Summary of Changes in the Revised Common Rule

1. **New definition of human subjects:**

   A living individual about whom an investigator 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

   [Old definition: A living individual about whom an investigator obtains one or both of the following: 1) Data through intervention or interaction with the individual, or 2) Identifiable private information about the individual]

2. **New definition of Intervention:**

   Both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject's environment that are performed for research purposes

   [Old definition: Physical procedures by which data are gathered and manipulations of the subject or the subject's environment are performed for research purposes]

3. **Listing of activities deemed not to be research:**

   Scholarly and journalistic activities, including the collection and use of information, that focus directly on the specific individual about whom the information is collected.

   Examples include but are not limited to:

   - Oral History
   - Journalism
   - Biography
   - Literary Criticism
   - Legal Research
   - Historical Scholarship

   Further OHRP guidance on such activities:
   "Although activities described in [this] category may sometimes be performed in such academic fields as anthropology or sociology, a significant portion of the activities that are characteristic of these fields fall outside of [this] category and therefore remain within the scope of [the regulations]. Studies using methods such as participant observation and ethnographic studies, in which investigators gather information from individuals in order to understand the beliefs, customs, and practices, not only of those individuals, but also of the community or group to which they belong, would not meet [this] category. The purpose and design of such studies or activities is to reveal something about the community or group – that is, to develop generalizable knowledge. Because the purpose of such studies or activities is not to limit the inquiry to knowledge about the particular individuals being observed, the protections provided by the requirements of [the regulations], such as the requirement to minimize any harm to the specific individuals from which the information was collected, are appropriate. Such activities would continue to fall within the scope of the definition of "research" under the 2018 Requirements."

4. **New definition of vulnerable subjects: Persons vulnerable to coercion or undue influence, such as**
    - Children,
    - Prisoners
    - ~~Pregnant women~~
    - ~~Mentally disabled persons~~
    - Individuals with impaired decision-making capacity
    - Economically disadvantaged
    - Educationally disadvantaged

5. **Increase in and changes to exempt research categories**

Change to exempt category #1
This exemption now includes the caveat that there must be no negative impact on subject's opportunity to learn required content or the assessment of the educational instructors.

Clarification to exempt category #2
This exemption is now explicitly limited to research involving interactions (verbal and written responses only – no interventions).

This exemption includes the opportunity for identifiable sensitive information to be collected provided a limited IRB review is conducted.

Completely new exempt category #3
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:

1. 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 though identifiers linked to the subjects.

2. 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.

3. 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.

Note: 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.

Note: 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 purpose of the research.

Significant change to exempt category #4:
This exemption has replaced the term Existing Data with the concept of Secondary Research. Data under this category is no longer required to exist at the time of IRB submission – data may be both retrospective and prospective.

Change to exempt category #5
This exemption has been updated to allow projects that are not only conducted by a federal agency, but are simply funded by a federal agency and includes projects that not only study/evaluate a program, but also improve the program being studied.

Completely new exempt categories #7 and #8
These exemptions involve the new concept of broad consent and the use of secondary research for which it is required. Brandeis University will not be implementing these exempt categories.

6. **The introduction of Limited IRB Review for exempt categories #2 and #3**

    - Limited IRB review must be conducted by a member of the IRB, but at Brandeis will be conducted within the HRPP office (by the Assistant Director of Research Integrity and Compliance).

7. **Additional elements of informed consent**

    - General elements of informed consent now include the future use of data, where the investigator must explain that data may be de-identified and retained for additional or subsequent research (or, if not applicable, that the data collected will not be distributed for future research, even with the identifiers removed).

    - Three additional elements to be used only when appropriate (generally for biomedical/ clinical research only).

8. **Additional criterion for the waiver of or alteration to informed consent**

    - The research could not practicably be carried out without the waiver

    - The research involves no more than minimal risk to the subjects

    - The waiver will not adversely affect the rights and welfare of the subjects

    - Whenever appropriate, the subjects will be provided with additional pertinent information after participation

    - If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format

9. **Additional category for the waiver of documented informed consent**

    - The consent document would provide the only link to the subject and the principal risk of the research would be a breach of confidentiality

    - The risk to the subjects is minimal and consent would not be required outside the research context

- The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained

10. **Informed consent forms must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research**

    - Note that this is not as relevant with social-behavioral (non-clinical/biomedical) research with inherently short consent forms.

    - We are setting a page limit of 3, after which such a presentation will be necessary (when appropriate).

11. **E-signatures are permissible**

    - This is not simply a matter of typing one's name. The electronic system must include a method to ensure that the person electronically signing the informed consent is the subject or LAR him/herself.

    - If verification is not possible, a waiver of documented informed consent must be requested.

12. **Subject must be provided with a physical copy of the informed consent form**

    - We assume this means that, if the investigator verifies the subject's ability to print out the form, this may be admissible.

13. **Grant congruency review is no longer required**

    - Note that it may still be required by some funding agencies.

14. **Obtaining information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects can be done without informed consent**

15. **Research that only incidentally includes prisoners may be exempt or expedited**

    - Protocols that focus on or actively recruit prisoners will still need to be reviewed by the full committee with a prisoner representative present.

16. **Rationale must be documented by expedited reviewer for why an application should be kicked up to full committee for review**

    - Rationale must explain why the research is not minimal risk.

17. **Continuing review of expedited research is no longer necessary**

    - If it is deemed necessary by the reviewer, the reason must be documented.

    - In lieu of continuing review, an annual email notification will ask researchers to close protocols if research is completed, and remind them to submit modification requests for any changes.

18. Continuing review is no longer necessary for (full-committee reviewed) research which has completed interventions and/or data collection, and only involves:

- Analyzing data, including analyzing identifiable private information or biospecimens.

- Accessing follow-up clinical data from clinical care procedures.

19. IRB review of exempt research

- OHRP continues to recommend that exempt determinations be made by someone other than the investigator, but this is not a requirement – it never was.

  OHRP FAQ on this subject:
  "The regulations do not require that someone other than the investigator be involved in making a determination that a research study is exempt. What they do require is that there be accurate determinations so that non-exempt research ends up being reviewed by an IRB. Because of the potential for conflict of interest in this situation, OHRP's long-standing recommendation is that investigators not be given the authority to make an independent determination that human subjects research is exempt."

20. Research *approved* prior to January 21, 2019...

- *May* continue to be reviewed based on the old rule or may be switched to the revised rule.

- *Will* be managed on a case-by-case basis at time of continuing review (default will be to switch).

  Why might we not switch them?

  - If continuing to consent subjects, changes to consent forms may need to be made (if changes are substantial, current subjects may need to be re-consented).

  - If the additional criterion for the waiver of or alteration to informed consent is not met.