual.
- It is research conducted
  - to answer questions
  - to gain knowledge

and

  - to benefit society

  - Participants must indicate <u>their agreements via a Consent Form</u>

What is Research? Who is a Research Participant?

Research means a systematic investigation, including research development, testing, and evaluation that is designed to develop or contribute to generalizable knowledge.

- A **research participant is** also called a human subject

OR

- study participant or subject,
- is a person who voluntarily participates in human subject research after giving informed consent to be the subject of the

To Whom Does the Protection of Human Subjects Apply?

All research involving human subjects.

Note: **there are some exemptions**.

- The policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects.

- Institutions engaged in human subject research and Institutional Review Boards (IRBs) must comply with the policy.

Examples of Non-Research Activities

- **Some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed NOT to be research:**

(1) **Scholarly and journalistic activities** (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

These will not require IRB Approval: Reason: It is not the particular field that removes the activity from the definition of research, but rather that the purpose and design of the activity.

Demonstration and Service Programs NOT deemed to be research

- (2) **Public health surveillance activities**, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or **authorized by a public health authority**.
- Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, (such as covid-19) or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products).
- Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

- Definition: Research from 45 CFR § 46.102 | LII / Legal Information Institute (cornell.edu)

Demonstration and service programs NOT deemed to be research con't

(3) **Authorized operational activities** (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

(4) **Collection and analysis of information**, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

- Definition: Research from 45 CFR § 46.102 | LII / Legal Information Institute (cornell.edu)

What are the **historic events** that provoked public concerns to Protect Humans in Research?

Two Pivotal Events

- **Nazi Experiments:** series of medical experiments on large numbers of prisoners, including children, by Nazi Germany in its concentration camps in the early to mid 1940s.

- **Tuskegee Syphilis Study:** in 1972, the American public became aware of
  - 399 poor black sharecroppers in Macon County, Alabama who were denied treatment for syphilis and
  - were deceived by physicians of the U.S. Public Health Service from 1932 to 1972.
    - The study was designed to document the natural history of the syphilis and these men were told that they were being treated for "bad blood."

Examples of **unapproved** experiments on Human Subjects

Ethical Milestones to **Protect Humans**

- **Nuremberg Code** was established in **1947** and emphasized that **Voluntary consent is absolutely necessary.** Nuremberg laid down 10 standards to which physicians must conform.
- **National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974)** was the first public national body to shape bioethics policy in the United States.
  - Formed in the aftermath of the Tuskegee Experiment scandal, the Commission was created in 1974 as Title II of the National Research Act.

- In **1978**, the national commission submitted, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research.* The report advocated **respect (be courteous), beneficence (charity, mercy, and kindness with a strong connotation of doing good to others including moral obligation), and justice (be fair)** as the fundamental principles for the ethical conduct of research involving human participants

The Consent Process

- Informed consent is an educational process that occurs between the Principal Investigator (PI) and the prospective subject.
- The basic elements of consent are:

  1) research 2) risks and 3) benefits

  There must be:

  - ❖Full disclosure of the nature of the research and subject's participation
  - ❖Adequate comprehension on the part of the potential subjects
  - ❖Voluntary choice to participate from the subject

COMMON RULE OF 1991: 45 CFR 46, SUBPART A

- **In 1991**, 16 federal agencies adopted **45 CFR 46, Subpart A**, also known as the Common Rule. This set of **regulations aims to protect human subjects** in federally funded research through three basic requirements.
- These include
  - **informed consent of research subjects;**
  - **review of the proposed research by an Institutional Review Board (IRB); and**
  - **assurances of compliance with regulations by the institutions involved.**

“HHS Federal Policy or Common Rule”

- The HHS regulations, 45 CFR part 46, include four subparts:
  - subpart A, also known as the Federal Policy or the “Common Rule”;
  - subpart B, additional protections for pregnant women, human fetuses, and neonates;
  - subpart C, additional protections for prisoners; and
  - subpart D, additional protections for children

National Science Foundation

- If a research project involves human subjects, the U.S. National Science Foundation requires that a responsible body has certified the project, and complies with the federal government's "Common Rule" for the protection of human subjects.
- See the overview of NSF's guidance on research with human subjects;
- The overview does not supersede the information provided in NSF's Proposal and Award Policies and Procedures Guide (PAPPG) II.E.5

Does the 45 CFR, part 46 apply to research in Foreign Countries?

- Procedures in foreign countries may differ from U. S.
- If procedures are equivalent, the department or agency may approve the substitution of the foreign policies in lieu of those in the U. S.
- Except when otherwise required by statute, the department or agency head may waive the applicability of some or all of the provisions of HHS Policy
- **https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html**

Revised Common Rule Regulations

- The revised common rule (new Final Rule) was implemented on January 21, 2019.
- It aims to facilitate research, remove ambiguity, reduce regulatory burden and better protect human subjects.

Revised Common Rule
Elimination of IRB Review of Funding Proposals

NOTE:

- The revised Common Rule eliminates the requirement for the IRB to review grant applications or proposals for the purpose of assuring "congruency" with the corresponding IRB protocol.

- This is not a productive use of IRB time. Thus, this change focuses the Human Subject Research Protection's (HRPP) and IRB's review and attention on the actual IRB protocol.
- The **University must still certify to the HHS sponsor** [per 45 CFR 46.103(d)] that each proposed non-Exempt research study has been reviewed and approved by the IRB.
- Such certification must be submitted as prescribed by the federal department or agency component supporting the research.
- As such, the onus is placed on the Principal Investigator to notify Human Subject Research Protection -HRPP - when a new funding source supports an active or new IRB protocol.

- **Reference: Revised Common Rule | Research at Brown | Brown University**

Continuing Review Guidelines

Expedited Protocols:

- Annual renewals will no longer be required for protocols that were approved under the Expedited Review process (with the exception of FDA regulated studies).
- Investigators will now be required to renew their Expedited protocols every 3 years

Important:

This applies to new studies approved on or after January 21, 2019.

- Studies approved prior to January 21, 2019, still need to comply with the expiration date listed in their IRB approval letter.
- For example, if a study was approved on November 1, 2018, then that study still needs to be renewed prior to November 1, 2019.
- When the PI submits the renewal for that project, that project will be transitioned to the Revised Common Rule and will then be granted a 3-year re-approval term (i.e., the study's expiration date will then be extended until November 1, 2022).

Expedited and Full Board Protocols:

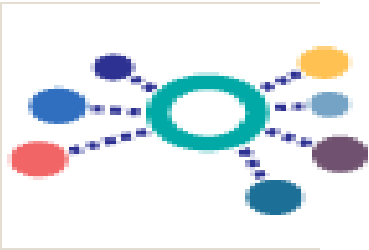
Continuing review will no longer be required for protocols that have progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

- (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
- (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

Important:

- This applies to new studies approved on or after January 21, 2019.
- Existing studies that were approved prior to January 21, 2019, need to continue operating under the old regulatory requirements (up until the point that the IRB has transitioned the study to the Revised Common Rule).
- Existing studies are only being transitioned to the Revised Common Rule at the time of the project's next renewal submission.

Single IRB-of-Record (sIRB) 45 CFR 46.114



- All institutions in the U.S. that are engaged in cooperative (multi-site) research conducted or supported by a Federal department or agency, must include in their grant applications multi-site research. The studies must utilize a single IRB of Record (sIRB).
- The sIRB is necessary to 1) streamline the review process
- and 2) to avoid duplicate review by an institutional review board at each site.
- The IRB at one of the collaborating universities will provide IRB oversight for all involved institutions via an authorization agreement known as reliance agreement or collaborative agreement or a commercial IRB is contracted.

SIRB - Search (bing.com); Also Research Ethics & Compliance, U of MI

Single IRB-of-Record (sIRB) 45 CFR 46.114

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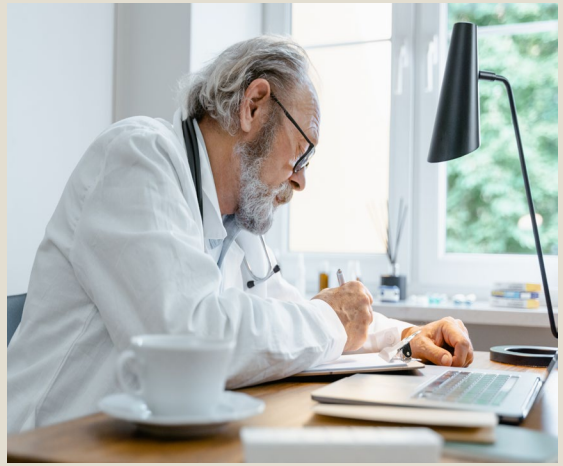
- These agreements/contracts document the a. respective authority b. roles c. responsibilities and d. communication plans among the IRB-of-Record (i.e., the "reviewing IRB") and the institutions relying on that IRB (i.e., "relying site" and "relying IRB") for project oversight.
- As of January 19, 2020 all multi-site research that is federally funded—not just NIH-funded—must rely on a single IRB-of Record for review.



Functions of sIRB

- The sIRB centralizes the regulatory review of the human research activities taking place at all of the participating sites for a project. This includes the review and approval of the:
  - Protocol for all sites
  - Recruitment process and documents
  - Informed consent process and documents
  - Data management and security for the project
  - Reports of serious or continuing noncompliance, unanticipated problems involving risks to participants or others and substantive subject complaints, including reporting to federal agencies when necessary.
- The participating institutions are responsible for oversight functions, ancillary reviews, such as conflict of interest review, verification of completed human subjects' protection training and conduct and reporting of the research.

IRB and Sensitive Issues with Children

(45 CFR 46, Subpart D)

- The federal law defines children as persons who have not reached the legal age of 18 for consent to research treatments or procedures.
- Assent refers to **willingness to participate in research** by giving an affirmative agreement to participate in research. They are old enough to give informed consent but who are **not** old enough to understand the proposed research
- The IRB must determine whether and how assent must be documented and should require use of a **written assent form**.
- IRB approval for the assent form must be issued prior to use, and only consent/assent forms with a valid **"IRB Approval" stamp** can be used when enrolling subjects (unless a waiver from this requirement is approved by the IRB).
- The **parent or guardian must provide consent** on behalf of the child to general medical care

CATEGORIES FOR IRB REVIEW PROCESS

A. FULL BOARD REVIEW
B. EXPEDITED REVIEW
C. EXEMPT

NOTE: The **IRB is responsible for making the final decision** on the category under which a research project falls

Institutional Review Board Membership (IRB) (46.107)

There shall be at least five members, with varying backgrounds to promote complete review

- All Members shall have professional competence and be diverse, including race, gender, cultural backgrounds and sensitive to such issues as community attitudes.
- If research involves a category of subjects that are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, a person with competence in special areas should be included, however, the person may not vote.
- Should include a person who is not affiliated with the University or immediate family member
- Should include a non-scientist
- Should include a scientist

Note: There shall not be a conflict of interest with any members.

The IRB Process

- The IRB reviews protocols to ensure appropriate safeguards to protect the rights and welfare of research subjects are in place, according to 45 CFR 46.111.
- Federal regulation and institutional operating procedure require that the IRB reviews all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research.
- The application or protocol, the consent/assent document(s), tests, surveys, questionnaires and similar measures, and recruitment documents are examples of documents that the IRB reviews.

• The IRB will consider 1. **The Risks to the subjects** 2. **The anticipated benefits to the subjects and others** 3. **The equitable selection of subjects** 4. **The protection of privacy and the confidentiality of data and** 5. **Informed consent**

Materials and Guidance Relevant to IRB

- Each institutions will have a Procedures Manual
- IRB Investigators Manual
- Protocol Submission Guidelines
- Forms and consent templates
- Guidelines for regarding student's research
- Guidelines for Human Subject Research Training
- Policies and Procedures
- Important Dates

All above requires discussion in separate sessions.

EXPEDITED REVIEW AND EXAMPLES

Section I

Expedited Review (45 CFR 46.110)

To qualify for expedited review, an activity must:

- (1) involve no more than minimal risk

AND

- (2) be a minor change in previously IRB approved research during the period of 1 year or less

Existing IRB Approved Projects

- All active Expedited or Full Board projects that were previously approved (on or before 01/20/19) will be transitioned to the new Revised Common Rule regulatory requirements at the time of the project's next renewal submission.
- NOTE: **Annual renewals** will no longer be required for protocols that were approved under the Expedited Review Process (with the exception of FDA regulated studies).

Investigators will now be required to renew their expedited protocols every 3 years.

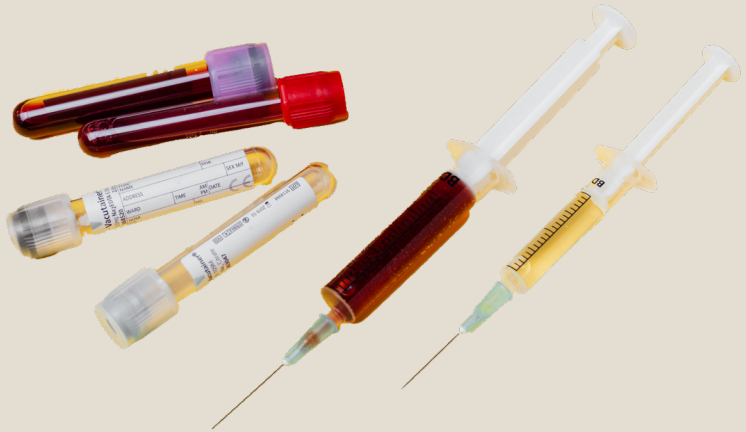
- If the project is still actively enrolling participants at the time of renewal, the PI will be required to switch to the new Informed Consent Form Templates that comply with the Revised Common Rule changes

- Until this transition has occurred, all existing active Expedited and Full Board studies are required to continue operating under the old regulatory requirements.

Reference: FIU.edu, IRB

Some Examples of **Expedited** Research are:

- studies involving collection of hair, saliva or dental plaque samples.
- studies of blood samples from healthy volunteers.
- analyses of voice recordings.
- studies of existing pathological specimens with patient identifiers.



Expedited Review Categories

- Healthy, non-pregnant adults who weigh at least 110 pounds. The amounts drawn may not exceed 550 ml in an 8-week period, and not more than 2 times per week; or

- Other adults and children, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period, and may not occur more than 2 times per week.

Expedited Review Categories include:

- **Clinical studies of drugs and medical devices** only when condition (a) or (b) is met:
  - (a) Research on drugs for which an investigational new drug (IND) application (21 CFR Part 312) is not required.
    - (Note: **Expedited Review Exception**:
    - Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
  - (b) Research on medical devices for which,
    - **(i)** an investigational device exemption (IDE) application (21 CFR Part 812) is not required; or
    - **(ii)** the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Clinical Trials

The clinical trial definition has been expanded in The Revised Common Rule:

- "Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes".

  (This is the same definition used by NIH)

Public Posting of Informed Consent Documents in Clinical Trials

- Researchers conducting clinical trials will now be required to post clinical trial consent forms on a federal website "after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol."
- For a multi-site study, only a single consent Form from the entire study is required to satisfy the posting requirement – not a consent form from each participating site.
- There are two publicly available federal websites that will satisfy the consent form posting requirement in the Revised Common Rule: http://ClinicalTrials.gov and a docket folder on http://Regulations.gov.(Docket ID: HHS-OPHS-2018-0021). Further instructions and guidance from HHS and other federal agencies will follow, and additional federal websites that satisfy the posting requirement may be identified in the future.
- Reference: Revised Common Rule | Research at Brown | Brown University

EXEMPT/NONEXEMPT RESEARCH AND EXAMPLES

Section II

Exempt Human Subjects Research

- 1. Exempt human subjects research is a subset of minimal risk research involving human subjects that **does not require approval** by an IRB
- 2. However, does require a review and a final determination of the exemption category
- 3. There are categories which are defined by federal regulations

Exempt research is not subject to continuing review

- Reference: Brown University Human Subject Protection Program

Exempt Research Activities

Exempt research projects are reviewed to determine which exemption category they fall under.

- These activities must present **no more than minimal risk** and there are some restrictions.
- See the 8 categories on the following slides

❑Reference for Exempt Information:

Federal Register; Vol 83, No. 118, June 19, 2018

45 CFR 46.104 Categories of **Exempt** Human Subjects Activities

Exemption 1 Example

- 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
  - (a) research on regular and special education instructional strategies or
  - (b) research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

Exemption to Category #1: Based on the Revised Common Rule Regulations, the following has been added: " Not likely to adversely impact student's opportunity to learn required education content, or assessment of educators who provide instruction".

45 CFR 46.104 Categories of **Exempt** Human Subjects Activities

Exemption 2 Example

- **Exempt** activities that which only includes interactions involving:
  - Educational tests (cognitive, diagnostic, aptitude, achievement), or Survey procedures, Interview procedures of public behavior or observation of public behavior including visual or auditory recording).

Activities Not Allowed (nonexempt)

- A. Subjects can be identified, directly or through identifiers linked to the subjects
- B. **IF** any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation

Exemption to Category #2, based on the Revised Common Rule Regulations, the following has been added: Expanded to allow identifiable information (even if sensitive) to be recorded, provided that an IRB member conducts a limited review

45 CFR 46.104 Categories of Exempt Human Subjects Activities

Exemption 3 Example

- Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
  - Identify cannot be readily ascertained
  - Any disclosures outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the financial standing, employability, educational advancement
  - or reputation

Exemption to Category #3, based on the Revised Common Rule Regulations, the following has been added: New category for benign behavior interventions; must be brief in duration (in no more than 3 hours in total), harmless, painless, not physically invasive, no significant adverse lasting impact, and nothing offensive or embarrassing; allows for identifiable information (even if sensitive), provided limited review is conducted; this category does not include research with minors.

45 CFR 46.104 Categories of **Exempt** Human Subjects Activities

Exemption 4, Example

Secondary research for which consent is not required.

- The identifiable private information or identifiable biospecimens are publicly available.
- Activities involving only the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available ("Existing" means at the time the project is proposed.)

or

- the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects.

Exemption to Category #4, based on the Revised Common Rule Regulations, the following has been added

Expanded to include prospective data review (no longer limited to existing data only)

45 CFR 46.104 Categories of **Exempt** Human Subjects Research

Exemption 5, Example

- Research and demonstration projects which are conducted by or subject to the approval of (federal) department or agency heads and which are designed to study, evaluate or otherwise examine:
  - (a) public benefit or service programs,
    - (b) procedures for obtaining benefits or services under those programs,
    - (c) possible changes in or alternatives to those programs or procedures o
    - (d) possible changes in methods or levels of payment for benefits or services under those programs.
    - Each federal agency or dept must establish a public website for institutions to add a list of the research and demonstration projects

Exemption to Category #5, based on the Revised Common Rule Regulations.

"If **Restriction** is added, the project must be published on a federal website."

45 CFR 46.104 Categories of **Exempt** Human Subjects Research

Exemption 6, Example

- Taste and food quality evaluation and consumer acceptance studies, if:

  a. wholesome foods without additives are consumed,

  b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, OR

  c. agricultural chemical or environmental contaminant at/or below the level found to be safe, by the Food and Drug Administration OR approved by the Environmental Protection Agency OR the Food Safety and Inspection Service of the U. S. Department of Agriculture.

  No Exemption to Category #6:

Exempt Human Subjects Research

45 CFR 46.104

Exemption 7,

Storage, maintenance and secondary research for which broad consent is required

- If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data
- Storage or maintenance and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with specific requirements
- Broad consent is appropriately documented or waiver of documentation is appropriate

No Exemption to Category #7

Exempt Human Subjects Research
45 CFR 46.104

Exemption #8

8) Secondary research for which broad consent is required:

- Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

❑ An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

❑ The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Exemptions (2018 Requirements) | HHS.gov

Important reminders for Prisoners 45 CFR 46.305; 45 CFR 46.306(a)(2) (B) (C) (D)

Exemptions **do not apply** to research involving prisoners

- The risks involved must be equal to that for non-prisoner volunteers;
- Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.
- Present information in language which is understandable
- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole
- Each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
- Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination

SUSPENSION OR TERMINATION OF IRB APPROVAL OF RESEARCH

Section III

Suspension or Termination of IRB Approval of Research

- Research that is not being conducted in accordance with IRB's requirements

- Research that has been associated with unexpected serious harm to subjects.

Note: The IRB will include a statement of the reasons for such as above

HUMAN SUBJECT ETHICS TRAINING

This is for all persons involved.

Collaborative Institutional Training Initiative (CITI) Program

The Trusted Standard in Research, Ethics, Compliance, and Safety Training

- All persons are required to complete the Collaborative Institutional Training Initiative (CITI) Program Training in human subject protection **prior to** conducting research using human subjects.
- CITI serves the training needs of colleges and universities, healthcare institutions, technology and research organizations, and governmental agencies, as they foster integrity and professional advancement of their learners.

CITI PROGRAM

Human Subjects Ethics Training

- CITI is an on-line training program and can be found at www.citiprogram.org
- The training applies regardless of whether such research receives external funding and it applies to all academic levels.
- The IRB requires researchers who have active protocols to complete human subjects training every three years AND Alternate basic and refresher courses every four years.
- **Training is required for both exempt and nonexempt research involving human subjects.**

Collaborative Institutional Training Initiative (CITI)

- Web-based training
- CITI Program's Responsible Conduct of Research (RCR) series consists of:

1) a basic course, complemented with a set of additional modules of interest, and

2) a refresher course

- Both courses contain modules that cover core norms, principles, regulations, and rules governing the practice of research

Questions/Concerns??

Thank you for your time and attention

- **Questions**
- **Discussion**
- **Contact Information for Dr. Mildred Huff Ofosu; milhuff@yahoo.com**

Human Subject Definition

- IRB is required when conducting "research" with "human subjects"

A human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research (a) obtains information or biospecimens through **intervention** or **interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or (b) obtains, uses, studies, analyzes, or generates **identifiable private information or identifiable biospecimens**.

•**Intervention** includes both physical procedures by which information or biospecimens are gathered (e.g., 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

•**Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

•**Identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Research Definition

- Research is defined as a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**.
- **Systematic investigation** is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.
- **Generalizable knowledge** relates to drawing general conclusions, informing policy, or generalizing findings beyond a single individual or an internal program (e.g., publications or presentations.)
- Activities that meet this definition constitute research whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.