Revised Regulations
Human Subject Research Protection

"2018 Requirements - Final Rule"
Implementation date 1/21/2019

Summary of Most Relevant Key Changes:

- **Exempt research is expanded to allow for collection of identifiable information or biospecimens, and new benign behavioral intervention research using adults is added.**
- **Expedited review is simplified to eliminate continuing review and allow for limited IRB review focused on privacy of participants and confidently of research data.**
- **Informed Consent is changed to include a required summary of key information at the beginning and a statement regarding possible future use of research data. Also, additional requirements are added regarding clinical and/or biospecimens research when applicable.**
- **Screening, recruiting, or determining eligibility of prospective participants can be done, under IRB review, without informed consent if it meets certain conditions.**
- **For waiving, altering or documenting consent, additional conditions are added.**
- **For federally funded clinical trials, a requirement for posting of an IRB-approved consent form used in the study is added.**
- **IRB grant review requirement is eliminated.**

(Note: The highlighted sections will be implemented by OU IRB starting 1/21/2019)

Detailed Summary of Most Relevant Key Changes:

- **Clarification of "Not Research"**
  - Scholarly and Journalistic activities
    - Focused on the specific individuals about whom information is collected (i.e. Biography, History, etc.)
  - Activities mandated by the government:
    - Public Health Surveillance activities
    - Collection of information for criminal justice purposes
    - Operational activities for national security purposes

- **Clarification of "Human Subject" and "Identifiable"**
  - Clarified by including "information or biospecimen"
  - "**Human Subject**" means 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.
  - "**Identifiable**" [materials] for which the identity of the subject is readily ascertained by the investigator or associated with the [materials].

- **Expanding Exempt Research** (Note: These changes will be implemented by OU IRB at a later time)
  - Exempt Category 1:

        - The following was added for clarification: Normal educational practices that are not likely to adversely impact:
            - students 'opportunity to learn required educational content, or
            - The assessment of educators who provide instructions
    - Exempt Category 2:
        - Included accounting for risk of "educational advancement"
        - Added using visual or auditory recording in observation of public behavior
        - A new section "iii" was added allowing the recording of identifiable information, with limited IRB review for privacy and confidentiality protection.
    - Exempt Category 3:
        - New category- 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 recordings if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
            - The information recorded cannot readily be linked back to subjects;
            - Any disclosure of information would not place subjects at risk of harm; or
            - Identifiable information recorded, with limited IRB review for privacy and confidentiality protection.
        - 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.
        - Includes authorized deception research.
    - Exempt Category 4:
        - Expanded to include <u>prospective</u> secondary research of <u>identifiable</u> private information or specimen (materials no longer need to be "existing") if:
            - The materials are publically available;
            - The information recorded cannot readily be linked back to subjects and the investigator does not re-identify subjects;
            - The use of the materials is regulated under HIPAA as "health care operations," "research," or "public health," or
            - Research is conducted by, or on behalf of, a federal agency using data collected or generated by the government for nonresearched purposes, and the information is protected by federal privacy standards.
    - New Exempt Categories 7 & 8 related to storage or maintenance for and use of secondary research for which "broad consent" is required (Additional HHS guidance is needed before implementation)
    - <u>Limited IRB Review</u>:
        - New- <u>limited expedited review</u> by an IRB member for research subjects privacy and data confidentiality protection.
        - Required for Exemptions 2(iii) and 3(i)(C) which involves recording of identifiable information
    - Prisoners Research- Exemptions apply **ONLY** when prisoners are included incidentally in research that aimed at involving a boarder subject population

- **Updating and Simplifying Expedited Review**

- Research on the Expedited category list unless the reviewer determines that the research involve more than minimal risk.
- Eliminating continuing reviews for the following:
  - Expedited research
  - Research requiring limited IRB review (new Exempt)
  - Research has completed interventions/interaction and follow-up and remains active only for data analysis including analysis of identifiable private information or identifiable biospecimen can be **closed**.

- **Changing Requirements of Informed Consent**
  - Key Information summary MUST be provided at the beginning
    - Concise and focused presentation of key information regarding why one might or might not want to participate
  - New Required Basic Element:
    - Future use of collected identifiable information or identifiable biospecimens. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
      - A statement that identifiers might be removed from the information or biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research without additional consent from the subject; OR
      - A statement that the subject's information or biospecimens, even if identifiers are removed, will not be used or distributed for future research)
  - New Additional Element "when appropriate":
    - A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
    - A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
    - For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
  - Additional conditions for waiving, altering or documenting consent:
    - For waiver or alteration of consent, additional conditions specifically related to identified private information or identifiable biospecimens is added.
    - For waiver of documentation of consent, an additional condition specifically related to distinct cultural group or community norm is added.

- **Facilitating Screening, Recruiting, or Determining Eligibility**
  - IRB may approve proposal for Investigator to obtain information or biospecimens to screen, recruit, or determine the eligibility of prospective subjects without informed consent, if the material is obtained through:
    - oral or written communication with the prospective subject; OR
    - accessing records or stored identifiable biospecimens

- **IRB grant review requirement is eliminated**
    - No need for the IRB to compare the IRB application to the grant application

- **Requirement for Posting of Consent Forms for Clinical Trials**
    - For Federal funded clinical trials, one IRB-approved informed consent form used to enroll subjects must be posted on a publicly available Federal website i.e. ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).
    - Must be posted after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.
    - Federal department or agency may permit or require redactions of the information posted.

- **Using Single IRB Review** (Implementation date is January 20, 2020)
    - Minimize duplication for collaborative research conducted at the US
    - Use IRB Authorization Agreement