UCI Office of Research

Changes Ahead in 2018: Other Key Revisions to The Common Rule

After gathering public comments for the 2011 ANPRM and the 2015 NPRM, the final rule updating the Federal Policy for the Protection of Human Subjects ("The Common Rule") was published in January 19, 2017. The revisions are intended: to better protect human subjects involved in research, facilitate research, remove ambiguity, and reduce regulatory burden.

Definition of Human Subjects

Human subject means a living individual about whom an investigator 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*

Definition of Research

The Common Rule now provides 4 examples of types of activities that in general would ***not*** constitute research:

- Scholarly/Journalistic activities
- Public Health Surveillance
- Collection/analysis of information/biospecimen/records for/by a criminal justice agency
- Authorized operational activities by an agency for intelligence, homeland security, defense, or national security missions

Vulnerable Population

- Pregnant women and handicapped/mentally disabled populations are ***no*** longer considered vulnerable.
- Individuals with impaired decision-making capacity and economically/educational disadvantaged ***are*** considered vulnerable population.

Informed Consent will require additional information (when applicable) *

- Begin with a concise presentation of the key information that would facilitate comprehension.
- Specific language regarding future research for studies that involves collection of identifiable private information or identifiable specimens
- A statement when specimens may be used for commercial profit
- A statement when clinically relevant research results will be disclosed to subjects
- A statement when whole genome sequencing may be performed
- For the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, the broad consent must contain 7 key elements
- Adequate provisions to protect privacy of subjects / maintain confidentiality of data *(DHHS guidance is forthcoming.)*

Screening, recruiting, and determining eligibility

An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects *without the informed consent of the prospective subject (or the subject's legally authorized representative)* ***when either of these conditions are met***:

- The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens

Posting of clinical trial consent form *

A copy of the template consent form must be posted on a federal website after the clinical trial (*sponsored by a federal department or agency*) is closed to recruitment and no later than 60 days after the last study visit by any subject. (*DHHS guidance is forthcoming.)*

NOTES:

**** The Department of Justice (DOJ) and the Food and Drug Administration (FDA) have not yet adopted the revised Common Rule.***

The Federal Policy for the Protection of Human Subjects will not affect any state/local laws or regulations, including tribal law passed by the official governing body of an American Indian or Alaska Native tribe