Proposed Changes to the Common Rule

What is the Common Rule?

- Common Rule was published in 1991. It is a federal policy of the protection of human subjects.
- No proposed changes until now. So why the change?
- Proposed rules were published on September 8, 2015.
  - It is a 16-agency collaboration.
- Comment period was extended to January 6, 2016.
- And now we wait…
Changes to the Common Rule

- Improve the informed consent process.
  - What information must be given
  - How information must be given
- Require informed consent for the use of biospecimens in secondary research.
  - Biospecimens example: leftover blood sample that is leftover after being drawn for clinical purposes.
  - Applicable even if investigator cannot identify to whom the biospecimens belong.
  - Obtain a broad consent.

Changes to the Common Rule

- Exclude from coverage under the Common Rule certain activities considered to be low risk, protections usually provided by IRB is mandated elsewhere.
- Add additional categories of exempt research. These studies would require no administrative or IRB review.
- Change the conditions or requirements for waiver or alterations of consent.
- Mandate U.S. institutions engaged in collaborative research rely on a single IRB.
- IRBs may be held directly responsible for compliance with the Common Rule.
**Changes to the Common Rule**

- Eliminate the continuing review requirement for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing data or involve only observational follow-up in conjunction with standard clinical care.
- Extend the scope of the policy to cover all clinical trials, regardless of funding source, conducted at a U.S. institution that receives federal funding for non-exempt human subjects research.

**Common Rule Information**

Changes to Regulations for Devices Used in Research

What is a Device?

- Devices range from:
  - Tongue depressors
  - Bedpans
  - Programmable pacemakers
  - Laser surgical instruments
  - In vitro diagnostic products
  - Lab equipment
  - Reagents
  - Ultrasound machine
Definition of a “device”

- “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is
  - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
  - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  - intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.”

In Vitro Diagnostics

- In vitro diagnostics are tests that can detect diseases, conditions, or infections. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.
- IVDs are medical devices.
- In vitro diagnostic products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.
Laboratory Developed Tests (LDTs)

- A laboratory developed test (LDT) is a type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory.
- While the uses of an LDT are often the same as the uses of FDA-cleared or approved in vitro-diagnostic tests, some labs may choose to offer their own test. For example, a hospital lab may run its own vitamin D assay, even though there is an FDA-cleared test for vitamin D currently on the market.
- FDA has identified problems with several high-risk LDTs including: claims that are not adequately supported with evidence; lack of appropriate controls yielding erroneous results; and falsification of data.

LDT Regulation on the Horizon

- On July 31, 2014 the FDA notified Congress of the Agency’s intent to issue a draft oversight framework for LDTs based on risk to patients rather than whether they were made by a conventional manufacturer or a single laboratory.
- Final guidance is still pending.
- During this period of transition, some newer tests have undergone premarket review under the FDA device regulations where pre-existing tests did not. As a result, for certain diseases there are both FDA-approved and non-FDA-approved clinical tests commercially available.
What to do when LDTs are involved?

- Review protocols carefully for the use of IVDs/LDTs.
- Communicate with the sponsor:
  - What is the status of FDA regulatory review of the IVD/LDTs?
- Check for FDA-approved versions of the LDTs.