Wake Forest School of Medicine

Human Research Protection Program

Standard Operating Procedures

2018 Common Rule

Effective: January 21, 2019

1. Transition Provisions

Effective January 21, 2019, the Office of Human Research Protections (OHRP) will require compliance with a revised set of regulations governing the protections of human subjects involved in research, known as the 2018 Common Rule. The 2018 Common Rule will apply to all federally funded research studies. Further, OHRP has removed the option of applying the 2018 Common Rule to all research. Therefore, institutions have the discretion of how to regulate studies that are not funded by the federal government, and not regulated by another federal agency (i.e. FDA). OHRP has given institutions some discretion as to when, how, or if existing studies will be required to follow the newly implemented regulations. If studies are in existence on the effective date and choose to transition to the 2018 Common Rule, then all parts, new and modified must be documented and in compliance with the 2018 Common Rule. The Wake Forest School of Medicine IRB has determined that studies in existence on the effective date will not transition to the 2018 Common Rule. Studies approved after the effective date that are funded by the federal government or those that are not funded by the federal government or regulated by another federal agency will apply the 2018 Common Rule. The remainder of this document describes how the 2018 Common Rule will be implemented.

2. Definitions

Except as noted below, all definitions listed in the pre-2018 Common Rule remain unchanged.

a) Human Subject means a living 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.
b) Research means a systematic investigation, including research development, testing, and evaluation, designed to contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not be research:
    i) Scholarly and journalistic activities (e.e., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected.
    ii) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increase in injuries from using consumer products). Such activities include those associated with providing timely situational

awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

iii) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

iv) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

c) 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.

d) Legally Authorized Representative: See the institutional policy on clinical informed consent to determine who may serve as a legally authorized representative.

e) Benign Behavioral Intervention: The exemption requires that the intervention only include adults, be brief in duration, harmless, and painless, among other criteria. The brief in duration requirement only pertains to the intervention itself, and not the data collection. Certain research that does not meet the requirements for this exemption may be eligible for expedited review.

f) Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

g) Interaction includes communication or interpersonal contact between investigator and subject.

h) Private Information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.e, a medical record).

3. Initial Application

    a. Full Board Review

        The 2018 Common Rule changes do not have any impact on initial full board submissions or processing. Please refer to the pre-2018 Common Rule procedures for more information on initial full board submissions.

    b. Expedited Review

The 2018 Common Rule changes do not have any impact on initial expedited submissions or processing. Please refer to the pre-2018 Common Rule procedures for more information on initial expedited submissions.

c. Exempt Review

Significant revisions have been made to the categories of research that are permitted to be classified as exempt. Additionally, the regulatory subparts may have limitations as to when certain exemptions may apply due to the vulnerabilities of their cohorts. Below is a summary of the new exempt criteria and further explanation as to when and how the subparts will be applied.

Citation	Category	Description	Conditions/Allowances/Limitations
46.104(d)(1)	1	Research in established or commonly accepted educational settings that involves normal educational practices	Must not be likely to adversely impact students' opportunity to learn or the assessment of educators
46.104(d)(2)	2	Research including educational tests, surveys, interviews, public observation, if at least one of the following criteria is met:	Data collection only; may include visual or auditory recording; may not include interventions
	2(i)	Recorded information cannot readily identify the subject (directly or indirectly/linked)	No children
	2(ii)	Any disclosure of response outside of the research would not reasonably place a subject at risk (criminal, civil, liability, financial, employability, reputation)	No children
	2(iii)	Information is recorded with identifiers and the IRB conducts a limited review	No children
46.104(d)(3)	3	Research involving benign behavioral interventions through verbal, written responses, (including data entry or audiovisual recording) from adult subjects who prospective agree and one of the following is met:	No children; no medical interventions; subject prospectively agrees
	3(i)	Recorded information cannot readily identify the subject (directly or indirectly)	No children

	3(ii)	Any disclosure of responses outside of the research would not reasonably place subjects at risk (criminal, civil, financial, employability, reputation)	No children; Intervention must be brief in duration, harmless/painless, not physically invasive, not likely to have significant lasting impact on subjects, unlikely that the subjects will find interventions offensive or embarrassing
	3(iii)	Information is recorded with identifiers and the IRB conducts a limited review	No children; no deception unless participant prospectively agrees
46.104(d)(4)	4	Secondary research for which consent is not required: use of identifiable biospecimens that have been or will be collected for some other primary or initial activity, if one of the following criteria are met:	No primary collection from subjects for the research; Allows both retrospective and prospective secondary use
	4(i)	Biospecimens or information is publically available	
	4(ii)	Information recorded so subjects cannot be readily identified (directly or indirectly/linked); Investigator does not contact subjects and will not re-identify the subjects	HIPAA still applies
	4(iii)	Collection and analysis involving investigators use of identifiable health information when use is regulated by HIPAA as health care operations, research, or public health activities and purposes	HIPAA still applies
	4(iv)	Research information collected by or on behalf of the federal government generated or collected information obtained for non-research activities	
46.104(d)(5)	5	Research and demonstration projects supported by a federal agency and designed to study public benefit or service programs	

46.104(d)(6)	6	Taste and Food Quality	

Exemption categories 7 and 8 regarding board consent will not be implemented at Wake Forest.

d. Limited IRB Review

Limited IRB review is established for review or research that will record, store, maintain or, make secondary use of identifiable private information. It is an alternative to the IRB approval criteria otherwise used for review of research. For purpose of conducting the limited IRB review, the IRB need not apply all the IRB approval criteria found at 45CFR46.111. Instead, the only criteria for approval that must be met is 45CFR46.111(a)(7) regarding the protections of privacy and confidentiality. Continuing review of research is not required for research reviewed in accordance with the limited IRB review. Instead, and abbreviated status report is required by the institution ervery three years for studies that initially were approved by limited IRB review. Additionally, the limited IRB review requirements only apply to certain exempt categories within the regulations, however a limited IRB review will be conducted for all exempt submissions within the institution.

4. Amendments

The 2018 Common Rule changes do not have any impact on amendment submissions or processing. Please refer to the pre-2018 Common Rule procedures for more information on amendment submissions.

5. Continuing Review

a. Full Board Review

The 2018 Common Rule changes do not have any impact on amendment submissions or processing. Please refer to the pre-2018 Common Rule procedures for more information on amendment submissions.

b. Expedited Review

The 2018 Common Rule change eliminate the requirements for continuing review in circumstances where one of the following applies:

- Research was originally approved by expedite procedures;
- Research was originally approved by limited IRB procedures;
- Research that has progressed to the point that it involves one or both of the following:
    - Data analysis, including analysis of identifiable private information or identifiable biospecimens;
    - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Studies that were initially approved by the convened IRB, and have yet to enroll any subjects and no new risks have been identified, may still be processed by expedited review procedures and the time of renewal.

c. Status Report
In place of continuing review, the institution does require an annual status report to be completed by investigators. The status report will be reviewed by an IRB chair or designee following similar procedures to the expedited review process. Lack of completion of the institutional status report may result in closure of the study.

6. Safety Events

The 2018 Common Rule changes do not have any impact on safety event submissions or processing. Please refer to the pre-2018 Common Rule procedures for more information on safety event submissions.

7. Informed Consent
    a. For applicable studies, additional requirements are necessary within the informed consent document.
        i. Listed below are the mandatory elements
        ii. Listed below are the optional additional elements
    b. For exempt studies, even though not required under the regulations, the Wake Forest IRB may require additional information to be communicated to potential subjects in the format of a consent document. The IRB will use its discretion regarding the type, content, length, elements, and signature requirements based on the study design and consider the most respectful and efficient way to communicate with potential study subjects.

8. HIPAA
The 2018 Common Rule does not impact HIPAA regulations within human subjects research. Wake Forest is classified as a covered entity under HIPAA. Therefore an authorization must be signed or a waiver appropriately justified in order to use or disclose PHI for research purposes. Historically, HIPAA authorization language has been compounded within the consent document. This practice will continue for non-exempt studies that require informed consent. For exempt studies, study information may be required at the discretion of the IRB, and if so, HIPAA authorization language must be included in the document.

9. Waiver of Informed Consent
The waiver of informed consent criteria have not been altered as result of the 2018 Common Rule. However, an additional category for the criteria for the waiver of documentation of consent has been included to address culturally sensitive populations that have distrust for signed documents.

10. Single IRB

    The single IRB mandate within the 2018 Common Rule does not go into effect until January 2020. Policies and procedures will be update at that time to address the new requirements of the single IRB mandate.