Implementing the Revised Common Rule

INSTITUTIONAL REVIEW BOARD

THE UNIVERSITY OF TENNESSEE AT CHATTANOOGA

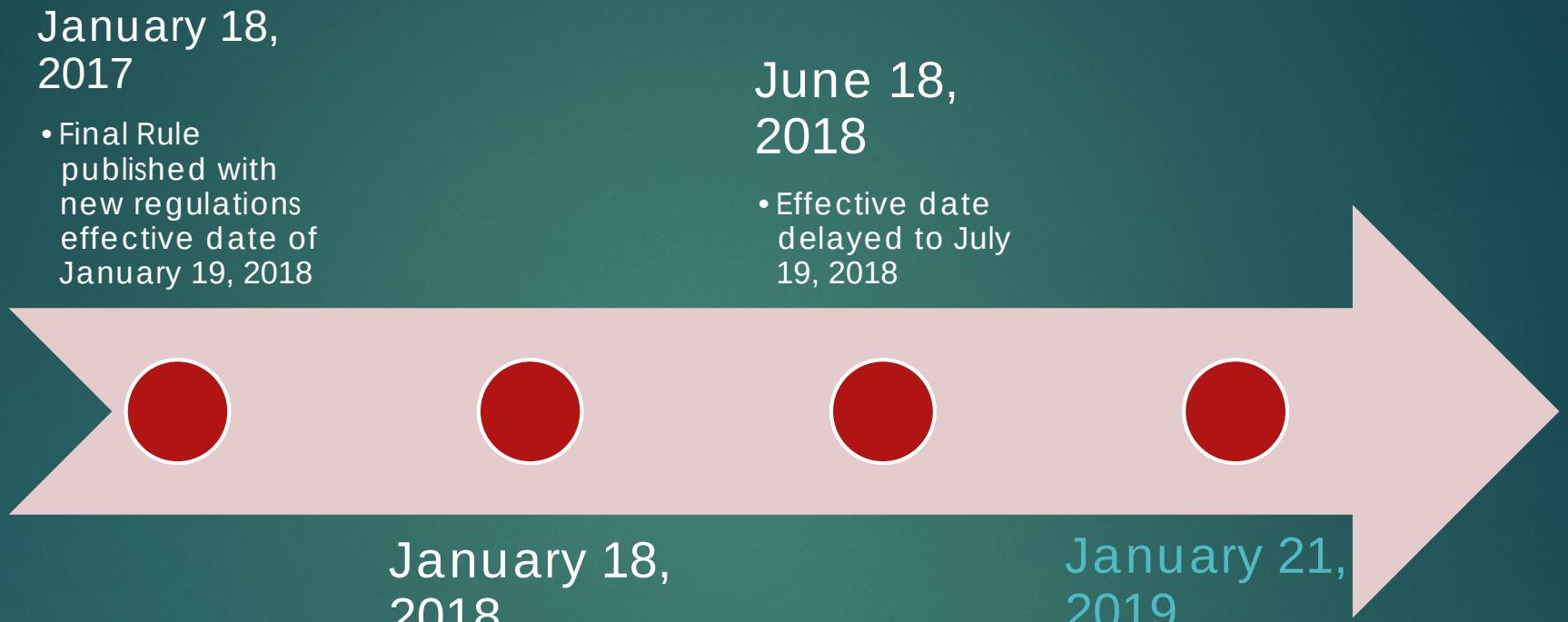
Federal Policy for the Protection of Human Subjects – Common Rule

- On January 18, 2017, the Federal Policy for the Protection of Human Subjects, or Common Rule, was updated for the first time since its publication in 1991.
- The goal of these revisions is to reduce administrative burden and better protect subjects in the modern research context.

What are the major changes to the Common Rule?

- Updates to Definitions
- Updates to Informed Consent Process and Document
- Updates to Exempt Categories and Limited IRB Review
- Updates to Expedited Review Process

Implementation Dates



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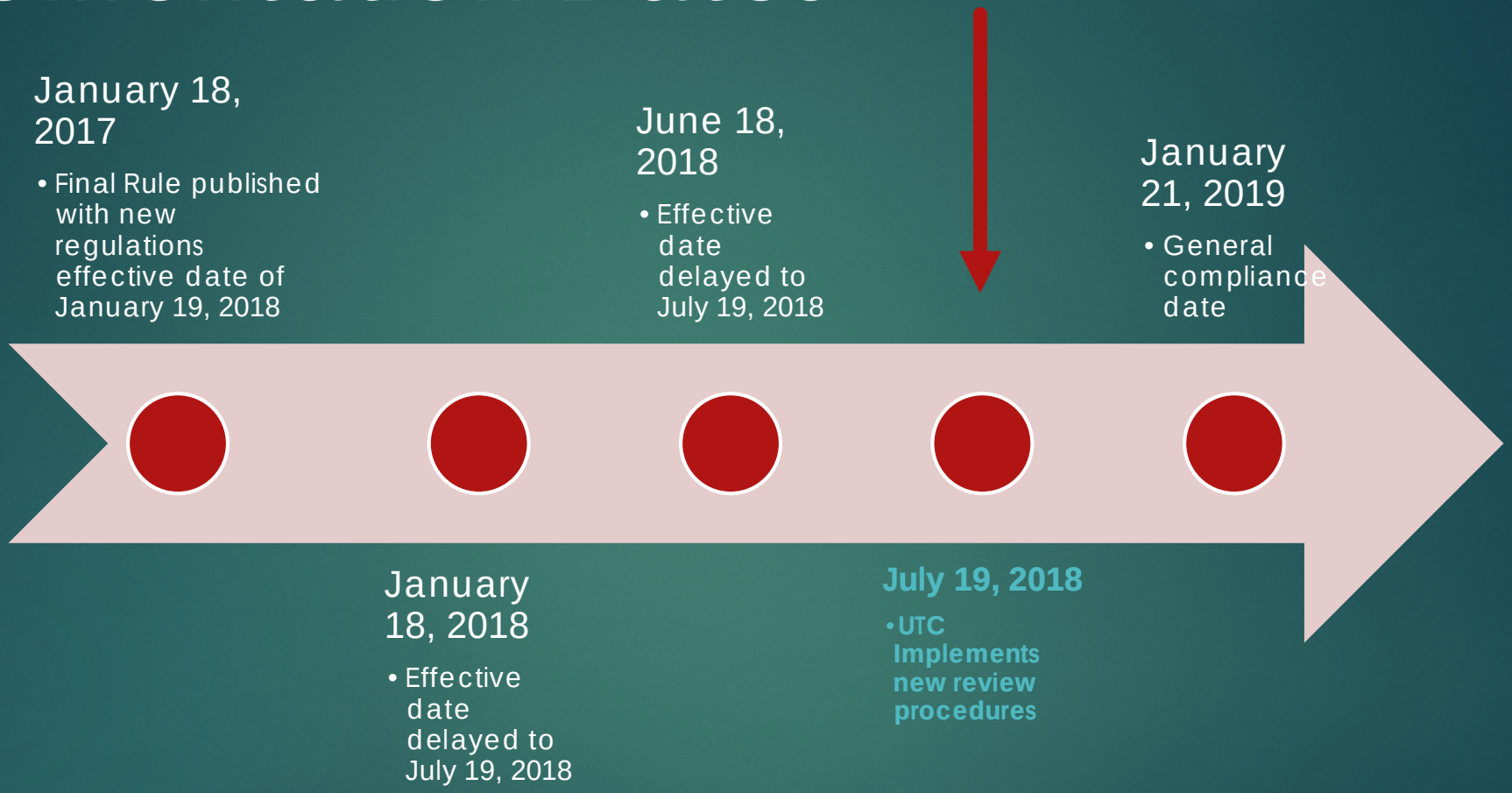

UTC Changes on July 19, 2018

- In order to prepare for the upcoming changes, UTC is implementing changes that will affect:
  - The Exempt Application Process
  - Informed Consent Requirements
  - The Annual Review Process
  - Forms and Documents

Updates to Exempt Application Process

- Under the existing process, the IRB made the determination regarding Exemption status.
- Exemptions were determined and approved by IRB Chair.
- After July 19, 2018, investigators will need determine whether or not their project is exempt and then complete the appropriate application.
- Exempt determinations will be made by ORI.

Exempt Categories

- Research is Exempt under the following categories
  1. Educational research using normal educational practices
  2. Educational tests, surveys, interviews, and public observation
  3. Research subjects are public officials
  4. Existing data
  5. Public benefit or service programs
  6. Taste and food quality evaluation

Exemption 46.101(b)(1)

- Research conducted in established or commonly accepted educational settings
- Involves normal educational practices
- Exemption applies if:
  - Data is identifiable but not sensitive, or
  - Data is sensitive but de-identified, and
  - Children are only undergoing educational tests or observation of public behavior without investigator interaction

Exemption 46.101(b)(2)

- "...interactions including educational tests....survey procedures, or observation of public behavior...unless:
  - Information obtained is recorded in such a manner that human subjects can be identified; and
  - Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk..."

Exemption 46.101(b)(3)

- "...interactions including educational tests....survey procedures, or observation of public behavior...that is not exempt under category (b)(2) if:
  - The human subjects are elected or appointed public officials or candidates for public office; or
  - Federal statue(s) require(s) without exemption that the confidentiality of the personally identifiable information will be maintained..."

Exemption 46.101(b)(4)

- “Research involving the collection or study of existing data, documents, records…if these sources are publicly available or if the information is recorded by investigators in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.”

Exemptions 46.101(b)(5) and (6)

- Exemption 5: Research and demonstration projects conducted/supported by a Federal department or agency or subject to approval by dept/agency head and are designed to study public benefit or service programs.
- Exemption 6: Taste and food quality and evaluation and consumer acceptance studies

Applying for IRB Exemption

- New Tools:
  - Exemption Decision Chart
  - Exemption Category Definitions
- Form D: Application for Exempt Designation

Exemption Category Definitions

Exemption Categories

45 CFR part 46.

Note:

Certain kinds of research with human subjects are not eligible for exempt determinations:

Prisoners: research involving prisoners as human subjects is not eligible for exemption. "Prisoners" are defined as "any individual involuntarily confined or detained in a penal institution." The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Detainees in administrative cases (such as immigration or deportation) are not considered detainees for this purpose, according to guidance obtained from DHHS.

Children: Research involving minors may not be exempted, with one exception. If the research consists solely of observation of public behavior where the investigator does not participate in the activities being observed, the research may be eligible for exemption. All other research involving minors is not eligible for exemption.

Category	Citation	Exemption Category Description	Conditions/Allowances/Limitations
1	46.101(b)(1)	Research Conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.	Exemption applies if: • Data is identifiable but not sensitive, or • Data is sensitive but de-identified. • Children are only undergoing educational tests or observation of public behavior without investigator interaction
2	46.101(b)(2)	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.	
3	46.101(b)(3)	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:	

Exemption Decision Tree

Human Subject Regulations Decision Charts

The Office for Human Research Protections (OHRP) provides the following graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. The charts address decisions on the following:

- whether an activity is **research** that must be reviewed by an IRB, and
- whether the review may be performed by **exempt procedures**.

Considerations

The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

These charts are necessarily generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics, at OHRP Policy Guidance by Topic. OHRP invites inquiries for additional information.

The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

Chart 1: Is an Activity Research Involving Human Subjects?

Chart 2: Is the Human Subjects Research Eligible for Exemption?

Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

Chart 4: Does exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?

Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

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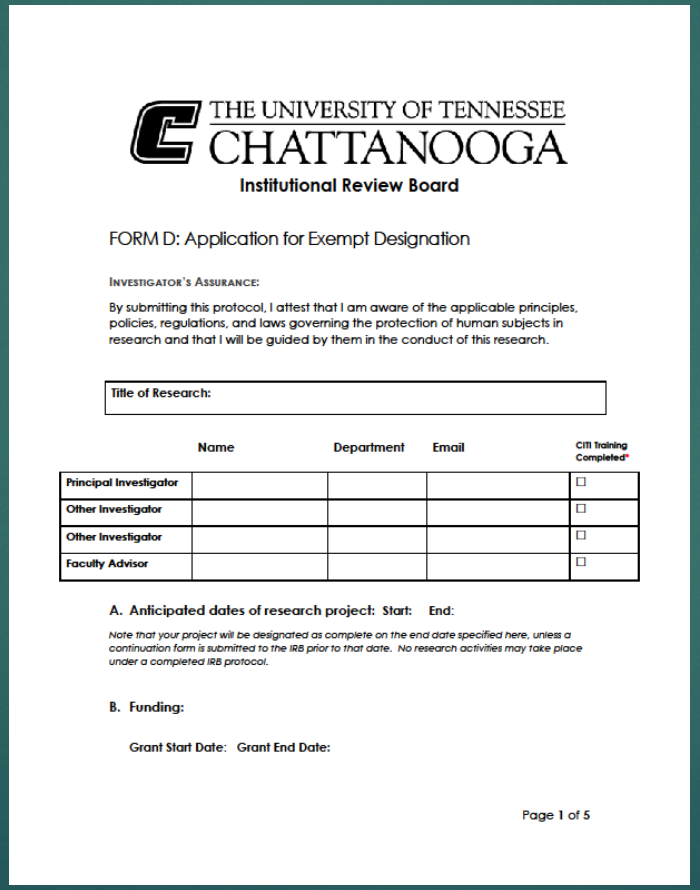
Form D: Application for Exempt Designation



THE UNIVERSITY OF TENNESSEE CHATTANOOGA

Institutional Review Board

FORM D: Application for Exempt Designation

INVESTIGATOR'S ASSURANCE:

By submitting this protocol, I attest that I am aware of the applicable principles, policies, regulations, and laws governing the protection of human subjects in research and that I will be guided by them in the conduct of this research.

Title of Research:

	Name	Department	Email	CITI Training Completed*
Principal Investigator				☐
Other Investigator				☐
Other Investigator				☐
Faculty Advisor				☐

A. Anticipated dates of research project: Start: End:

Note that your project will be designated as complete on the end date specified here, unless a continuation form is submitted to the IRB prior to that date. No research activities may take place under a completed IRB protocol.

B. Funding:

Grant Start Date: Grant End Date:

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Updates to Informed Consent Process and Document

- Changes meant to facilitate subjects' understanding of the reasons to participate (or not) in the research.
- Requires that key information essential to decision making receive priority by:
  - Being presented first in the consent discussion;
  - Appearing at the beginning of the consent document.
- Prospective subject must be provided with "the information that a reasonable person would want to have to make an informed decision about whether to participate, and be given an opportunity to discuss that information."

Informed Consent Document

- New elements of informed consent
  - Statement on whether the identifiers might be removed and information or biospecimens could be used for future research without additional informed consent.
  - When appropriate:
    - Commercial Profit
    - Return of clinically relevant results
    - Whole genome sequencing of biospecimens

Informed Consent Document

- If your consent document is lengthy (more than 1-2 pages), you will need to include a “concise and focused presentation” at the beginning that includes “key information” to facilitate comprehension.
- New UTC IRB templates & updated checklist

Updates to Expedited Review Process

- Annual Review no longer required for project approved AFTER July 19, 2018.
  - IRB reserves the right to determine that research should be reviewed annually.
- Investigators still need to request approval before implementing changes via a Form B: Application for Changes, Annual Review, or Project Termination/Completion
- All Forms and Checklists have been updated. Always download forms from the IRB website. (www.utc.edu/irb)

Changes to Form A – End date

- New requirement to indicate a project End Date.
  - This date will be used to track if project is active. Unless the investigator submits a Form B indicating that the project is still ongoing, ORI will close out the IRB on its end date.
  - After the IRB is closed, NO ADDITIONAL RESEARCH may take place under this IRB number.
  - ORI will endeavor to remind investigators of upcoming end date, but it is the investigator's responsibility to submit the Form B with adequate time for review and approval PRIOR to the expiration date.

For Protocols approved before July 19, 2018

- Projects can continue as approved.
- Consent Forms do not need to follow new guidelines.
- Annual Review is still required.

For More Information….

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Questions?