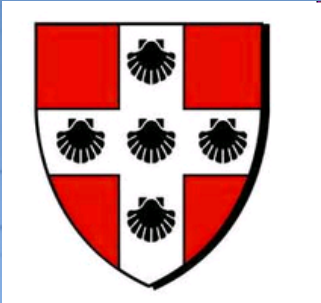


# The Revised Common Rule



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## What is research?

- A systematic investigation designed to develop or contribute to generalizable knowledge or prediction; and involving human subjects

## What is a human subject?

- An individual from whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual

## What is the Common Rule?

- Federal policy for protection of human subjects (45 CFR 46)
- Revised Common Rule went into effect on January 21, 2019



# Examples of what is *NOT* research

- Scholarly and journalistic activities that are designed solely to create a record of the specific event(s) or individual(s)
- Service or course evaluations, unless they can be generalized to other individuals
- Services, courses, or concepts where it is not the intention to share the results beyond the Wesleyan community
- Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
- Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the Wesleyan community.

# Main Common Rule Revisions

## Continuing review

- No longer required for most minimal risk research that has undergone expedited review
- Researchers complete an annual Project Update Form

## Exemptions

- Revised terminology and criteria
- New exemption for *benign behavioral interventions*

## Informed consent

- Some rearrangement of content to improve potential participants' understanding of the research so that they can make a more informed decision whether to participate

## Single IRB of record (sIRB)

- IRB oversight for most federally-funded collaborative research will be required to use a single IRB starting January 20, 2020\*

\* already required for NIH funded research

# Continuing Review



*Researchers still need to complete an annual Project Update Form!!*

- **No longer required** for most minimal risk research that has undergone expedited review
- **No longer required** for any study that has **completed subject intervention/interaction** and activity is limited to final **analysis of identifiable information or biospecimens**

## Exemption 1: Educational Exemption

- Research conducted in educational settings that involves normal educational practices, *so long as the research is not likely to adversely affect (a) students' opportunity to learn required content or (b) the assessment of teachers*
- An **educational setting** is any place where educational activities regularly occur
- **Normal educational practices** are activities that typically occur in a classroom or other educational setting.

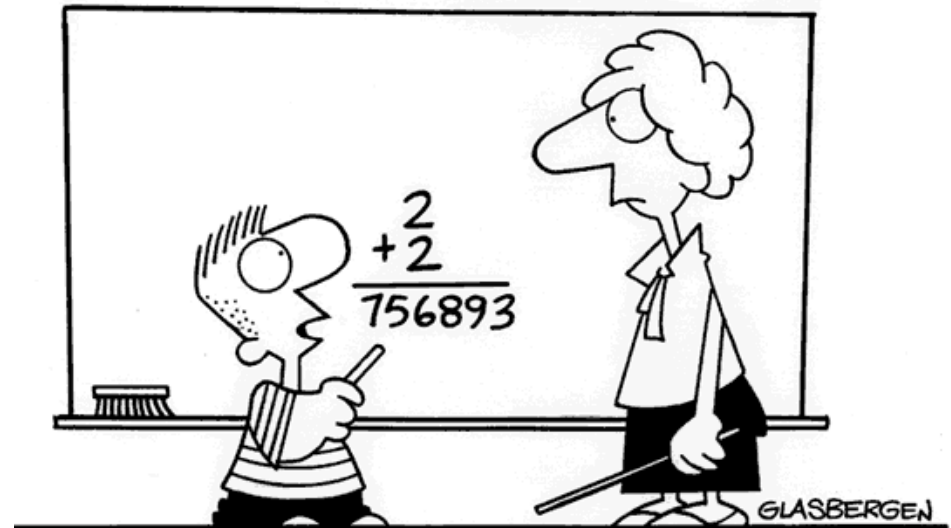
# Exemption 1: 45 CFR 46.104(d)(1)

In order to qualify for Exemption 1 research must not:

Take time or attention away from normal instruction in a way that might negatively affect student achievement **-OR-**

Impact individual teachers in a way that could adversely affect assessment of their practice or performance.

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**“In an increasingly complex world,  
sometimes old questions require new answers.”**

## Exemption 2: Surveys, Interviews, Educational Tests, Focus Groups, and Observation of Public Behavior

- Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior if:
  - Information is collected anonymously. No one, not even members of the study team, has the ability to link data with individual subjects at any time, directly or indirectly. **-OR-**
  - The study does not collect sensitive information about subjects that could place them at risk if inadvertently disclosed outside the research. **-OR-**
  - *Sensitive, identifiable information is collected, but the research has undergone “Limited IRB Review” to ensure that adequate protections are in place to protect subject privacy and the confidentiality of data.*



# Exemption 2: 45 CFR 46.104(d)(2)

**Sensitive information** includes, but is not limited to:

- Illegal activities
- Genetic or medical information
- Sexual behaviors
- Negative attitudes/opinions about one's instructor, employer, or coworkers

**Risks** include, but are not limited to:

- Criminal liability
- Social stigmatization
- Loss of job or poor review
- Other negative impacts

## **Limited IRB Review**

- IRB must review and approve procedures for data management and security where sensitive information is collected with direct identifiers or indirect identifiers

## Exemption 3: Benign Behavioral Intervention

- *Research involving benign behavioral interventions with adults who prospectively agree to the research, when the information collected is limited to verbal or written responses, including data entry or audiovisual recordings if:*
- Information is collected anonymously. No one, not even members of the study team, has the ability to link data with individual subjects at any time, directly or indirectly. **-OR-**
- The study does not collect sensitive information about subjects that could place them at risk if inadvertently disclosed outside the research. **-OR-**
- Sensitive, identifiable information is collected, but the research has undergone “Limited IRB Review” to ensure that adequate protections are in place to protect subject privacy and the confidentiality of data.

## Benign behavioral interventions must be:

- Brief in duration
- Harmless
- Not physically invasive
- Not likely to pose a significant, lasting adverse impact on subjects
- Not offensive or embarrassing

## Examples:

- Performing cognitive tasks
- Providing educational materials to participants with the intention of changing their behavior
- Playing online games or economic games
- Exposure to stimuli such as color, light or sound at safe levels
- Solving puzzles under various noise conditions

# Exemption 3: 45 CFR 46.104(d)(3)

## Other requirements for Exemption 3:

- Only applies to adult participants
- The investigator must describe the intervention and data collection procedures to potential subjects and seek their **prospective** agreement to participate.
- Concealment or deception is not allowed unless subjects are told prior to their participation that they will be unaware or misled about the nature or purposes of the research and they agree to participate.

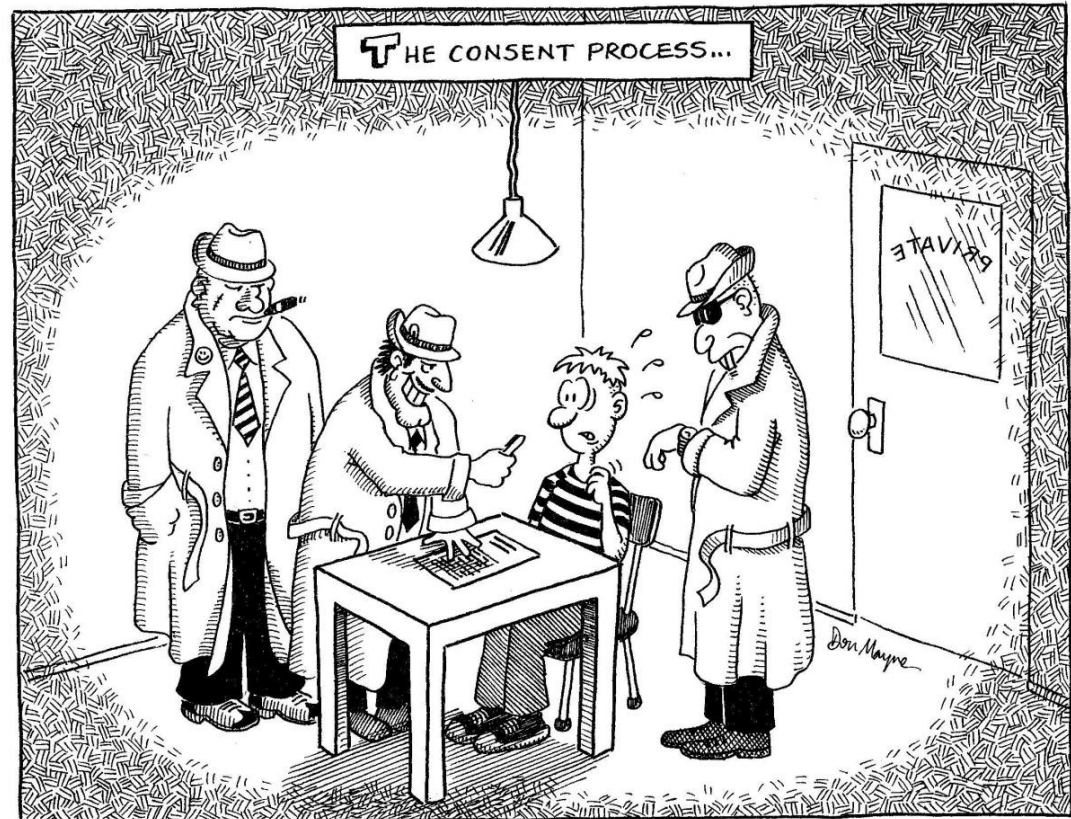


## Exemption 4: Secondary Research with Identifiable Private Information and/or Biospecimens

- Research involving the collection or study of data, documents, records, pathological specimens, or biospecimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. *This exemption also applies to research using identifiable private information or identifiable biospecimens, if:*
  - *The identifiable private information or identifiable biospecimens are publicly available*
  - *Information is recorded by the investigator such that:*
    - *participants cannot be identified directly or through identifiers linked to the subjects*
    - *the investigator does not contact the subjects*
    - *the investigator will not re-identify subjects*

# Informed Consent

- Revised to improve participants' understanding of the research so that they make a truly informed decision about whether to participate
- Must begin with a concise and focused presentation of key information
- **Broad consent** may be requested **only** for the storage, maintenance, and secondary use of identifiable private information or biospecimens for future, yet-to-be-specified research. Investigators must 1) identify the types of research that may be conducted, 2) record and track who has agreed to or refused consent, and 3) track the terms of consent



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# How do I submit a protocol for review?

Wesleyan IRB:

- Go to the Wesleyan IRB web site:

<https://www.wesleyan.edu/acaf/support/reviewboard.html>

- Scroll down to **SUBMISSION MATERIALS** and click on the **new Description of Research Form**
- Complete the form and e-mail the form and other study materials (consent forms, questionnaires, etc) to **irb@wesleyan.edu**
- Any changes in the research protocol have to be approved by the IRB/Ethics Committee before being implemented.
  - Complete and submit a **Change of Protocol Form**
- IRB approval is valid for 1 year. If study continues beyond the 1 year approval period, then a **Project Update Form** must be submitted for research not requiring continuing review. A **Project Continuation Form** must be submitted for research requiring continuing review.
- Use the available consent form template.