# Human Subjects Protections

## A Regulations Update

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# What will we talk about?

- The regulations (the Common Rule)
- The bigger picture—a human subjects ethical and regulatory framework
- A look at the current and revised regulations, and their impact
- Anything you would like to talk about…

# Before we get started…

I believe the culture at Grinnell College points us in the right direction when it comes to protecting people who participate in research, and it also encourages and promotes excellence and integrity in research.

Why?  Because of our core values: excellence in education, diversity and social responsibility

Examples:

- Active scholarship in traditional and interdisciplinary fields.
- Personal, egalitarian, and respectful interactions among all members of the college community.
- Our strong tradition of social responsibility and action.

# What is the Common Rule?

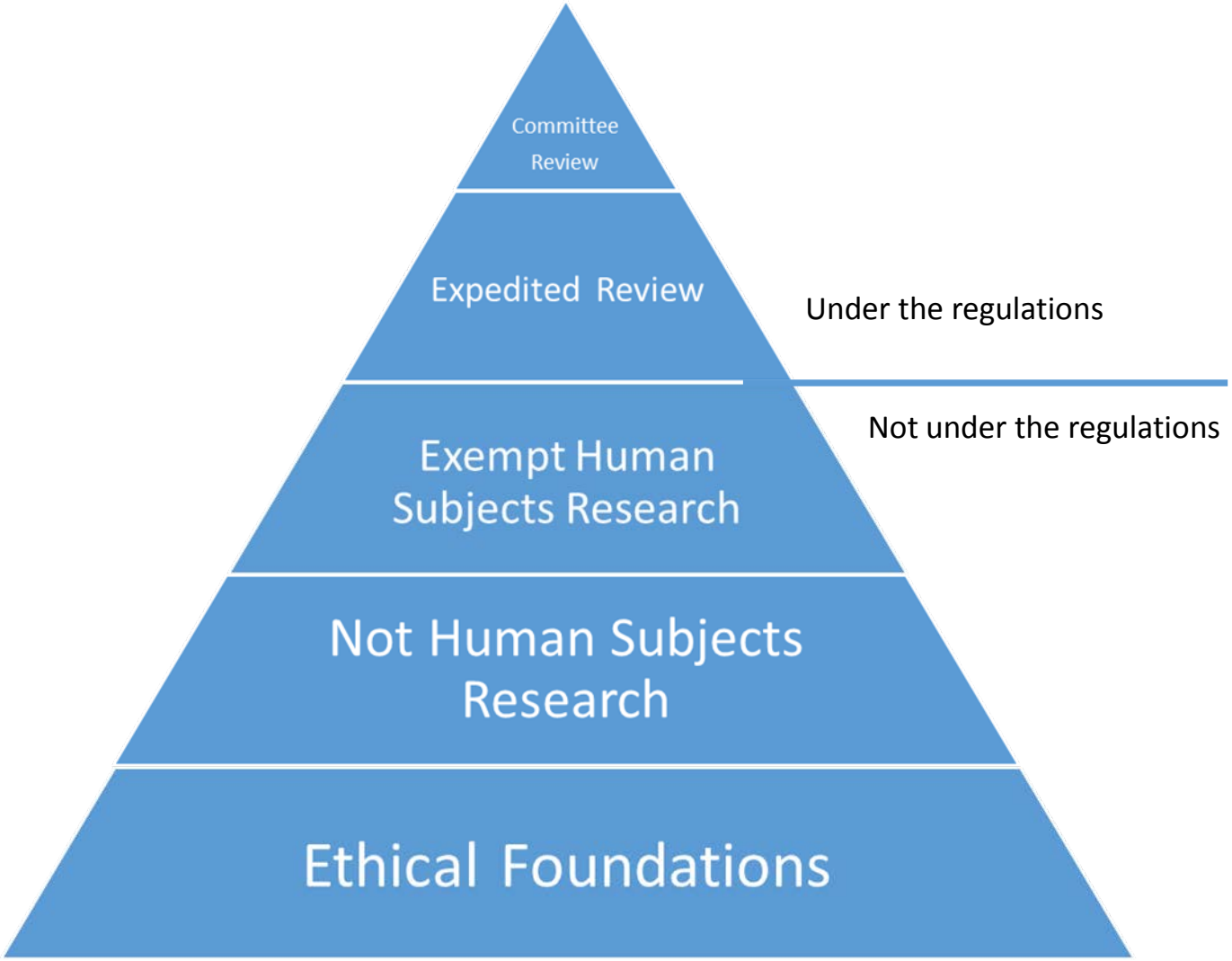
- The “Federal Policy for the Protection of Human Subjects,” our regulations protecting human subjects
- We use 45 CFR 46, issued by the Dept. of Health and Human Services (HHS), enforced by the Office for Human Research Protections (OHRP)
- Adopted by 18 federal agencies and appearing in 14 other places in the Code of Federal Regulations
- Only applies to federally-supported research, however…
- Part A only
- Other regulations for protecting human subjects are promulgated by the Food and Drug Administration (FDA)

# Brief history of human subjects regulations

- 1979, Belmont Report (ethical foundation for human subjects research)
- 1981, HHS and FDA regulations
- 1991, The Common Rule
- 2011 “Advanced Notice of Proposed Rulemaking”
- 2015 “Notice of Proposed Rulemaking”
- January 19, 2017 Final Rule, to be implemented 1/19/18
- January 17, 2018, announcement of delay in implementation to 7/19/18

- ~~July 19, 2018~~ January 21, 2019 implementation (published on 4/20/18)

# A representation of the ethical and regulatory (and procedural) framework for characterizing human subjects research.



# A summary of the revised Common Rule

- To be effective ~~July 19, 2018~~ January 21, 2019
- Revised definitions, and carve-outs for “not human subjects research” (can implement early)
- New and revised exemptions
- “Limited review”
- Tweak to regulations for incarcerated individuals
- No continuing review is required for many studies (can be implemented early)

# Definition of Human Subjects Research

***(New language is in red.)***

***Human subject*** means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains ~~data~~ 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*** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

*The following activities are deemed not to be research*: 1) oral history, journalism, biography, literary criticism, legal research, historical scholarship, 2) health surveillance, 3) criminal investigation, and 4) operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

# Exemptions, an overview

## Current:

1. “Scholarship of teaching and learning;”
2. Educational tests, surveys, interviews, and observation (with 2 conditions);
3. Surveys/interviews of elected or appointed officials;
4. Use of existing data, documents, specimens (2 conditions);
5. Activities that a federal agency (or law) declares to be exempt; and
6. Food tasting.

## Revised:

1. “Scholarship of teaching and learning;”
2. Educational tests, surveys, interviews, and observation (with 3 conditions);
3. Benign behavioral interventions, with conditions;
4. Secondary research (2 conditions);
5. Activities that a federal agency (or law) declares to be exempt;
6. Food tasting;
7. Establishment of a data/specimen archive with broad consent; and
8. Use of data/specimen archives, established under #7.

# A look at the old and new exemptions:

Exemption 2 (current): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Exemption 2 (revised): Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by Sec. __.111(a)(7).

**Note:** Minors in this exemption only can be part of public observation with no intervention.

# Old and new exemptions (continued):

**Exemption 3** (current): Surveys and interviews of elected and appointed officials.

**Exemption 3** (new): (i) 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:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by Sec. __.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

# Limited review

45 CFR 46, Section 111(a)(7): “When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.”

An investigator should design experiments that respect an individual’s privacy.

When an investigator is collecting identifiable data, and release of the data could put an individual at risk (i.e., there is an “information risk”), a limited review is conducted to make sure that data security protections are in place to reasonably assure that the individual’s confidential information is secure.

Note: Grinnell College (and every other college) already does this review. Now projects that provide data security and privacy assurances are EXEMPT, as opposed to expedited.

# A look at the old and new exemptions (continued):

**Exemption 4** (current): Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, 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

**Exemption 4** (revised): Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

# Changes to continuing review requirements

Currently, all HSR activity falling under the regulations is subject to continuing review after one year. The IRB can require that continuing review occur earlier than one year.

Under the revised regulations, continuing review is no longer required for minimal risk research, i.e., all research reviewed using an expedited procedure.

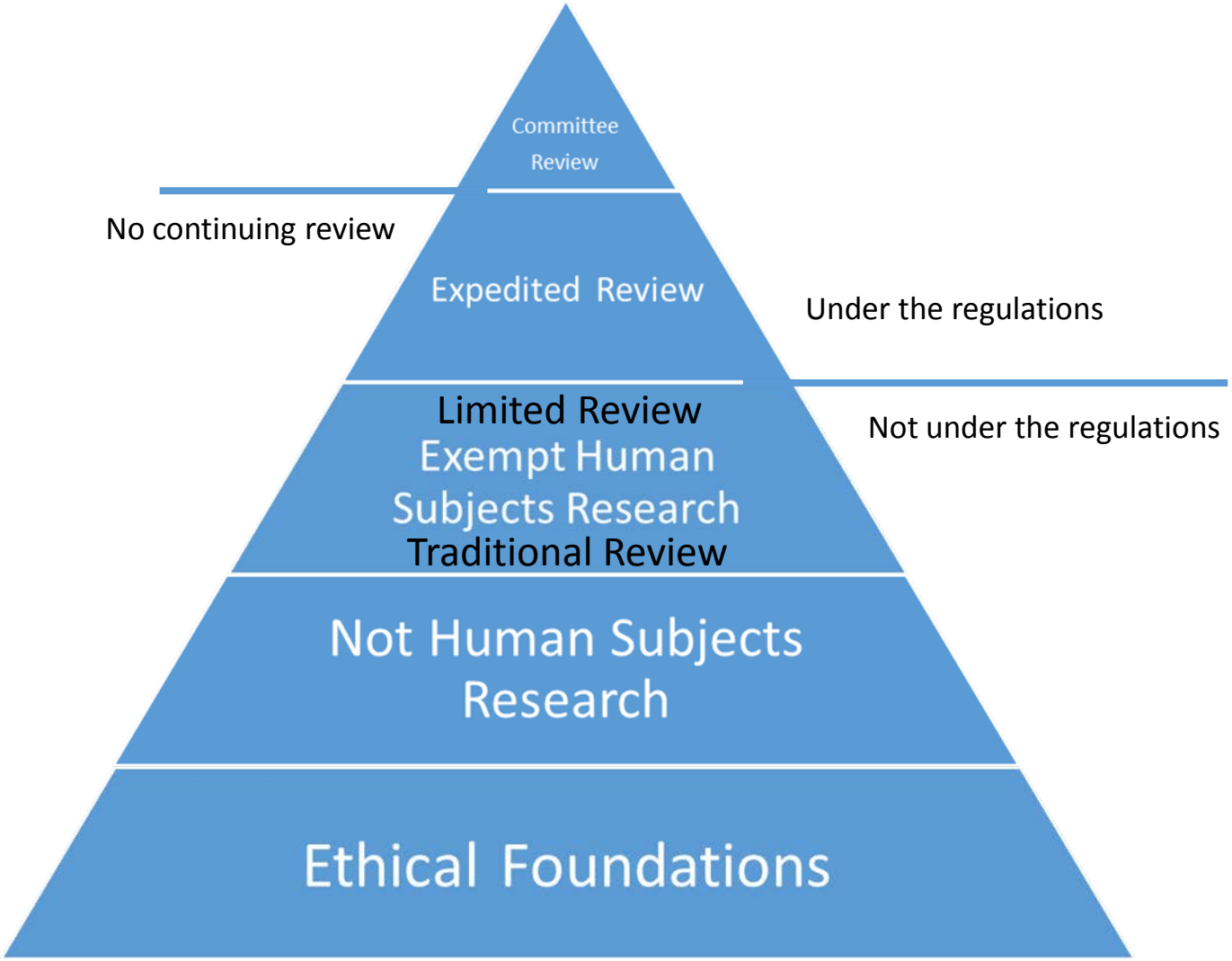
Perhaps we default **student** research to one year?

Researchers should tell the IRB that their research has concluded, in order that we can close a study.

# Incarcerated individuals

- If a study is designed for a certain population, and one or two of the individuals in the population are incarcerated either before or during the study, the prisoner regulations do not need to be applied.
- The individuals who became incarcerated can continue in the study. The use of prisoners is not the focus and the involvement of them is considered “incidental.”

# A representation of the ethical and regulatory framework for characterizing human subjects research (revised regulations).



# Implications for Grinnell College

- Most of our research falls under the exempt and expedited review categories.  There will be no continuing review requirement for almost all of this research.
- Some survey/interview research will move from “expedited” to exempt. (increase exempt 2, decrease expedited 7).
- Some research from psychology (benign behavioral interventions) will be exempt. (decrease expedited 7)
- More data will fall under exempt 4, decreasing expedited 5 & 6.

# Help with human subjects protections questions/concerns

- This presentation, should we do more?
- I’m always available to speak to your students…
- The IRB, and Marna Montgomery
- Revised IRB form and revised reviewer checklist
- A tool to help folks decide if their research meets the definitions of ‘human subject’ and research
- Exempt determination tool?