

## IRB CHANGES AS A RESULT OF THE REVISIONS TO THE COMMON RULE

Effective date = January 21, 2019. This is also the compliance date. Exception to this is the Single IRB Mandate, which has a compliance date of January 20, 2020.

In the following the notation §\_\_\_\_.### refers to the section in the Federal Register for various federal agencies. For example, “Definitions for the Purpose of this Policy” is §431.102 for the Social Security Administration and §1230.102 for the National Aeronautics and Space Administration. The first set numbers denotes the agency while the second set of numbers denotes section of the Federal Policy for the Protection of Human Subjects.

The Office for Human Research Protections (OHRP) is announcing the availability of three draft guidance documents that relate to three burden-reducing provisions in the revised Common Rule that institutions may choose to implement during the delay period (July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 The three draft guidance documents are titled: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>

*Impact at UNK: Some studies no longer require IRB review at all. Under the revised definition of human-subjects research in the new Common Rules certain activities are explicitly excluded in the new definition. The activities below are not research.*

### Activities That Are Not Research Involving Human Subjects

Scholarly and journalistic activities such as oral history, journalism, biography, literary criticism, legal research, historical scholarship, etc. that focus on specific individuals for legal or historical purposes;

Public health surveillance: the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority;

Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law court order solely for criminal justice or criminal investigative purposes;

Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense or other national security missions;

Program improvement activities – collection and analysis of data, including biospecimens, for the purpose of an institution’s internal evaluation, monitoring or program improvement; and

Quality assurance and quality improvement – the implementation of an accepted practice to improve the quality of care, or the analysis of data or biospecimens to evaluate the effectiveness of an accepted practice.

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>

*Impact at UNK: Studies that received expedited review under the current (old) Common Rule and that involve no more than minimal risk to participants as well as studies that have progressed to the point of only involving data analysis or collection or follow up clinical care data.*

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>

*Impact at UNK: Studies funded by federal grants from HHS no longer require IRB to review the grant proposal as well as the research protocol.*

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).

## **General Information**

### Federal wide Assurance (FWA)

1. Elimination of the “voluntary extension of the FWA to non-federally funded research;”
2. Institutions are no longer obligated to provide a statement of ethical principles by which an institution will abide as part of the assurance process;
3. Institutions are no longer required to provide a current list of IRB committee members and their qualifications (IRBs should maintain their own list); and
4. Institutions are no longer required to designate one or more IRBs on its FWA.

### Definitions

Clinical trial – A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions or biomedical or behavioral health-related outcomes.

Cooperative research – Research involving more than one institution, noting that each institution is responsible for safeguarding subject rights and welfare.

Identifiable biospecimen – A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Legally authorized representative (LAR) – Now includes specific authorization to use institutional policy when there is no applicable law.

State law or local law – Now includes “tribal law passed by the official governing body of an American Indian or Alaska Native tribe.”

Vulnerable membership – No longer includes pregnant women; replaced “handicapped or mentally disabled persons” with “individuals with impaired decision-making capacity;” and added “economically or educationally disadvantaged persons.”

Written or in writing – Refers to writing on a tangible medium or in an electronic format.

## **Exempt Research**

### Exemption Categories (\* = revised):

1\* Research, conducted in established or commonly accepted educational settings, that specifically involves 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. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

*Impact at UNK: Now includes a statement that the research cannot “adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. Provides clarification on risk.*

2\* Research that only includes interactions involving 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 criteria is met:

- i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily be ascertained, directly or through identifiers linked to the subjects;
- ii. 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, education advancement or reputation; or
- iii. The information obtained is recorded by the investigator in such a manner that the identity of the human can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §\_\_\_\_.111(a)(7).

*Impact at UNK: Includes a clarification that the data may involve visual or audio recording as well as a “carve-out” that allows for the collection of sensitive, identifiable data to be collected as long as a “limited review” is conducted by the IRB. Allows for sensitive, identifiable data to be determined as exempt.*

- 3\* Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
- A. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily be ascertained, directly or through identifiers linked to the subjects;
  - B. 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, education advancement or reputation; or
  - C. The information obtained is recorded by the investigator in such a manner that the identity of the human can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §\_\_\_\_.111(a)(7).
    - i. For the purposes 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
    - ii. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subjects authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

*Impact at UNK: This is a new category specific to "benign interventions" involving adults that allows for deception under certain conditions. Data may also be sensitive and identifiable as long as a "limited review" is conducted by the IRB. "Benign interventions" are currently reviewed as expeditied review, as there is no current exempt category that this activity would fit in with the Final Rule, this type of research would be permitted as an exempt review.*

- 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 is met:
- i. The identifiable private information or identifiable biospecimens are publicly available;
  - ii. 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;
  - iii. 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 parts 160 and 164, subparts A and E [HIPPA], for the purposes of "health care operations" or

“research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

- iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

*Impact at UNK: This category has been revised to also include biospecimens, as well as special carve-outs for HIPAA-covered data, federally conducted research, and federally generated data. This provides greater clarity on what is allowable under this category.*

- 5\* Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of other mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

- i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

*Impact at UNK: The revisions provides further clarification about what are “research and demonstration projects that are conducted or supported by Federal department or agency. To note, research that is reviewed under this category has always been quite rare.*

- 6 Taste and food quality evaluation and consumer acceptance studies:

If wholesome foods without additives are consumed; or

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 FDE or approved by the EPA or the Food Safety and Inspection Service of the USDA.

- 7\* Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determination required by §\_\_\_\_.111(a)(8).

*Impact at UNK: This new category is specifically for identifiable data and/or biospecimen repositories as long as a "limited review" is conducted by IRB. Repositories are currently reviewed as expedited review, as there is no current exempt category that this activity would fit in. With the Final Rule, this type of research would be permitted as an exempt review.*

- 8\* Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
- i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §\_\_\_\_.116(a)(1) through (4), (a)(6), and (d);
  - ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §\_\_\_\_.117;
  - iii. An IRB conducts a limited IRB review and makes the determination required by §\_\_\_\_.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
  - iv. The investigator does not include returning individual research results to subjects as a part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

*Impact at UNK: This new category pertains to the use of identifiable data and/or biospecimens from a repository as long as certain conditions are met. The review of secondary use of identifiable data is currently reviewed as expedited review, as there is no current exempt category that this activity would fit in. With the Final Rule, this tpe of research would be permitted as an exempt review.*

*Note: If broad consent is not adopted, exempt categories 7 and 8 cannot be used.*

## Limitations on Exemptions

Application of the exemption categories to research subject to the requirements of 45CFR part 46, subparts B, C, and D, is as follows:

Subpart B [pregnant women, fetuses, neonates]. Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

Subpart C [prisoners]. The exemption at the section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Subpart D [children]. The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met.

Paragraphs (d)(2)(i) and (ii) of this section only my apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.

Paragraph (d) (2) (iii) of this section may not be applied to research subject to subpart D.

## Limitations on Exemptions – Children

Restricted: Exempt category 2(i) and (ii) – restricted to research involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.

Not permitted: Exempt category 2(iii) – educational tests, survey procedures, interview procedures or observation of public behavior when the information obtained is recorded in such a manner that the identity of the human subjects can readily be ascertained.

Not permitted: Exempt category 3 – benign behavioral interventions.

## **Limited IRB Review**

### Regulatory Authority

§\_\_\_\_.109(a). An IRB shall review and have authority to approve, require modifications in (to secure approval) or disapprove all research activities covered by this policy, including exempt research activities under §\_\_\_\_.104 for which limited IRB review is a condition of exemption (under §\_\_\_\_.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).

*Impact at UNK: An IRB may use the expedited review procedure to review research for which limited IRB review is a condition of exemption. “Under an expedite review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB” (HHS, 2018).*

## **Expedited Review – No Changes**

## Continuing Review

§\_\_\_\_.109(f)(1) Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

- i. Research eligible for expedited review in accordance with §\_\_\_\_.110;
- ii. Research reviewed by the IRB in accordance with the limited IRB review described in §\_\_\_\_.104(d)(2)(iii), (d)(3)(i)(c), or (d)(7)m or (8);
- iii. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
  - A. Data analysis, including analysis of identifiable private information or identifiable biospecimens; or
  - B. Accessing follow-up clinical data from procedures that subjects would undergo as a part of clinical care.

§\_\_\_\_.115(a)(3) Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in §\_\_\_\_.109(f)(1)

## Consent

### Informed Consent

#### 1. New Concise Presentation of Key Information

*Impact at UNK: Must begin with a concise and focused presentation of the key information that will assist in understanding the reasons why one might or might not want to participate in the research. This section is organized in a way that facilitates comprehension.*

#### 2. Changes in Basic and Additional Elements

- A. Research collecting identifiable private information and/or identifiable biospecimens must state that collected samples/data may be de-identified and used for future research or be given to another investigator for future research without additional informed consent, OR state that collected samples/data will not be used or distributed for future research even if de-identified.

*Impact at UNK: If the research involves the collection of identifiable private information or identifiable biospecimens, a statement on whether the identifiers might be removed and information or biospecimens could be used for future research without additional informed consent.*

- B. Statement that biospecimens, even if de-identified, may be used for commercial profit and whether/if that profit will be shared.

*Impact at UNK: A statement that biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

- C. Statement regarding whether clinically relevant research results will be given to the subject and under what conditions.

*Impact at UNK: A statement about whether clinically relevant research results, including individual research results, will be disclosed to subjects.*

- D. For research involving biospecimens, whether the research will or might include whole genome or exome sequencing.

*Impact at UNK: A statement about whether the research project might include whole genome sequencing.*

#### Waiver of Signature of Informed Consent

1. Signature can be waived if it is the only record linking the subject to the research and there is a potential risk of breach of confidentiality; OR
2. The research is no more than minimal risk and involves no procedures for which written consent is normally required outside of the research setting; OR
3. It is not the cultural norm for subjects to sign such documents, as long as:
  - A. The research is no more than minimal risk; and
  - B. An alternative documentation mechanism is used.
4. If this is used, the research presents no more than minimal risk and there is an appropriate alternative mechanism for documenting informed consent.

#### Elements of Broad Consent (§ \_\_\_\_ .116(d))

This is a new type of consent as an alternative to regular informed consent. Specifically for the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

1. The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section:
  - (b)(2) reasonably foreseeable risks or discomforts;
  - (b)(3) any benefits to the subject or two others that may reasonably be expected;
  - (b)(5) confidentiality of records;
  - (b)(6) participation is voluntary, refusal to participate will involve no penalty or loss of benefits, may discontinue participation at any time without penalty or loss of benefits;
  - (c)(7) biospecimens may be used for commercial profit and whether the subject will or will not share in this commercial profit; and
  - (c)(9) whether the research will or might include whole genome sequencing.

2. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
3. 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;
4. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time 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 period of time could be indefinite);
5. Unless the subject or 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 subject'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;
6. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances a statement that such results may not be disclosed to the subjects; and
7. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

#### Waiver or Alteration of Documentation of Consent

Waiver – an IRB can grant a waiver of consent if certain criteria are met.

Alteration – an IRB can approve a consent procedure that omits some, or alters some or all of the basic and additional elements of informed consent if the conditions below are met.

These conditions apply if the research involves using identifiable private information or identifiable biospecimens, and the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

The waiver of consent cannot be used if an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent.

Waiver or alteration of consent can be granted if the IRB finds and documents:

1. The research involves no more than minimal risk;
2. The research could not practicably be carried out without the requested waiver or alteration;

3. The waiver or alteration will not adversely affect the rights and welfare of the subjects;  
AND
4. Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participating.

117(c)(1): An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

- (i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or LAR) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
  - (ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
  - (iii) If the subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
- (2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or LARs with a written statement regarding the research.

### **IRB Records – Additional Documentation Requirements**

1. Documentation of the rationale for conducting continuing review of research that otherwise could not require continuing review (3);
2. Documentation of the rationale for an expedited reviewer's determination that research appearing on the expedited review list if more than minimal risk (8); and
3. Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of the final rule (9).

### **Cooperative Research**

There is a mandate for single IRB. Domestic institutions engaged in cooperative research must rely on a single IRB that is:

1. Identified by Federal department/agency supporting or conducting the research; or
2. Proposed by lead institution and agreed upon by department/agency.

*Of note, the implementation for the sIRB requirement will not occur until January 20, 2020! However, the NIH has also imposed a sIRB requirement which has an implementation date of September 15, 2017 for NIH funded multi-site clinical trials.*

**Establish a Plan for Existing Studies**