

# Housekeeping notes:

- Please sign in and grab your lunch ticket!
- Enjoy the music and your lunch!
- Please complete the evaluation survey for the QI purposes.
- And Buckle UP !!!!!!!!!!!!!!!!



**BUCKLE UP !!**  
**Revised IRB Common Rule**  
**is**  
**HERE**

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# Training Objectives

1. Become familiar with the IRB Revised Common Rule
  - a) Purpose
  - b) The changes that impact **BU** directly
  
2. Understand the Implementation of the changes
  - a) Policy and Procedures
  - b) IRB Forms
  - c) Business Process

- 1. Become familiar with the IRB  
Revised Common Rule**

# The purpose of revised Common Rule

- To strengthen protection of human subjects while decreasing administrative burden.

# Direct Impact for Butler Research Community

- Effective Dates
- Definitions of Research and Human Subjects
- **Exclusions** and Exemptions
- Informed Consent
  - **Broad Consent**
- **Limited IRB Review**
- Continuing Review

# Effective Date

**01/21/2019**

“Old” rules will apply to ongoing research.

# Definitions

- **Human Subjects:** a living individual about whom an investigator (whether professional or student) conducting research:
  - (i) Obtains **information or biospecimens** through intervention or interaction with the individual, **and uses, studies, or analyzes the information or biospecimens;** or
  - (ii) **Obtains, uses, studies, analyzes, or generates** identifiable private information or **identifiable biospecimens.**”
- **Research:** What’s NOT research - “Exclusions”.  
*a systematic investigation, including research development, testing and evaluation, **designed to develop or contribute to generalizable knowledge.***



# Exclusion

- Exclusion: “Not Research”

Scholarly and  
journalistic activities

Public health  
surveillance activities

Collection of  
information for criminal  
justice purposes

Operational activities in  
support of homeland  
defense, national  
security missions.

# New Exemptions

1. Educational research
2. Interactions: educational tests, surveys, observation of public behavior
3. Benign behavioral intervention
4. Secondary research for which consent is not required
5. Federal research and demonstration projects
6. Taste and Food quality
7. Storage or maintained for which broad consent is required
8. Secondary research for which broad consent is required

# Exemption 1: Restriction Added

Normal Educational Practices in established or commonly acceptable educational settings.

Restrictions:

Normal educational practices that are not likely to adversely impact:

- Students' opportunity to learn required educational content or
- The assessment of educators who provide instruction.

# Exemption 2: Expanded

Research that **only** includes interactions involving educational tests, surveys, interviews, and observations of public behavior, exempt, when:

- i. Information recorded cannot be readily linked back to the subjects, OR
- ii. Any information disclosure would not place subjects at risk of harm (the risk of criminal or civil liability or be damaging to the subjects' financial, employability, **educational advancement**, or reputation, OR
- iii. **Identifiable information recorded, with limited IRB review for privacy and confidentiality protection.**

***#No children is allowed.***

# Exemption 3: Removed & Replaced with new

- Removed: Almost all research related to public officials would be deemed not to be research or Exempt #2.
- New Exemption #3: Research involving benign behavioral interventions with adults who prospectively agree when information collection is limited to verbal or written responses (including data entry) or audiovisual recording, and:
  - i. Information recorded cannot be readily linked back to the subjects, OR
  - ii. Any information disclosure would not place subjects at risk of harm (the risk of criminal or civil liability or be damaging to the subjects' financial, employability, educational advancement, or reputation, OR
  - iii. Identifiable information recorded, with limited IRB review for privacy and confidentiality protection.

# Exemption 3, Cont'd

- **Benign behavioral interventions:**

These are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and investigators has no reason to think the subjects will find the interventions offensive or embarrassing.

Example: having subjects play an online game, having them solve puzzles under various noises etc.

- **Allows authorized deception research through prospective agreement.**
- **May not be used for research involving children.**

# Exemption 4: Expanded & Added New

**Secondary Research:** Research use of information or biospecimens collected for research studies other than proposed one, or non-research purposes.

Secondary research use of identifiable private information or identifiable biospecimens (**materials no longer need to be existing**) if one of the following criteria are met:

- i. They are publically available, OR
- ii. Information, which may include information about biospecimens, is recorded by the investigators in such manner that the identify of the human subjects cannot be readily ascertained directly or through identifiers linked to the subjects, **the investigators does not contact the subjects or re-identify subjects**, OR
- iii. **Investigators' use is regulated under HIPAA as "health care operations", "research" or "public health", OR**
- iv. **Research is conducted by, or on behalf of, a Federal agency using nonresearch purposes data which is protected by federal privacy standards.**

# Exemption 7 and 8: New

- **Exemption 7: Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research**
- **Exemption 8: Secondary research using identifiable private information or identifiable biospecimens.**

Both require:

- **Broad Consent.** Investigator should ask permission on the consent whether or not to allow secondary research use of the subjects' identifiable materials.
- **Limited IRB Review.** No change at BU since all research are reviewed by IRB Member.



# Continuing Review

## Not required for:

1. Exempt research requiring limited IRB Review.
2. Research approved by Expedited Review
3. Research has completed interventions and only involves:
  - Analyzing data
  - Accessing follow up clinical data from clinical care procedures.

IRB can require Continuing Review, but it has to be documented.

## **2. Understand Implementation of the changes**

# Policy and Procedures

- The IRB committee and BIRS office have revised the IRB SOP to reflect the changes.
- The revised SOP is posted on the BIRS website. **AND** the old SOP will remain in our website for research that is approved prior to new rule.

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## INSTITUTIONAL REVIEW BOARD

At Butler University, responsibility for overseeing the policies and procedures for the protection of human subjects in research resides with the Provost/Vice President for Academic Affairs. Relevant functions and responsibilities include the development of an institutional policy, establishment of procedures to ensure protection for human subjects in research, continuing education of personnel with respect to the policy, modification of the policy to maintain its conformity with laws and regulations, and provisions of appropriate administrative support and legal assistance for the IRB. Management of compliance and maintenance of records also occurs under the aegis of the Office of the Provost, within the Butler Institute for Research and Scholarship (BIRS).

The IRB is the institutional body that governs the procedures to be used in research with humans, including protocol approvals as well as suspensions and terminations. The board ensures compliance with the Code of Federal Regulations and the Federal wide Assurance, a declaration of compliance for the protection of human subjects in research. Butler IRB members are appointed by the Provost/Vice President for Academic Affairs for three-year staggered terms.

Butler IRB policies prior to January 21, 2019.

Revised IRB policies, effective January 21, 2019.

# IRB Forms

- The IRB Exemption form has been revised to reflect the changes.
- It is posted on our website to replace the old form.

# Business Process

- The pre-new rule approved research will be grandfathered to remain under the rules in place at the time of approval
- For the currently approved Expedited research, during the next continuing review, the IRB will determine if it will require continuing review in the following year or not.
- We've been applying "Limited IRB Review" process by having the IRB Member review all IRB application regardless the level of review.

# STAY TUNED!

- BIRS Lunch and Learn
  - Consent and Waiver of Consent

**Questions or Comments ???**

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