# EXPLORING OBSERVATIONAL REGISTRIES AND HUMAN SUBJECT RESEARCH

PROGRESS WHERE AMBIGUITY IS THE ONLY CONSTANT

## 2 WHAT IS THE COMMON RULE?

- The Common Rule is the Federal Policy for the protection of human subjects.
- The Common Rule was first published in 1991.
- The recent revisions mark the first major overhaul to the regulations pertaining to protecting human subjects in over 20 years.

## 3 DEFINITION OF RESEARCH

- a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

## 4 FORMER DEFINITION OF HUMAN SUBJECT

- a living individual about whom an investigator (whether professional or student) conducting research obtains:
  - Data through intervention or interaction with the individual, or
  - Identifiable private information.

## 5 REVISED /CURRENT DEFINITION OF HUMAN SUBJECT

- an individual about whom an investigator (whether professional or student) conducting research:
  - Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens or
  - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

## 6 DO YOU HAVE HIPAA CONSIDERATIONS?

- Please note that HIPAA and the Common Rule definitions for research are the same.
- HIPAA does not define human subject.
- Please note the Common Rule human subject definition change and that HIPAA applies to individuals for 50 years following death.

## 7 APPLICABILITY OF THE COMMON RULE

- Although it was proposed, the final rule does not extend coverage of the rule to non-federally funded studies.
- Did the researcher's institution sign a Federal Wide Assurance and check the box?
- What is the researchers plan moving forward since the implementation date of the final rule?

## 8 DOES YOUR INSTITUTION EXTEND COVERAGE TO NON-FEDERALLY FUNDED STUDIES?

- Yes
- No

## 9 FOCUS ON SINGLE IRB REVIEW

- The revised rule mandates the use of a single IRB for multisite studies.
- The final rule does give agencies tremendous flexibility to waive this mandate.

## 10 SINGLE IRB REVIEW AND ENGAGEMENT IN RESEARCH

- In many instances of secondary research, researchers may seek oversight for the activities under a single site protocol and not seek oversight for institutions providing data.
- The researcher must determine if the institutions providing data are engaged in human subject research?

## 11 FLEXIBILITY IN EXEMPTION DETERMINATIONS

- The proposed rule suggested a specific methodology for making exempt determinations.
- The final rule does not fully implement this suggestion but in certain circumstances requires limited IRB review for certain exempt categories.

## 12 NO EXCLUSIONS BUT ENHANCED EXEMPTIONS!

- The final rule did not implement the proposed exclusions and the final rule did not exclude quality assurance and quality improvement activities from the definition of research.
- The final rule does have expanded exemption categories.

## 13 SECONDARY RESEARCH EXEMPTION

- One exemption of particular note to Registry Operators is a category that exempts secondary research using identifiable private information without consent if the research only covers the collection and analysis of identifiable information regulated under HIPAA.

## 14 BROAD CONSENT

- The final rule permits the use of broad consent for secondary research on identifiable private information or identifiable biospecimens.
- The research is considered exempt with limited IRB review.

## 15 BROAD CONSENT

- Six additional elements of consent are required.
- Broad consent is new and further guidance on this subject will likely be provided.

## 16 CONTINUING REVIEW

- Continuing review is eliminated for all studies that undergo expedited review.
- The final rule does give the IRBs flexibility in justifying requiring continuing review in certain circumstances.

## 17 SAFEGUARDING PRIVATE HEALTH INFORMATION

- The final rule does not specify privacy and security provisions as was stated in the proposed rule.
- IRBs continue to have a role in appropriately safeguarding research studies.
- The final rule requires the development of additional guidance on privacy and security safeguards.

## 18 CONSIDERATIONS FOR BIG DATA IN SECONDARY RESEARCH CONTRACTS

- If research is not the primary purpose of the collection of data, Registry Operators must ensure that the customer contract permits use of the data for research as a secondary purpose.
- Registry Operators must consider a Data Use Agreement where the primary data collector gives the Registry Operator the right to conduct research using a Limited Data Set as defined by HIPAA.

## 19 RESEARCH INFRASTRUCTURE

- Research Governance/ Oversight
- Research Specific Policies:
  - Human Subject Research
  - Research Related Conflicts of Interest
  - Responding to Allegations of Research Misconduct
- Insurance Policies
- Research Specific Privacy and Security Considerations
- Research Pipeline Management

## 20 FUNDING SOURCES

- There are multiple models for funding registry based research including research funded by:
  - Registry Operators
  - Investigators
  - Industry
  - Federal Funding

## 21 EVOLVING FDA REGULATED RESEARCH

- Regulations pertaining to FDA regulated research are different than the Common Rule regulations.
- New guidance on waiving informed consent for clinical investigations involving no more than minimal risk to human subjects and the NPRM.
- In addition there are additional regulatory considerations that must be considered including regulations pertaining to conflicts of interest, data management, and governance.