OVERVIEW OF COMMON RULE FINAL RULE

PREPARED FOR ASIP RESEARCH & SCIENCE POLICY COMMITTEE

WHAT'S IN THE FINAL RULE

COMPLIANCE DATE:

- January 19, 2018 effective date, except for cooperative research (single IRB) regulations which are effective January 20, 2020

IDENTIFIABLE BIOSPECIMEN PROVISIONS

- Defines identifiable biospecimen as "a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen." Definition of human subject specifically mentions identifiable biospecimens.
- Requires federal departments consult with experts to re-examine the meaning of "identifiable biospecimen" within one year and at least every four years thereafter. Requires an assessment of whether there are analytic technologies or techniques that generate an identifiable biospecimen. A biospecimen would be rendered identifiable by using the specified technique/technology (not whether the technology could be used but whether it is used).
- Whole genome sequencing will be one of the first technologies to be evaluated.

IRB – RELATED PROVISIONS

- Requires US-based institutions engaged in cooperative research to use a single IRB. Allows greater role for grantee input on choosing the IRB of record. Single IRB review may not be required when research involves Alaskan native or American Indian tribal law.
- A federal department or agency supporting or conducting research may determine that the use of a single IRB is not appropriate.
- Clarifying language added that IRBs have the authority to approve, require modification in, or disapprove all research activities covered by the Common Rule.
- Removes the requirement of continuing review for studies that underwent expedited review, as well as for studies that have completed interventions and are merely analyzing data or conducting only observational follow-up in conjunction with standard clinical care.
- Requires that IRBs determine that there are adequate provisions to protect the privacy of subjects and to maintain data confidentiality. States that the Sec. of HHS will issue guidance to assist IRBs in doing this.
- Allows IRB approval of research proposal in which researchers obtain information or biospecimens without individuals' consent to screen, recruit or determine eligibility of prospective human subjects.

EXEMPT RESEARCH & RETURN OF RESEARCH RESULTS

- Adds secondary research uses of identifiable private information or identifiable biospecimens as an exempt category for which consent is not required if at least one of the following criteria is met:
    - biospecimen is publicly available;
    - investigator records information about biospecimens such that the identity of the subject cannot be ascertained directly or through identifiers linked to the subjects, investigator does not contact the subjects, and the investigator will not re-identify subjects;
    - the research involves only information collection and analysis using identifiable health information when that use is regulated under HIPAA/HITECH regulations as "health care operations" or "research" as those terms are defined in the regulation; or
    - research is conducted by or on behalf of a federal department or agency using government-generated or government-collected information obtained for nonresearch activities.
- Storage and maintenance of identifiable biospecimens for secondary research is considered exempt from full IRB review. IRB must conduct a limited review finding that:
    - appropriate broad consent was obtained and documented; and
    - if there is to be a change made for research purposes in the way the identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain data confidentiality.
- Secondary research under a broad consent is considered exempt if:
    - appropriate broad consent was obtained and documented;
    - IRB conducts a limited review determining that research falls within the scope of the broad consent; and
    - individual research results will not be returned to subjects as part of the study plan (does not prevent an investigator from abiding by any legal requirements to return individual research results). It is important to note that a research plan that includes returning research results is <u>not</u> considered exempt research, regardless of whether this is the primary research project for which the specimen was gathered or subsequent secondary research conducted under broad consent. The role of the IRB in review of nonexempt, secondary research includes considering what subjects were told in the broad consent regarding the return of research results.

FINANCIAL IMPACT

	Present Value of Benefits over 10-year period*	Present Value of Costs over 10-year period*
Final Rule (in 2015 dollars)	$1,904 million	$528 million
NPRM (in 2013 dollars)	$2,629 million	$13,342 million

*Assumes 3% discount rate

CONSENT & BROAD CONSENT PROVISIONS

General Consent Provisions

- Researchers can now obtain information or biospecimens without individuals' consent to screen, recruit or determine the eligibility of prospective human subjects.
- Requires posting consent form on federal website.

Broad Consent Provisions

- No template for obtaining broad consent.
- Clarifies that broad consent is appropriate only for secondary research and no other types of research. Broad consent may be obtained in lieu of informed consent. Secondary research is not defined in the regulation itself. In the narrative, it is defined as "referring to re-using identifiable information and identifiable biospecimens that are collected for some other 'primary' or 'initial' activity. The information or biospecimens … would generally be found by the investigator in some type of records… or some type of tissue repository…"
- IRBs are prohibited from waiving consent if individual was asked and declined to provide broad consent.

Standard consent language	***Additional standard consent language specific to biospecimens***	***Broad consent language for storage, maintenance & secondary research on pvt info & biospecimens***

INFORMED CONSENT PROVISIONS (*Italics for new/updated provisions)*

Describe research, giving information reasonable person would want, *facilitate understanding, concise & focused presentation*	√		√ *General description including who might use it*
Foreseeable risks/discomforts	√		√
Potential benefits	√		√
Alternatives, if any	√		
Confidentiality steps	√		√
If more than minimal risk, compensation (if any) and what happens if injury	√		
Voluntary participation & no loss of benefits if don't join or choose to stop	√		√
Who to contact	√		√
Whether clinically relevant results will be shared, including individual results	√	√	
Whether specimen might be made nonidentifiable and used in future research		√	
Biospecimen may generate profit and whether profit will be shared		√	√
Whether research will/may use whole genome sequencing		√	√
Description of what specimens will be stored and potential for sharing		√ *(nonidentified only)*	√
How withdrawals are handled and whether can withdraw if identifiers are removed			√
Duration of specimen storage & use			√
Whether subject will be told how specimen is used in secondary research			√
Whether results of secondary research will be disclosed			√

OTHER INTERESTING POINTS

- Risk remains that Congress will rescind under Congressional Review Act.
- Provisions in the Newborn Screening Saves Lives Reauthorization Act of 2014 are replaced as the changes made by Act applied only until the changes to the Common Rule were promulgated. No longer will research on nonidentified newborn dried blood spots be considered human subjects research.
- Department of Labor and the Consumer Product Safety Commission intend to adopt final Common Rule provisions. These entities were previously not part of the Common Rule agencies.

WHAT FINAL RULE DOES NOT DO

- No requirement that research involving nonidentified biospecimens be subject to the Common Rule.
- No expansion of coverage to include clinical trials that are not federally funded.
- No standardized privacy safeguards for identifiable private information or identifiable biospecimens.
- No requirement that the Secretary of HHS publish a list of minimal risk activities; however, the Commentary indicates a continued interest in pursuing this through a separate process.
- No clarification that the definition of research excludes quality assurance/quality improvement activities, as well as internal program improvement activities. Commentary stated that trying to do this created more confusion than it resolved.
- No provision requiring consent, or refusal to consent, to having investigators recontact the subject to seek additional information or biospecimens or to discuss participation in another research study.