The Texas A&M University System

Meeting New Challenges:

Implementing the Revised Common Rule

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Objectives

- Key changes to the Common Rule and the impact on policies, process and templates
- Guidance documents available and forthcoming (hopefully)
- Action items necessary to implement changes

Compliance Dates

Compliance Dates

January 21, 2019, for the revised Common Rule, except for the requirement for mandated single IRB review which remains January 20, 2020

Transition: Easiest Route

- Before January 21, 2019, all activities must comply with the pre-2018 rule
  - These studies are grandfathered in provided that you do not apply any of the revisions to these studies
- After January 21, 2019, all studies must comply with the 2018 revised Common Rule
- Requirement for single IRB (sIRB) review in multi-institutional studies goes into effect January 20, 2020

Transition

Changes that can be implemented before January 21, 2019

- Revised Common Rule provisions that do not conflict with the pre-2018 rule
- The 3 burden-reducing provisions (effective July 19, 2018)
  - Revised definition of research (scholarly and journalistic activities)
  - Elimination of continuing review for certain minimal risk research
  - Elimination of IRB review of grant applications or funding proposals

Action items

- Review and revise IRB policies/SOPs/review forms/IT system prior to implementing
- Track any research to which a burden-reducing provision was applied
  - It must be re-reviewed on 1/21/19, to ensure that all other required revisions have been applied to that research.

Guidance

OHRP Announces the Availability of Three Draft Guidance Documents Related to the Revised Common Rule

July 20, 2018

The Office for Human Research Protections (OHRP) is announcing the availability of three draft guidance documents that relate to three burden-reducing provisions in the revised Common Rule that institutions may choose to implement during the delay period (July 19, 2018 through January 20, 2019) for general compliance with the revised Common Rule. The three draft guidance documents are titled:

1. Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements; it can be accessed at https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-scholarly-and-journalistic-activities-deemed-not-to-be-research/index.html.

2. When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements; it can be accessed at https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-when-continuing-review-is-not-required-during-the-6-month-delay-period/index.html.

3. Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements; it can be accessed at https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-elimination-of-irb-review-of-research-applications-and-proposals/index.html.

OHRP plans to issue a Federal Register Notice of Availability (NOA) about these draft guidance documents soon, but is posting the draft guidance documents here in recognition of the general compliance delay period, which began July 19, 2018. The NOA that will be issued will include a docket for each draft document in which the public can submit comments during a 30-day period (starting from the day the NOA publishes).

Guidance


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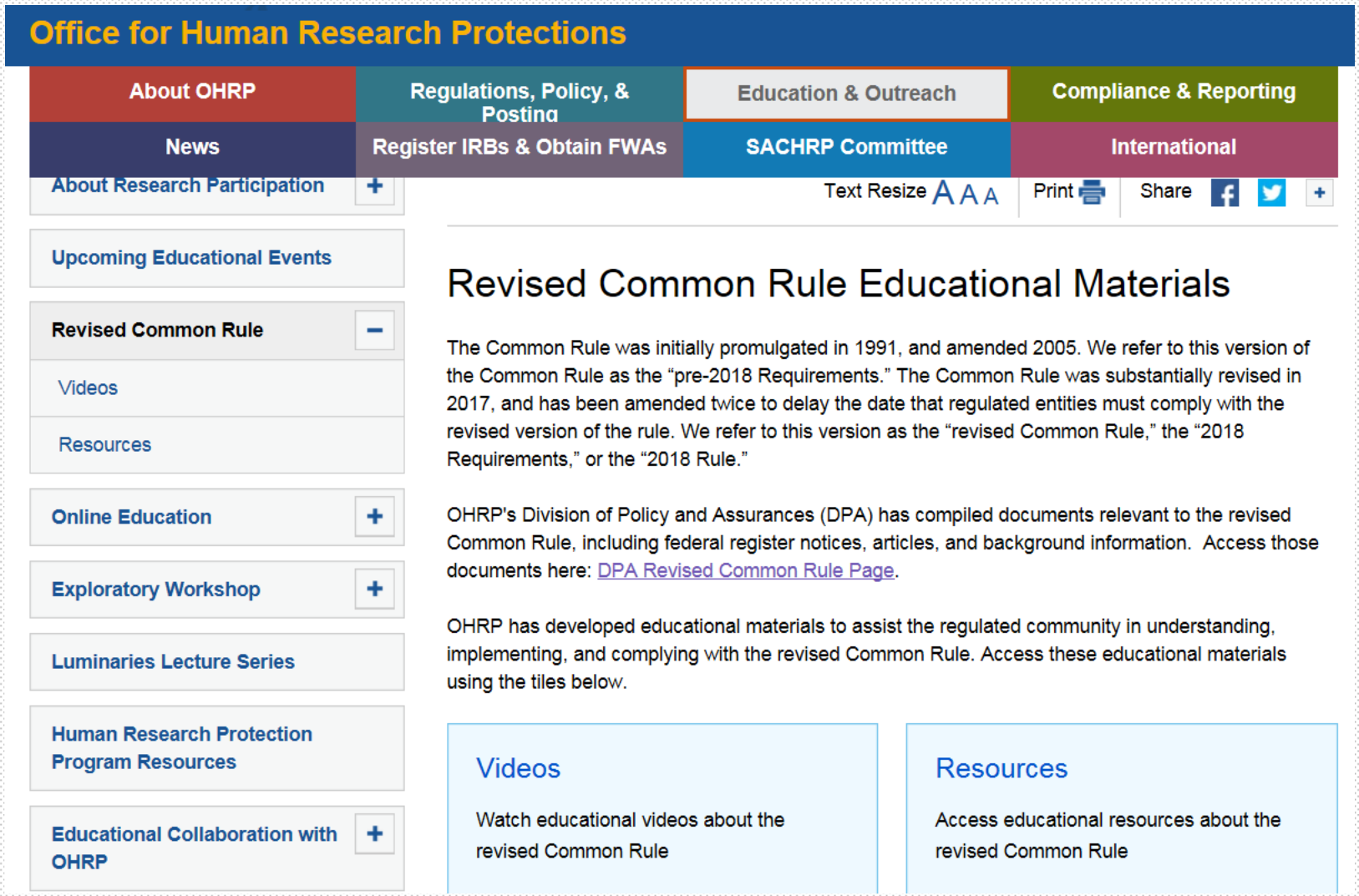
Activities Deemed Not to Be Research: Public Health Surveillance 2018 Requirements
NOTE: This guidance is consistent with the 2018 Requirements (i.e., the revised Common Rule).
Draft
This guidance, when finalized, will represent the Office for Human Research Protections' (OHRP's) current thinking on this topic. This guidance does not create or confer any rights for or on any person and does not operate to bind OHRP or the public.
OHRP guidance should be viewed as recommendations unless specific regulatory requirements are cited. The use of the word "must" in OHRP guidance means that something is required under the Department of Health and Human Services (HHS) regulations at 45 CFR part 46. The use of the word "should" in OHRP guidance means that something is recommended or suggested, but not required. An institution may use an alternative approach if the approach satisfies the requirements of 45 CFR part 46. OHRP is available to discuss alternative approaches by telephone at 240-453-8237 or 866-447-4777, or by email at ohrp@hhs.gov.
Date: November 7, 2018
Scope:

Guidance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Revised Common Rule Educational Materials
The Common Rule was initially promulgated in 1991, and amended 2005. We refer to this version of the Common Rule as the "pre-2018 Requirements." The Common Rule was substantially revised in 2017, and has been amended twice to delay the date that regulated entities must comply with the revised version of the rule. We refer to this version as the "revised Common Rule," the "2018 Requirements," or the "2018 Rule."
OHRP's Division of Policy and Assurances (DPA) has compiled documents relevant to the revised Common Rule, including federal register notices, articles, and background information. Access those documents here: DPA Revised Common Rule Page.
OHRP has developed educational materials to assist the regulated community in understanding, implementing, and complying with the revised Common Rule. Access these educational materials using the tiles below.
Videos
Watch educational videos about the revised Common Rule
Resources
Access educational resources about the revised Common Rule

Additional Guidance Needed …

- Consent revisions
- Broad consent
- New expedited review list
- Guidance on limited IRB review
- Posting Consent forms in multi-site research
- Guidance on exemptions
- Guidance on new elements for waiver

Summary of Key Changes

Revisions that require changes to policies, procedures, forms & IT systems

- Revised definitions
- Exempt categories
- Limited review
- Expedited categories
- Continuing review
- Consent form requirements
- Grant review
- Single IRB
- Screening and recruitment
- Secondary research
- Broad consent

Revised Definitions

Definition of research – 4 new exclusions

- Scholarly and journalistic activities
- Public health surveillance activities
- Activities for criminal justice/investigative purposes
- Activities for national security missions

Definition of human subjects

- "Data" replaced with "information or biospecimens"

Action items:

- Review and revise IRB policies/SOPs/review forms/IT system prior to implementing
- Expect further guidance from OHRP on these definitions

Definition of "Human Subject"

A living individual about whom an investigator conducting research

1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

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Changes to Exemptions

Pre-2018 Rule (Current)		Revised Common Rule
# 1: Educational practices	→	Restrictions added
# 2: Educational tests, surveys, interviews, observation of public behavior	→	Expanded
# 3: Research on public officials	→	Removed and replaced with new
# 4: Research on existing data	→	Expanded old and added new
# 5: Public benefit service	→	Expanded with changes
# 6: Taste and food evaluations	→	No change
		+ New Exemption # 7
		+ New Exemption # 8
		*New - limited IRB review

Exempt Categories

What's changed

- 6 existing exemptions expanded to 8 exemptions
- Exemptions 3, 7 & 8 are new
- Exemption 1 – an additional restriction was added
- Exemptions 2, 4&5 – expanded
- Exemption 6 – unchanged

Action items:

- Review and revise IRB policies/SOPs/review forms/IT system
- Develop limited IRB review process for exemptions 2, 3, 7 & 8
- If exempt reviews are currently conducted by non-IRB members, modify practice to require limited IRB review by an IRB member

Limited IRB Review

Limited IRB review is required for certain exemptions and does not require an IRB to consider all of the IRB approval criteria at 46.111.

There are 4 exemptions that may require it:

- Exemption 2: Educational tests/surveys/interviews/observations of public behavior – if identifiable information is recorded, limited IRB review is required to protect privacy and confidentiality
- Exemption 3: benign behavioral research – same as Exemption 2
- Exemption 7: storage and maintenance of identifiable private information/biospecimens for secondary research use
- Exemption 8: Secondary research involving identifiable private information/biospecimens

Action items:

- Develop IRB policies/SOPs/review forms/IT system for limited IRB review (to be conducted by IRB Chair or expedited reviewer)

Continuing Review

Continuing review is not required for:

- Research eligible for expedited review
- Research that had limited IRB review
- Research that has completed all interventions and now is limited to
  - Analyzing data (even identifiable)
  - Accessing follow-up clinical data from clinical care procedures

Note:

IRB has authority to require continuing review for special circumstances.

If IRB determines continuing Review should be conducted when it is not required, the rationale must be documented.

Continuing Review

Action items:

- Develop process for documenting if IRB will conduct continuing review when not otherwise required
- Revise IRB approval notice to indicate when continuing review is not required (with reminder that amendments, adverse events, unanticipated problems, study completion report are still required)
- Alternate process (staff review, administrative check-in, etc.) may be considered to maintain oversight of research when continuing review is not required.
- Generally, review and revise IRB policies/SOPs/review forms/IT system to reflect these changes to continue review policy

Continuing Review

Continuing Review may still be needed:

- When the research is FDA-regulated
- When the research is supported by the Dept. of Justice/National Institute of Justice (DOJ is not a signatory on the revised Common Rule)
- When a study was IRB-approved prior to the compliance date of the revised Common Rule and has not been transitioned to comply with the revised Common Rule
- When continuing review by the IRB is a term of a grant or contract.

Consent Form

What's changed?

- Key information must be added at the beginning of the ICF
- 1 new basic element and 3 new additional elements (when appropriate) should be added to the ICF template
- ICFs for clinical trials must be posted to a public federal website
- Legally authorized representative (LAR) for purpose of consent

Action items:

- Revise ICF template
- Create policy and disseminate information to investigators on posting ICFs to the identified public federal websites
- Revised policy on LAR if applicable to your jurisdiction
- Generally, review and revise IRB policies/SOPs/review forms/IT system to reflect these changes to consent form

Broad Consent

What's changed?

- Broad consent is a new process geared toward repositories and focused on secondary research use, recognizing the type of future research use may not be known at the time the broad consent is obtained
- It is permitted as an alternative to the standard informed consent requirements

Note:

If an individual refused to provide broad consent, the IRB can't waive informed consent for the subject's identifiable private information/biospecimens used in the secondary study.

Much of the discussion around broad consent concerns tracking and determining what future research has actually been refused.

Broad Consent

Action items:

- Develop an active method for tracking broad consent agreement and refusal
- Create a broad consent template for institutional use
- Update investigator guidelines for informed consent to reflect changes and explain context for specific/standard vs. broad consent
- Create broad consent review form for IRB reviewers
- Review and revise IRB policies/SOPs/review forms/IT system to reflect the addition of broad consent

Grant Review

What's changed?

- Eliminating the requirement that IRB review of grant applications or other funding proposals related to the research
- Certification is required when the research is supported by a federal department or agency and not otherwise waived or exempted
  - For such research, institutions shall certify that each proposed research study covered by the assurance has been reviewed and approved by the IRB

Action items:

- Revise IRB policies/SOPs/review forms
- Confirm the grant/research administration office is aware of these changes

Single IRB Review

When is it required?

NIH POLICY

Required for all multi-site, domestic, non-exempt NIH research with grant application receipt after January 25, 2018.

COMMON RULE

Required for all domestic, cooperative research that is ready for IRB submission on or after January 20, 2020.

DHHS, DOD, DO Energy, DO Education, NASA, NSF, SSA, DO Homeland Security, USDA, VA, DO Commerce, EPA, Agency for International Development, DOHUD, DO Labor, DO Transportation

Applicability

- U.S. institutions engaged in cooperative research for the portion of the research conducted in the U.S.
- Regardless of whether research is biomedical or SBER

Single IRB (sIRB)

Action items:

- Ensure all current reliance arrangements are documented and the responsibilities of both entities are set forth in the agreement or otherwise in an institutional policy
- Set up communication plan between grant/research administration offices and the IRB

Does not apply to cooperative research

- When more than single IRB review is required by law (e.g. tribal law)
- If federal department or agency funding the research determines and documents use of a single IRB is not appropriate for the particular context

Making a Determination of Non-Exempt Human Subjects Research