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REGIONAL MEDICAL CENTER

The Heart of a Healthy Community

Common Rule-How it applies to your Research

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Common Rule

- The common rule is a rule of ethics regarding biomedical and behavioral research involving human subjects
- It is the baseline of ethics by which any government funded research holds their researchers to these statement of rights
- The common rule was published in 1991, however there was a significant revision made in 2018
- The next slides touch on the core revisions made to the common rule in 2018. Although, anyone who wishes to participate in research should be familiar with the entirety of the common rule.

New and Revised Definitions:

- **Clinical Trial** -This term and definition was added to the common rule and defined as "a research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes
- **Human Subjects** -a living individual about whom an investigator obtains information or bio specimens through intervention or interaction
- **Activities deemed not to be research** include but not limited to Journalistic activity, public health surveillance activity, collection and analysis or information for criminal justice investigative purposes, activities in support of homeland security or national security missions

New Exemption Categories Regarding Secondary Research

- If certain conditions are met for secondary research, consent may not be required. This is only if the following applies:
  - Research using PHI or research defined under HIPAA rules to eliminate duplication between the common rule and HIPAA
  - Storage for secondary research use of identifiable private information when broad consent is obtained and if an IRB conducts a limited IRB review
  - Other exemption categories include educational, benign behavioral interventions and surveys or interviews

Elimination of Continuing Review

- The new common rule eliminated continuing review for minimal risk studies
- Unless an IRB decides otherwise continuing review of research is not required for expedited review studies
- FDA still requires annual continuing review for FDA regulated studies

Revised Informed Consent Requirements

- The consent must be presented in such a way that facilitates comprehension

- The new informed consent should include the following:
  - Statement explaining the purpose, and reasonable risks and discomforts

Harmonization with Other Agency Guidance

- The revised common rule states that guidance can only be issued after consultation with federal departments and agencies that adopted the common rule, unless the consultation is not feasible
- The rule requires the Secretary of HHS to issue guidance to assist IRBs in assessing privacy protections

Guidance on Application to Clinical Data Registries

- The Section 511 of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") requires HHS to provide guidance on how the Common Rule applies to clinical data registries. In an effort to provide such guidance, the preamble to the final rule states that the final rule does not apply to clinical data registry activities.

- Refer to the revised common rule to see what circumstances apply to this