Implementing the Revised Common Rule
Objectives

• To describe major changes to the Common Rule which are applicable to investigators
• To discuss how UTHSA will implement changes based on the Revised Common Rule
• Describe when the changes go into effect
What is the Common Rule?

- The set of Federal Regulations, designed to protect human subjects in research that are promulgated by the Office for Human Research Protections (OHRP)
- Received the title, “Common Rule,” because 15 other federal agencies have signed onto the DHHS regulations
- Can be found in the Code of Federal Regulations 45 CFR 46
Why was the Common Rule revised?

- Originally published in 1991 after 10 years of development
- After about 25 years, time, technology, and research technique outgrew regulations
- Decrease administrative burdens associated with:
  - New research methodologies;
  - Incorporation of new technology;
  - Allow for more collaborative research; and
  - Change review levels to be commensurate with research risk exposure
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**Timeline**

- **ANPRM**
- **NPRM**
- Final Rule on the Revised Common Rule
- Original effective/compliance date
- First 6 month delay (July 19, 2018)
- Second 6 month delay (January 21, 2019)
- Effective date for 3 burden-reducing provisions
- Compliance Date 2018 Common Rule

- July 2011
- September 2016
- January 19, 2017
- January 19, 2018
- January 23, 2018
- June 19, 2018
- July 19, 2018
- January 21, 2019

**Cooperative research provision (single IRB) – compliance date remains January 20, 2020.**
What are the major changes to the Common Rule?

- Definitions
- Informed Consent
- Exempt Review
- Continuing Review
Definitions

**Human subject**

a living individual about whom an investigator (whether professional or student) 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**
Definitions

Research

• No change to the definition; however, there are new categories that are no longer deemed research
  • Scholarly and journalistic activities
  • Public health surveillance activities
  • Collection and analysis of information, biospecimens, or records for activities authorized by law or court order for criminal justice or criminal investigative purposes
  • Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions
Implementation at UTHSA

• Revisions include updates to:
  • Glossary terms
  • Determining Whether an Activity is Research Involving Human Subjects Policy and Procedure
  • Non-Research/Non-Regulated Research Application Form
  • Non-Human Research Application Form
Informed Consent

- Requirement to include a Key Information Sheet
  - The fact that consent is being sought for research;
  - Participation is voluntary;
  - The purposes of the research;
  - The expected duration of the prospective subject’s participation;
  - The procedures to be followed in the research;
  - The reasonably foreseeable risks or discomforts;
  - The benefits to the prospective subject;
  - Appropriate alternatives procedures or course of treatment, if any that may be advantageous to the prospective subject.
Informed Consent

• **One new required element of Informed Consent**
  • For all studies that involve the collection of identifiable private information or identifiable specimens, include a statement on whether specimens if subsequently de-identified will be used for future research or not
Informed Consent

• **Three new additional elements when research involves biospecimens**
  • Statement whether specimens may be used for commercial profit and if subject will share in the profit.
  • Statement whether clinically relevant research results will be disclosed to subjects and if so under what conditions.
  • Statement whether research might include whole genome sequencing.
Waiver of Informed Consent for Screening and Recruiting

Use of identifiable information or identifiable specimens without the subject’s consent for the purpose of screening, recruiting, or determining eligibility of prospective subjects can be approved by the IRB without the need for Waiver of Consent.
Implementation at UTHSA

• Revisions made to:
  • The Informed Consent Policy and Procedure
  • Informed consent SOP
  • Identification and Recruitment Policy and Procedure
• Revised consent templates will be made available
• For screening and recruiting, there no longer is a requirement to complete a Waiver of Consent - Form F.
Posting of Clinical Trial Consent Form

One IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department conducting the clinical trial on a publicly available Federal website after the last study visit by any subject and no later than 60 days after the last study visit by any subject.
Postion of Clinical Trial Consent Form Implementation at UTHSA

- After a study receives IRB approval:
  - OCR will submit the consent form to a Clinicaltrial.gov queue before institutional activation
  - The consent form must be reviewed/approved by the investigator
  - After investigator approval, the consent form is posted

Important Note: Posted consent form must be a version that was used for consenting subjects.
Exempt Research Categories

- Pre-2018 Common Rule had **six** Exempt Categories
- The Revised Common Rule has **eight** Exempt Categories and includes:
  - New restrictions
  - Expansions
  - New categories
Exempt Research Categories

- **Exempt Category 1** - research conducted in established or commonly accepted educational settings involving normal educational practices
  - Clarifies that the educational practices must **not** adversely impact:
    - Students opportunity to learn the required curriculum; and/or
    - The assessment of the educators who provide instruction
Exempt Research Categories

- **Exempt Category 2** - involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior
  - Expanded to required that an IRB conducts Limited IRB Review
  - Additional review to ensure privacy and maintain the confidentiality of the subject’s data
- Study will have an **institutional expiration date**
- Will require yearly reminders
- A re-review by OCR will be required at the three year mark or study may be inactivated
Exempt Research Categories

• **Exempt Category 3** - involving research using **benign behavioral interventions** that an **adult** prospectively agrees to
  • This new category replaces the previous category
  • If the subjects’ identities can readily be ascertained and if a disclosure of subjects’ responses has potential to harm subjects, the IRB will conduct a Limited IRB Review
Exempt Research Categories

- **Exempt Category 4** - involving the collection or study of existing data, documents, records, pathological or diagnostic specimens if publicly available or recorded such that subjects cannot be identified
  - Expanded on old information and added new information
  - Re-labeled as secondary research for which informed consent is not required
  - Data does not have to exist at the time of the approval
  - Information may still be regulated by HIPAA requirements
Exempt Research Categories

- **Exempt Category 5** - Research and demonstration projects conducted by or subject to the approval of department or agency heads designed to evaluate public benefit or service programs
  - Addition of “improve” to clarify that the government conducts such activities to improve the benefits and services provided
  - Requires that each federal department or agency supporting these projects must publish a list of projects that the department or agency supports under this provision prior to commencing research
Exempt Research Categories

- **Exempt Category 6** - Taste and food quality evaluation and consumer acceptance studies
  - No changes to this category
Exempt Research Categories

- **Exempt Category 7***
  - involves the *storage or maintenance* of identifiable private information or identifiable biospecimens for potential secondary use for which broad consent obtained

- **Exempt Category 8***
  - involves the secondary *use* of identifiable data and identifiable biospecimens for which broad consent obtained

*Because both of these categories involves Broad Consent, we will not implement these two exempt categories until we can confirm the institution’s process for regulatory compliance.
Implementation at UTHSA

- Revisions include:
  - Exempt Research Policy and Procedure
    - Categories have been revised
    - Exemption will expire after 3 years instead of 5 years
    - Development of yearly email reminders – for Exempt research requiring additional oversight
  - Form B-3
- Certain Exempt categories will require:
  - an **institutional expiration date**;
  - yearly reminders;
  - re-review by OCR at the **three** year mark or study may be inactivated.

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Continuing Review

• **Elimination of continuing review**
  • For all studies approved using Expedited Review
    • Unless the reviewer explicitly justifies why continuing review would enhance protection of research subjects
  • For all studies which has progressed to the point that it involves only data analysis or accessing follow-up clinical data as part of clinical care

**Because the FDA has not revised its regulations, continuing review is still required annually**

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Implementation at UTHSA

• Revisions include updates to:
  • Continuation Review Policy and Procedure
  • Initial Review of Research Policy and Procedure
  • Continuing Review Notices
  • IRB determination letters
  • New Institutional process to follow studies which do not required Continuing Review
Implementation at UTHSA

• For studies which require continuing review **annually**, there are no changes to the process.
Implementation at UTHSA

• For studies which **do not require continuing review annually:**
  • Study receives an Institutional Expiration date in lieu of an IRB Expiration date
  • An Institutional email reminder will be sent each year reminding investigators of responsibilities to:
    • Submit amendments for project changes
    • Prompt reporting of Noncompliance and possible UPIRSO
    • Inactivation request
  • An institutional review (Brief Project Update) will be required every 3 years.
When do the changes go in effect?

- January 21, 2019
- Studies submitted **before** January 21, 2019 will be reviewed using the Pre-2018 Common Rule.
- Studies submitted **after** January 21, 2019, will be reviewed in accordance with the 2018 Revised Common Rule.
What does this mean for research approved before January 21, 2019?

- Research approved according to current (Pre-2018) regulation will continue as approved.
- Research determined Exempt prior to January 21, 2019 will continue to be Exempt
- A decision on whether to transition any study approved pre-2018 will decided on a case-by-case basis.
When can I find updated policies/forms on the IRB/OCR Website?

January 21, 2019
Summary

• Changes to the Common Rule are aimed at reducing burdens
• Major changes include:
  • Informed consent requirements
  • Exempt research categories
  • Elimination of continuing review for certain research
• Contact the IRB and OCR for questions
References

• 2018 Requirements
• Pre-2018 Requirements
• Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations