Institutional Review Board
THE NEW COMMON RULE
- New Rule Timeline / Basics
- Definitions and Overview
- Final Rule Changes Not Related to Exemptions
  - Informed Consent / Informed Consent Forms
- Final Rule Changes – Exemptions
- Limited IRB Review
- Continuous Reviews
- Single IRB (sIRB)
Timeline

- All activity before January 21, 2019 must comply with the old common rule.
- Studies started on/after January 21, 2019 MUST comply with the New Rule.
- Single IRB (sIRB) requirements are not required until January 20, 2020.
Why are these changes being made?

- To better protect and inform potential and recruited human subjects for research purposes.

- To reduce administrative and unnecessary burden currently required for researchers.
IRB Flowchart

- Is it research?
  - No → STOP
  - Yes → Does it involve human subjects?
    - No → STOP
    - Yes → Is it exempt?
      - Yes → STOP
      - No → IRB review

OHRP recommends investigators not make the determination
Key Change Overview

- Definition of Research
- Definition of Human Subject
- Informed Consent
- Exemptions
- Expedited Reviews
- Continuing Review
- Single IRB (sIRB)
- Other changes
Systematic inquiry leading to generalizable knowledge. (Generalizability is not intent, but design).

No changes to the definition; however, specific approaches deemed to *NOT* be research were listed:

- Scholarly or journalistic activities with focus on individual(s) – (e.g., case study, self-study designs). This excludes certain activities, not entire fields.

- Public health surveillance activities.

- Collection of information for criminal justice statistic purposes. (Bureau of Justice Statistics)

- National security data collection.
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**Human subject** - a living individual about whom an investigator conducting research either:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; OR

2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
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Informed Consent - Overview

1. General Improvements to Informed Consent
2. Broad Consent
3. Posting of Consent Form for Clinical Trials
4. Waiver and Alteration of Informed Consent
The revised Common Rule explicitly establishes a new standard:

To provide the information that a reasonable person would want to have in order to make an informed decision about whether to participate or not.
Consent forms must have a section presented FIRST that is focused on providing concise and focused presentation of key information regarding why one might or might not want to participate (executive summary)...and...

Must contain notice about possible future research use of information or biospecimens with identifiers:

- Notifying prospective subject that subjects’ information or biospecimens could be used for future research without additional consent; or

- Notifying prospective subject that subjects’ information or biospecimens will not be used for future research.
Consent Form (con’t)

Common additional elements:

▪ Notice about whether clinically relevant research results, including individual research results, will be given to subjects, and if so, under what conditions

▪ Notice about possible commercial profit, and whether subject will share in this profit (for research involving biospecimens)

▪ Notice about whether research might include whole genome sequencing (for research involving biospecimens)
Broad Consent

- Only applies to:
  - The storage, maintenance, and secondary use of identifiable private information, or biospecimens
  - For information collected for a different research study, or for non-research purposes.
  - Has very specific guidelines about future use
  - Is *NOT* equivalent to “Blanket” consent
Federally funded research must post the consent form on a publicly available government website and must remain until 60 days after the last subject is recruited.
Waiver/Alteration of Consent

- Researchers must show that obtaining consent is not practical and other methods could not be used.
- Altered / Short Form consent remains an option
- Waiver of Documented Consent is also an option
- These must be justified, and convenience is not an acceptable justification
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## Exempt Categories - Overview

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Exemption 1 – Educational Practices

Normal educational practices in established or commonly accepted educational settings that are not likely to adversely impact:

- Students’ opportunity to learn required educational content, or
- The assessment of educators who provide instruction
Exemption #2: Surveys, etc.

- Educational tests, surveys, interviews, and observations of public behavior exemption when:
  - Information recorded cannot be readily linked back to subjects, OR
  - Any information disclosure would not place subjects at risk of harm, OR
  - Identifiable information recorded with limited IRB review for privacy and confidentiality protection
  - Not applicable to children or prisoners
Exemption #3: Benign Behavioral Interventions

- New exemption for 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:
  - Information recorded cannot be readily linked back to subjects, or
  - Any information disclosure would not place subjects at risk or harm, or
  - Identifiable information recorded with limited IRB review for privacy and confidentiality protection
- Does not apply to children or prisoners
Benign Behavioral Intervention?

- These are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
- Includes authorized deception research.
Exemption #4 – Secondary Data

Secondary research use of identifiable private information or identifiable biospecimens (materials no longer need to be “existing”) if:

1. Identifiable private information or identifiable biospecimens are publically available, OR

2. Information (which may include information about biospecimens) is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects or re-identify subjects, OR
Exemption 4 (con’t)

Secondary research use of identifiable private information or identifiable biospecimens for which consent is not required, if:

3. Investigator’s use is regulated under HIPAA as “health care operations,” “research,” or “public health” OR

4. Research is conducted by, or on behalf of, a Federal agency using data collected or generated by the government for non-research purposes, and the information is protected by federal privacy standards

**Applies to children, but not prisoners**
Exemption 5 - Public Benefit

- Public benefit and service programs research and demonstration projects:
  - Expanded to apply to such federally-supported research; no longer limited to federally-conducted research
  - Added requirement that Federal agency publish a list of projects covered by this exemption prior to commencing the research
Exemption 6 – Consumer / Food

- Taste and food quality evaluation and consumer acceptance studies
Exempt 7 & 8 – Future Use

- 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
- Requires Limited IRB Review
Limited IRB Review

- For privacy and confidentiality protection
- For other safeguards related to privacy and confidentiality protection, and broad consent
**Expedited Continuous Review**

- In general, no continuing review required for:
  - Research approved by expedited review
  - Exempt research requiring limited IRB review
  - Research has completed interventions and only involves:
    - Analyzing data, including analyzing identifiable private information or identifiable biospecimens
    - Accessing follow-up clinical data from clinical care procedures
- Review period can be set by protocol or a general policy can be created
- IRB can override this default and require continuing review, but this must be documented in the standard operating procedures.
Duquesne University has set the default review for Expedited protocols at three (3) years from the initial approval date, and every three years following.

- Researchers are expected to terminate their protocol once the research is completed.
- The university reserves the right to make the continuous review period shorter at their discretion. The researcher will be notified of the shortened review period and the rationale for the alteration.
More attention will be needed to prevent coercion of vulnerable subjects

Pregnant women are no longer considered “vulnerable”

Persons with physical disabilities (previously referred to as ‘handicapped’) are no longer considered vulnerable subjects

Those with intellectual or cognitive impairments are vulnerable subjects, but does not automatically make them full board

Prisoners and children remain the two main vulnerable groups

The consent process is critical
Vulnerable Subjects (con’t)

- **Children**
  - Defined as those under the age of 18 years old
  - There are two EXEMPT categories that can be used with children as long as the criteria for these categories are met:
    - Educational Practices
    - Secondary Research

- **Prisoners**
  - Defined as an individual being physically placed in detention or residency against their own free will (e.g., jail, prison, treatment facility, etc.)
  - Probation / Parole do not constitute a prisoner vulnerability under the regulations since they are not being physically placed against their free will. However, Duquesne still seeks additional protections for these groups.
Single IRB (sIRB)

- **Applicability**
  - U.S. institutions engaged in cooperative research for the portion of the research conducted in the U.S.

- **Does not apply:**
  - When more than single IRB review is required by law (including tribal law)
  - Whenever any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context – flexibilities allowed
Single IRB (sIRB)

- **One IRB Review across multiple institutions**
  - Duquesne MAY be the IRB of record OR
  - Duquesne may RELY on another IRB of record
  - Both institutions must agree and sign the IAA
  - Typically, the PI’s institution is the IRB of record
- **Data Use Agreement**
  - Used to give permission from one institution or researcher to use data collected at a different site where the other site/research owns the data
  - Typically in the form of a letter
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Agenda

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