

Common Rule Changes - January 21, 2019

Changes to the federal guidance for human subjects research protection, known as the Common Rule, will take effect on January 21, 2019. This means that ALL protocols being reviewed by Texas A&M University-Central Texas' IRB after that deadline (regardless of submission date) MUST meet the new standards. Some of the **principal** areas of change are:

- A new definition of “human subject”
- Continuing review requirements
- New categories of studies that do not require IRB review
- Categories of research excluded from IRB review
- Changes to exempt categories
- Additional elements of consent
- Broad consent provisions/Elements of broad consent
- Single IRB (compliance date for this component is **January 19, 2020**)

A new definition of “human subject” (changes shown in red)

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**

New Categories of Studies That Do NOT Require IRB Review

Continuing review will not be required for:

- minimal risk studies, and
- greater than minimal risk studies where interventions/interaction with participants are complete.

Submission of enrollment numbers still needs to be reported annually for institutional measures

Categories of Research Excluded from IRB Review

This is one of the most important changes but it is not very straightforward. Research in the following disciplines do not need IRB review, but our IRB encourages researchers who have questions about whether this applies to their study to contact the IRB Chair at irb@tamuct.edu:

- Scholarly and Journalistic Activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship) that involve the collection and use of information **focused directly on specific individuals** about whom the information is collected (i.e., not being generalized to other people).
 - Public Health Surveillance that has been authorized by a public health authority
 - Criminal Justice research by or for a criminal justice agency authorized by law or court order
 - Authorized Operational Activities in support of intelligence, homeland security, defense, or national security missions
-

Changes to Exempt Categories

New categories have been added and some existing categories have been modified:

- 45 CFR 46.104(d)(1): Modified provisions, formally 45 CFR 46.101(b)(1)
- 45 CFR 46.104(d)(2): Modified provisions, formally 45 CFR 46.101(b)(2)
- 45 CFR 46.104(d)(3): New Category
- 45 CFR 46.104(d)(4): New Category
- 45 CFR 46.104(d)(5): Same as 45 CFR.46.101(b)(5)
- 45 CFR 46.104(d)(6): Same as 45 CFR 46.101(b)(6)
- 45 CFR 46.104(d)(7): New Category
- 45 CFR 46.104(d)(8): New Category

Details for changes (changes shown in red):

- **45 CFR 46.104(d)(1)**: Research involving normal educational practices **that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction** such as: (1) **Most** research on regular and special education instructional strategies; or (2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management.
- **45 CFR 46.104 (d)(2)**: Research that **only includes interaction** involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior **(including visual or auditory recording) if at least one of the following is met**: (1) Information obtained is recorded **by the investigator** in such a manner that **the identity of** human subjects **cannot** be readily ascertained, directly or through identifiers linked to the subjects; or (2) Any disclosure of the human subjects' responses outside of the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial

standing, employability, educational advancement, or reputation or; (3) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, **and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7)**. Children may only be included in research under this exemption when involving educational tests or observation of public behavior if the investigator(s) do not participate in the activities being observed and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly, or through identifiers linked to the subjects.

- **45 CFR 46.104(d)(3)**: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collected and at least one of the following is met; (1) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects; (2) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (3) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, **and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7)**. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing (e.g., playing an online game, solving puzzles, etc.) If the research involves deception, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research and the subject is informed that they will be unaware of or they will be misled regarding the nature or purposes of the research. **Children may not be included in research under this exemption.**
- **45 CFR 46.104(d)(4)**: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria are met: (1) The identifiable private information or identifiable biospecimens are publically available; or (2) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; or (3) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR 160 and 164, Subparts A and E (HIPAA), for the purposes of "health care operations" or "research" as those terms are defined under HIPAA or for "public health activities and purposes" under HIPAA; or (4) The research is conducted by, or on behalf of a Federal department or agency using government-generated or government-collected information obtained for non-research activities.

- **45 CFR 46.104(d)(5):** Research and demonstration projects, which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (1) Public benefit or service programs; this exemption is for Federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency. The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining “public benefit or service programs:” ◊ The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services under the Older Americans Act); ◊ The research or demonstration project must be conducted pursuant to specific Federal statutory authority; ◊ There must be no statutory requirements that the project be reviewed by an IRB; and ◊ The project must not involve significant physical invasions or intrusions upon the privacy of participants. (2) Procedures for obtaining benefits or services under those programs; (3) Possible changes in or alternatives to those programs or procedures; or (4) Possible changes in methods or levels of payment for benefits or services under those programs. (5) This exemption is for projects conducted by or subject to approval of Federal agencies and requires authorization or concurrence by the funding agency.
- **45 CFR 46.104(d)(6):** Taste and food quality evaluation and consumer acceptance studies; (1) If wholesome foods without additives are consumed; or (2) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
- **45 CFR 46.104(d)(7):** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for postsecondary research use **if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).**
- **45 CFR 46.104(d)(8):** Secondary research for which broad consent is required: Research involving the use of identifiable private health information or identifiable biospecimens for secondary research use, if the following criteria are met: (1) Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116 (a)(1)-(4), (a)(6), and (d); (2) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117; (3) **An IRB conducts a limited review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in (d)(8)(i); and** (4) The investigator does not include returning individual research results to subjects as part of the study plan. *(This provision does not prevent an investigator from abiding by any legal requirements to return individual research results).*

Limited IRB Review: 45 CFR 46.111(a)(7) review will be conducted by the IRB sub-Committee or designee: (1) For exempt categories 104(d)(2), 104(d)(3), 104(d)(7), and 104(d)(8) to verify adequate provisions to protect the privacy of subjects and to maintain confidentiality of

the data are assessed. (2) For exempt category 104(d)(7) and 104(d)(8) to verify broad consent or a waiver of documentation for broad consent is appropriate. Any change in the way identifiable private information or identifiable biospecimens are stored or maintained will also require review.

Additional Elements of Consent

Except for broad consent (see below), informed consent must begin with a concise and focused presentation of key information that is most likely to assist a prospective participant or legally authorized representative to understand the reasons why someone might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. **Currently, there is no federal guidance defining "key information".**

Additional required elements: One of the following statements about research that involves the collection of identifiable private information or identifiable biospecimens:

- A statement that identifiers may be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or their legally authorized representative, if applicable; or
- A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future studies.

Additional optional elements:

- A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit;
 - A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
 - For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
-

Broad Consent

The term ***broad consent*** applies to obtaining consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens collected for either research studies other than the proposed research or for non-research purposes (e.g., in a medical

clinic) and is permitted as an alternative to standard informed consent in cases where later research use of identifiable private information or identifiable biospecimens is expected.

- There are 12 required elements of broad consent (see below).
- The IRB cannot waive or approve an alteration of broad consent.
- Further, if a participant has refused broad consent, the IRB cannot waive consent for storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

Elements of Broad Consent

Required elements of broad consent:

1. A description of any reasonable foreseeable risks or discomforts;
2. A description of any benefits to the participant or others that may reasonable be expected from the research;
3. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
4. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled;
5. If appropriate, a statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit;
6. If appropriate, for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen);
7. A general description of the types of research with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect broad consent would permit the types of research conducted;
8. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
9. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which could be indefinite);
10. Unless the participant or their legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the participant's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

11. Unless it is known that clinically relevant research results, including individual results, will be disclosed to the participant in all circumstances, a statement that such results may not be disclosed to the participant; and
 12. An explanation of whom to contact for answers to pertinent questions about the storage and use of information and specimens, and to voice comments or concerns about participants' rights, and whom to contact in the event of a research-related harm.
-

Single IRB

All federally-funded studies where more than one institution/site is conducting the same protocol must be reviewed by a single IRB. The participating institutions must determine which institution's IRB will serve as the oversight IRB.

LINKS TO HELPFUL FEDERAL WEBPAGES

HHS Overview of new Common Rule:

<https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-resources/index.html>

Videos of topics on the new Common Rule:

www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-videos

Broad Consent further information:

<https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-august-2-2017/index.html>

(Initial draft of material drawn with permission from Vanderbilt University website)