COMMON RULE 2019

IMPLEMENTATION DATE: JANUARY 21, 2019

HISTORY

The 'Common Rule' has been in effect since 1991, and was adopted by 15 federal departments and agencies, including the Department of Health and Human Services, at 45 CFR 46.

The update to the Common Rule has been adopted by most of the original signatories, with the current exception of the Department of Justice.

HOW WILL THE NEW COMMON RULE IMPACT YOU?

CURRENT ACTIVE STUDIES

- As under the Current Rule, our institution will still hold research that is not funded by a Common Rule agency (and not subject to FDA regulations) to the same standards that we do research funded and therefore subject to the Common Rule.

STUDIES APPROVED AFTER 1/12/2019

- Application of new/changed definitions
- More exempt categories
- Changing of CR requirements
- Changing of Informed Consent process and documentation

DEFINITIONS

Human Subject

A human subject as defined by the Common Rule is a living individual about whom an investigator conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. [45 CFR 46.102(e)(1)].

DEFINITIONS

Research

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge. Activities which meet this definition constitute research whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

DEFINITIONS

Clinical Trial

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

New posting requirement

At this time, two publicly available federal websites that will satisfy the consent form posting requirement, as required by the revised Common Rule:

- ClinicalTrials.gov
- Docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

EXEMPTION CATEGORIES

Exemption categories are changing, and some of them will require a 'limited IRB' review for the activity to be considered exempt.

	TYPE of RESEARCH	CHANGES
ONE	**EDUCATIONAL SETTING**	The research must have no adverse impact on students' learning or assessment of educators
TWO	**SURVEYS, INTERVIEWS, EDUCATIONAL TESTS, AND OBSERVATION OF PUBLIC BEHAVIOR**	The scope will be expanded to include the collection of sensitive and identifiable data. However, the following are **not allowed**: Interventions, the collection of biospecimens, linking to additional personally-identifiable data, research with children (except for educational tests or some public observation).
THREE	**BENIGN BEHAVIORAL INTERVENTION (NEW)**	Permits data collection via an interaction from adult subjects with prospective agreement. However, the following is **not allowed**: Research with children, deception, unless prior agreement obtained, physiological data collection methods, linking to additional personally identifiable information
FOUR	**SECONDARY RESEARCH (IDENTIFIABLE PRIVATE INFORMATION/ BIOSPECIMENS)**	The scope of this exemption will be expanded to allow: prospective data review, maintenance of identifiers, if **all** study data is PHI, research that is conducted by, or on behalf of, a Federal Department/agency or using government-generated or government-collected information obtained for non-research activities.
FIVE	**PUBLIC BENEFIT/SERVICE PROGRAM RESEARCH**	A new *eligibility* criterion for this interaction/intervention exemption will be that the project must be published on a federal website.
SIX	**TASTE/FOOD QUALITY EVALUATION & CONSUMER ACCEPTANCE**	No changes

NEW CONTINUING REVIEW REQUIREMENTS

CONTINUING REVIEW IS NOT REQUIRED IN THE FOLLOWING CIRCUMSTANCES:

- Research eligible for expedited review in accordance with 45 CFR 46.110;
- Research reviewed by the IRB in accordance with the limited IRB review;
- Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
  - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
  - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

NOTE : EVEN THOUGH CONTINUING REVIEW BY THE IRB MAY NOT BE REQUIRED FOR THE ABOVE REFERENCED CATEGORIES, YOU WILL STILL NEED TO COMPLETE AN "ANNUAL CHECK-IN"

CHANGING OF INFORMED CONSENT REQUIREMENTS

1. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's LAR
2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence
3. The information that is given to the subject or the LAR shall be in language understandable to the subject or the LAR
4. The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information
5. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension
6. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate
7. No informed consent may include any exculpatory language through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

ADDITIONAL ELEMENTS OF INFORMED CONSENT

1. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
2. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;
3. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

MODIFICATION FOR WAIVER OF CONSENT CRITERIA

1. The research or clinical investigation involves no more than minimal risk to the subjects;
2. The research or clinical investigation could not practicably be carried out without requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participation.

NEW!

Screening, Recruiting, or 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, if either of the following 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.

NJH HRRP STAFF WILL CONTINUE TO KEEP YOU INFORMED OF PROGRESS REGARDING COMPLIANCE WITH THE NEW RULE, AND PROVIDE GUIDANCE ON IMPLEMENTATION AS IT BECOMES AVAILABLE.

NEXT SESSIONS

28 NOVEMBER 2018 2PM
19 DECEMBER 2018 2PM

Please let us know if you have any questions or concerns regarding this, or any aspect of our human research protection program!