

# Revised Common Rule & Other Regulatory Changes

Special Series

November 6, 2018

Issue 4



**Coming January 21, 2019!**

*What to expect and how to prepare.*

**In this issue: Exempt Research – New Category 3  
(Benign Behavioral Interventions)**

## Overview

**What is Exempt Research?**

**Category 3 Exemption Criteria**

**What is a Benign Behavioral Intervention?**

**Allowable Procedures**

**Who Can Participate?**

**Privacy Protections**

**Transition Plans**

**Resources**

**Questions**

**Schedule of Topics**

## Overview

---

The revised Common Rule changes the exemption categories to reflect recent trends in research oversight to reduce administrative burden on researchers and IRBs for minimal risk research. These changes include:

- modification to most existing categories.
- expansion in scope to several existing categories
- addition of new categories
- identification of specific regulatory requirements that must be met as a condition of being exempt from the other regulatory review requirements.

The current category 3 exemption under the Pre-2018 Requirements will be eliminated. In its place, the revised Common Rule establishes the long-awaited exemption category, *Benign*

*Behavioral Interventions*. Though certain to be popular, this exemption category is complex. Researchers should thoroughly review the requirements and limitations of this exemption category.

## What is Exempt Research?

---

Exempt research is a sub-set of research activities in which the **only** involvement of human subjects (or their information/biospecimens) falls into one or more specific categories defined in the Common Rule<sup>1</sup>.

Although exempt research is not subject to the same requirements as is expedited and full board research, it must still meet ethical and institutional standards. UT policy mandates that exempt research is reviewed and is determined (i.e., certified) to meet one or more of the federal exemption categories. At UT, this review and determination is performed by the Human Research Protection Program (HRPP) Office in consultation with the IRB.

While exempt research is not subject to continuing review, the researcher is obligated to

- submit an amendment for any changes to the research;
- report any unanticipated problems; and
- submit a closure report upon completion of the research activities.

### What to Expect:

Aside from changes to specific exemption categories, there will be some general changes to the oversight and processing of exempt research.

- The IRB application was revised last spring to include an item asking researchers to enter a specific date.
- If the study has been completed by expected completion date, the principal investigator (PI) will be required to submit a Closure Form within 30 days of completion or termination of all the study's research activities to provide a final report and request that the IRB close its research records.
- As a courtesy, the HRPP Office will issue an email reminder to the PI through iMedRIS prior to the study's expected end date instructing the PI to either submit a Closure Form if the research has been completed or submit an amendment request to extend the study's end date. The PI bears ultimate responsibility for making sure the required documents are completed and submitted in a timely manner.

## Category 3 Exemption Criteria

---

The revised regulations at 45 CFR 46.104(d)(3) lay out the criteria that must be met for research to qualify as a benign behavioral intervention.

---

<sup>1</sup> 45 CFR 46.104 (Revised)

(3)(i) 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 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, educational advancement, or reputation; or
- (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects 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).

(ii) 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. 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.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject 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.

## What is a Benign Behavioral Intervention?

---

### What is an *Intervention*?

In order to understand what a benign behavioral intervention is, we need to clarify what is meant by "*intervention*."

The **Common Rule defines *intervention*** as including both physical procedures by which information or biospecimens are collected (e.g., venipuncture) and manipulation of the subject or the subject's environment that are performed for research purposes.<sup>2</sup>

---

<sup>2</sup> 45 CFR 46.102 (e)(2) (Revised)

In simpler terms, **intervention** means an action that is taken with the intent of finding out whether it will change subjects and their behavior, performance, emotions, thinking, or physical being.

## What Constitutes a *Behavioral Intervention*?

**Behavioral interventions** are limited to the performance of a cognitive, intellectual, educational, or behavioral task; or the manipulation of the subject's physical, sensory, social, or emotional environment. Interventions that include medical tests, medical procedures, or use of medical devices are not eligible for this exemption.

## What Constitutes a *Benign Behavioral Intervention*?

A "**benign**" behavioral intervention<sup>3</sup> is:

- **Brief in duration** lasting from a few minutes to a few hours. The duration pertains to only the intervention, not the data collection conducted to study the intervention.\* Although the intervention does not have to occur in a single session, the entire time it takes to conduct the intervention should occur on a single day and not exceed a few hours in its entirety.
- **Not physically invasive** (e.g., finger stick, venipuncture). Behavioral interventions do not involve the introduction or administration of instruments, substances or energy onto or into the body. Alterations in the subject's physical or sensory environment may not be harmful, painful or distressing, such as exposure to extremes of heat, cold, noise or light.
- **Not expected to cause physical or emotional harm or discomfort, pain or persistent discomfort** or to have a significant adverse impact on the subject. The intervention can involve ordinary, mild, transient forms of discomfort, such as the stress associated with completing a timed cognitive task, anxiety about performance, and boredom.
- **Not offensive or embarrassing.** The researcher has no reason to think subjects will find the intervention or the data collection methods used in the research embarrassing or offensive considering
  - the characteristics of the subject population,
  - the research context, and
  - how they might impact the subject's experience of the research context.\* If the intervention and the data collection are intertwined or difficult to separate, the entirety of the activity should be brief in duration.

\* If the intervention or data collection methods may reasonably be expected to cause embarrassment or offence, the researcher must justify how the research context and/or subject population will make such a result unlikely.

---

<sup>3</sup> Secretary's Advisory Committee on Human Research Protections, August 2, 2017, Letter to the HHS Secretary and Attachment B, [Recommendations on Benign Behavioral Intervention](#).

# Allowable Procedures

---

This new exemption category specifies the procedures allowed for both interventions and data collection.

## Intervention Procedures

Allowable intervention procedures are limited to:

- communication or interpersonal contact with the subject,
- the performance of a cognitive, intellectual, educational or behavioral task\*\*, or
- manipulation of the subject's physical, sensory, social, or emotional environment.
- Deception is allowable under the following conditions:
  - The deception is limited to the nature/purpose of the research,
  - Participants prospectively agree to the use of deception, and
  - A debriefing is conducted after the intervention as appropriate.

\*\* Procedures involving the performance of a cognitive, intellectual, educational or behavioral task cannot include physical (bodily) tasks or physical manipulations (e.g., range of motion activities, physical exercise) unless these are minor activities that are incidental to the behavioral intervention and do not increase risk. **Example:** manipulating a keyboard, doing a puzzle, or walking while listening to music would be physical activities that could be considered minor activities that are taking place incident to the benign behavioral intervention.

## Data Collection Procedures

Data collection procedures are limited to:

- verbal (oral) or written responses by the subject;
- data entry by the subject;
- observation of the subject, including audiovisual recording

Physical procedures that are low risk, such as the application of sensors to the body (e.g. blood pressure monitoring, electroencephalogram (EEG), wearable activity trackers), minimally invasive procedures (e.g. blood drawing), the collection of bodily fluids via introduction of a tool or sensor into the body (e.g. buccal/cheek swab), and data entry by a device (e.g., a Fitbit) would not qualify for this exemption category.

## Who Can Participate?

---

The 2018 Requirements are very specific about the participant population allowed for this exemption category. Eligible participants must meet the following requirements.

- Participants must be adults.

- Participants must be able to consent for themselves. Individuals who cannot legally consent for themselves (children) and those whose decision-making must be made by a legally authorized representative would not qualify for this exemption category.
- Participants must prospectively agree to the research and that agreement must be meaningful. Participants must be aware of both the specific intervention and information being collected.
- Vulnerable populations are not allowed under this exemption category with the exception of the incidental involvement of a prisoner when the research targets a broader participant population.
- If deception is used, individuals may only participate if they prospectively agree to the use of the deception.

## Privacy Protections

---

The research must include procedures that meet one of the following conditions concerning privacy protections.

- A) The information obtained 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;
- 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, educational advancement, or reputation; or
- C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects 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 §45 CFR 46.111(a)(7).

\*\*\* *Limited IRB Review* is a type of expedited review process introduced by the revised Common Rule which may allow some research, that would otherwise be reviewed by expedited procedures, to qualify for exemption. A more in-depth discussion on limited IRB review will be provided in the November 13, 2018 issue of this newsletter series.

## Transition Plans

---

### Now

We are revising the IRB application to allow researchers to apply for this new exemption category and creating additional guidance with examples of studies that may qualify for this benign behavioral intervention category.

## Beginning January 21, 2019

The revised IRB application form in iMedRIS must be used for all new IRB applications submitted on or after this date.

We will provide additional information about the transition timeline and options for ongoing research later this month.

## Resources

---

To learn more, check out these resources.

**Watch OHRP Video:** Overview of Changes to Exemptions in the Revised Common Rule (Focusing on Exemptions 1, 2, 3, and 5) [June 22, 2018].

This video explains these changes concentrating on the requirements for categories 1, 2, 3, and 5). The discussion includes the requirement for Limited IRB review.

Secretary's Advisory Committee on Human Research Protections, August 2, 2017, Letter to the HHS Secretary and Attachment B, ***Recommendations on Benign Behavioral Intervention***.

**Revised Common Rule Q&As**, Office for Human Research Protections, July 30, 2018.

**45 CFR 46.104**, Federal Policy on the Protection Human Subjects (the Common Rule), January 19, 2017.

**Revised Common Rule Educational Materials**, Office for Human Research Protections.

**CITI Program Final Rule Resources**, Collaborative Institutional Training Initiative

**Watch UT IRB Video:** The Revised Common Rule: Revised Regulations on Human Subjects Research January 21, 2019.

In this video UT IRB Chair, Colleen Gilrane, explains expected changes related to the revised regulations **regarding Informed Consent** and their impact on the UT research Community. To access the video you will be prompted to enter your UT NetID.

## Questions

---

We encourage members of our research community to contact us with any questions about the revised Common Rule, plans for their implementation or other regulatory revisions. We will do our best to answer your questions in future issues of this newsletter series. Submit your questions to [utkirb@utk.edu](mailto:utkirb@utk.edu) and use the subject line **revised Common Rule question**.

## Schedule of Topics

---

Below is our schedule of topics. New issues will be distributed through the iMedRIS users distribution list and posted on the **Newsletter Archive** page of our website.

Issue	Date	Topic
1	10.17.2018	<b>Revised Common Rule – Background and Basics</b>
2	10.23.2018	<b>Informed Consent – New Elements</b>
3	10.30.2018	<b>Informed Consent – Informed Consent Process &amp; Other Related Changes</b>
4	11.6.2018	Exempt Research – New Category 3 (Benign Behavioral Interventions)
5	11.13.2018	Exempt Research – Revised Category 4 (Secondary Research)
6	11.20.2018	Exempt Research – Other Changes to Exempt Research
7	11.27.2018	Continuing Review
8	12.4.2018	Transition to revised Common Rule – Existing Studies
9	12.11.2018	Definitions
10	12.18.2018	NIH Policy Changes <ul style="list-style-type: none"> <li>• ClinicalTrials.gov</li> <li>• CGP Training</li> </ul>
	12.25.2018	No Newsletter – Winter Break
11	1.8.2019	Grant Application Review
12	1.15.2018	Single IRB Review

We would like to express our thanks to the Human Subjects Division at the University of Washington whose own newsletter inspired this special series.