Changes to 45 CFR 46
Effective January 21, 2019

Major Changes for UT Knoxville Research Community:

- Definitions are clarified
- Exempt Categories 2, 3 and 4 are changed
  - "Limited IRB Review" for Privacy and Confidentiality
- Continuing Review (renewal) requirements are changed
  - Post-approval monitoring
- Informed Consent procedures and forms have new requirements
- Single IRB for some cooperative research
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**Definition: Research means**

...a systematic investigation including research development, testing, and evaluation, designed to develop or 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.
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Definitions: Activities defined as not necessarily research

- Certain oral history, journalism, biography, literary criticism, legal research and historical scholarship
- Certain public health surveillance activities
- Certain criminal justice activities
- Certain operational activities for national security purposes
Definition: A human subject is...

... 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. §46.102(e)(1)(i)

Changes to Exempt Categories

- Category 2 now allows the collection of identifiable data, with “limited IRB review”

- Category 3 is brand new: Benign Behavioral Interventions; data can be anonymous, or identifiable “with limited IRB review”

- Category 4 is revised to allow prospective data collection; clarified to apply only to identifiable information and biospecimens
Exempt Category 2 §46.104(d)(2)

Research using educational tests, survey procedures, interview techniques, or observations of public behavior (including visual or auditory recording) if

- the information is recorded in such a manner that the identity of the human subjects cannot readily be ascertained, or
- the information is recorded in such a manner that the identity of the human subjects can readily be ascertained, and an IRB conducts a limited IRB review to make a determination regarding privacy and confidentiality.

Flowchart:

- iMedRIS application
- Select Exempt Category 2 Tests, Surveys, Interviews, Obs of Public Behavior
- Complete Exempt Application with (2800) Privacy and Confidentiality
- Collect data with identifiers?
  - YES
    - Limited IRB Review (Exempt Review + 45 CFR 46.111 (a) 7)
    - Approval
  - NO
    - Complete Exempt Application
    - Exempt Review

REVISED Exempt Category 2
Exempt Category 3 §46.104(d)(3)

Research involving benign behavioral interventions if

- the information is recorded in such a manner that the identity of the human subjects cannot readily be ascertained, or

- the information is recorded in such a manner that the identity of the human subjects can readily be ascertained, and an IRB conducts a limited IRB review to make a determination regarding privacy and confidentiality.

NEW Exempt Category 3
Single IRB for some cooperative research

- NIH = required for multi-site research in which research activities are the same at each site
- Requires IRB Authorization Agreements (reliance agreements) to be executed between institutions (these are institutionally-approved, not IRB-approved)
Federal-Wide Assurances (FWA)

• Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46. Terms:
  1. Guided by statement of principles
  2. Applicability
  3. Compliance with laws, regulations, policies, and guidelines
  4. Written procedures
  5. Institutional support for the IRB
  6. Reliance on an External IRB
  7. Renewal or Update of the Assurance

Institution or Organization Providing IRB Review:
Name (Institution/Organization A): __________
IRB Registration #: __________
Federalwide Assurance (FWA)#, if any: __________

Institution Relying on the Designated IRB (Institution B):
Name: __________
FWA#: __________

The Officials signing below agree that __________(name of Institution B) may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (check one):

(____) This agreement applies to all human subjects research covered by Institution B's FWA.
(____) This agreement is limited to the following specific protocol(s):
Name of Research Project: __________
Name of Principal Investigator: __________
Sponsor or Funding Agency: __________
Award Number, if any: __________
(____) Other (describe) __________

The review performed by the designated IRB will meet the human subject protection requirements of Institution A's OHRP-approved FWA. The IRB at Institution B will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available on Institution B's open request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution/Organization A):
________________________________________
Date: ___________
Print Full Name: __________
Institutional Title: __________

Signature of Signatory Official (Institution B):
________________________________________
Date: ___________
Print Full Name: __________
Institutional Title: __________
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For cooperative research

- Sometimes it is appropriate for each IRB to review
- Sometimes an IRB Authorization Agreement is appropriate
- When an investigator is not under an FWA, a Non-Affiliated Investigator Agreement is needed

- Check with HRPP Director Kristine Hershberger (kh@utk.edu)
  - most appropriate procedure
  - UT Knoxville specific templates
Continuing Review (Renewal)

Unless an IRB determines otherwise, continuing review of research is not required in certain circumstances.

Criteria for Continuing Review of Expedited Studies at UT Knoxville

- Vulnerability of the participant population
- Risk/sensitivity level of the research activity
- The investigator is a student
- The investigator has a noncompliance history in the past 5 years
- The study is FDA-regulated
- There is an IRB Authorization Agreement deferring IRB oversight of non-UTK personnel to the UTK IRB
- There is a Nonaffiliated Investigator Agreement
- Other
Studies approved under Expedited Review before 1/21/2019

1. The next continuing review will include a determination as to whether the study is still Expedited, or qualifies for Exempt under the new categories.

2. If the study is still Expedited, a determination will be made as to whether or not Continuing Review is required.

Changes to Informed Consent Process

- The investigator shall seek informed consent only under circumstances:
  - that provide sufficient opportunity to discuss and consider whether or not to participate and
  - that minimize the possibility of coercion or undue influence §46.116(a)(2)

- The participant must be provided with the information that a reasonable person would want to have in order to make an informed decision. §46.116(a)(4)
New Required Element of Informed Consent §46.116(b)(9)

If research collects identifiable private information or identifiable biospecimens, one of the following is included in the consent form:

- a statement that identifiers might be removed and de-identified information or biospecimens may be used for future research without additional informed consent,

or

- a statement that participant's information or biospecimens will not be used or distributed for future research, even if identifiers are removed.
iMedRIS screen-by-screen advice in handout

Effective January 21, 2019

• Studies approved January 21 and afterward must be compliant with the revised regulations; built into new iMedRIS application
• The new application will be required January 14, 2019
**Encourage investigators to...**

- check with the IRB to determine if their project constitutes human subjects research subject to regulation
- not wait for funding to submit IRB application
- contact HRPP office if research involves investigators from outside UT Knoxville
- explore the guidance materials in the iMedRIS Help menu
Review June 2018 updates to iMedRIS application

(2800) Privacy and Confidentiality

- participant privacy
- data collection
- data storage
- data transmission
- data disposition

Data storage and transmission

- The IRB recommends the use of UT Vault for secure data transmission. See https://vault.utk.edu/
- Consult OIT's advice about secure data storage using university-sponsored accounts that are determined to be secure for various purposes (e.g., FERPA- and HIPAA-protected records). See https://oit.utk.edu/news/google-office365/
- Be sure enough details are included in the application that reviewers can follow the data trail from the time of being obtained until analysis is completed and the data are destroyed, returned, or otherwise handled.
Questions, comments, education requests

- utkirb@utk.edu
- 974-7697
- https://irb.utk.edu
- Help menu in iMedRIS