

# 2018 Revised Common Rule

## Table of Contents

<b>Overview of the Revised Common Rule</b>	<b>2</b>
<b>Key Features of the Revised Common Rule</b>	<b>2</b>
<b>Guidance for Exempt Research</b>	<b>5</b>
<b>Guidance for Benign Behavioral Interventions</b>	<b>10</b>
<b>Guidance for Limited IRB Review</b>	<b>13</b>

# 2018 Revised Common Rule Overview

## **Background**

The Revised Common Rule is the set of regulations governing human subjects research that is federally funded or supported. It has been adopted by 19 federal agencies and went into effect on January 21, 2019. The revision updates the 1991 Common Rule to address new areas of research and to streamline administrative burdens for minimal risk research so that IRBs may focus more attention on higher risk projects.

## **Applicability**

KUMC applies the Revised Common Rule to all research that is federally funded or supported or that pertains to FDA-regulated projects. The FDA is not a common rule agency and, as of January 2020, the FDA has not harmonized its regulations with the Revised Common Rule. However, KUMC and many academic medical centers broadly apply the rule's new informed consent standards to FDA-regulated studies as part of best practice. See the [Appendix](#) for a checklist of applicability for the Revised Common Rule.

Please note:

- Minimal risk research that is not federally funded or supported and does not pertain to FDA-regulated products is reviewed under [SOP 20: Flexible IRB Review](#).
- Ongoing research that was IRB-approved before January 21, 2019 remains under the 1991 version of the regulations.

## **KEY FEATURES OF THE REVISED COMMON RULE**

### **Informed Consent**

KUMC consent forms that are more than 8 pages must begin with a new section called **Key Information**. The purpose of this section is to provide a concise summary of the study and to help potential subjects start to decide whether or not they are interested in participating. The IRB's [Forms and Templates](#) page has consent templates showing this new section and examples of Key Information language.

Under the revised regulations, consent forms must have new statements about the use of de-identified information, use of biospecimens, potential for commercial profit, and return of clinically-relevant results. KUMC consent form templates reflect these new elements.

KUMC investigators who conduct investigator-initiated clinical research must post their consent forms to [clinicaltrials.gov](#). The posting must occur no more than 60 days after the last study visit by any subject. The [KUMC Research Institute](#) assists investigators with this process.

### **IRB Reliance**

All multi-center research funded by federal agencies must use IRB reliance or "single IRB review" for the domestic sites. KUMC serves as the Reviewing IRB when our investigators conduct multi-site trials. We also have numerous agreements allowing us to rely on the review of other institutional IRBs or commercial IRBs. For more information, please refer to our [IRB Reliance Website](#). For assistance, you can email the [IRB Reliance Team](#).

## Exempt Research

The Revised Common Rule broadens the types of research that qualify for exemption. Several exempt categories have been revised, and there are new categories of exemptions. Additional guidance documents which effect exempt research include:

- [Guidance on Exempt Research](#)
- [Guidance on Benign Behavioral Interventions](#)
- [Guidance on Limited IRB Review](#)

## Continuing Review

Unless the research is FDA-regulated, the Revised Common Rule removes the requirement for continuing review for minimal risk research and for full-board research that is in long-term follow-up or data analysis only.

New minimal risk research will not automatically undergo continuing review by the IRB unless it is FDA-regulated. The IRB may require continuing review for special circumstances such as studies involving conflict of interest, IRB reliance or prior compliance concerns.

**Even when continuing review is not required, investigators remain responsible for updating the IRB about adverse events and other unanticipated problems, seeking IRB approval for changes to personnel, protocol amendments, recruitment materials, etc., and informing the IRB when the research is complete.**

## Resources

[Revised Common Rule](#)

[KUMC Training Presentation on the Revised Common Rule](#)

[Appendix: Applicability of the Revised Common Rule](#)

## Appendix: Applicability of the Revised Common Rule

The Revised Common Rule applies to all research that is federally funded or supported. Regulations do not define “federally funded or supported.” KUMC uses these criteria to determine applicability:

- Funded by a direct federal grant
- Funded through a sub-award or pilot grant associated with federal dollars
- Includes personnel on a federally-funded training grant
- Research conducted under a no-cost extension
- Data will be used to support an application for FDA approval or a grant application (e.g., data collection in response to a scored grant submission with plans to re-submit)
- Involves an FDA-regulated product or dietary supplement
- Involves registries about FDA-regulated products
- Conducted under a contract that requires the investigator to adhere to federal human subjects regulations (e.g., 45 CFR 46, 34 CFR 97 or other references to the HHS Common Rule)
- Involves any services that could be billed to a federal program

Additionally, the KUMC IRB applies the new consent elements from the Revised Common Rule regardless of funding source. They include:

- Key Information section (for consent forms longer than 8 pages)
- A statement about the possibility of de-identifying the data and specimens and using them for other research purposes in the future
- If applicable, a statement that biospecimens may be used for commercial profit
- A statement about whether participants will be told about clinically relevant research results

# EXEMPT RESEARCH UNDER THE REVISED COMMON RULE

**This guidance applies only to research that is federally funded or supported.  
Minimal risk research that is not federally funded or supported is reviewed under  
[SOP 20: Flexible IRB Review](#)**

As of January 21st, 2019, the federal government changed the types of human subjects research that are considered “exempt.” These projects are exempt from annual IRB review and from the informed consent requirements that apply to other types of research; however, some of the new categories will require prospective participant agreement and a limited form of IRB review.

Even when research is exempt from further requirements of federal regulations, basic ethical standards still apply.

- Except in the case of chart reviews or database research, potential subjects must be provided with enough information to be able to choose whether or not to participate. The information should include the voluntary nature of their participation, the purpose of the research, the nature of the subject’s involvement, time commitments, and contact information for the investigator.
- Research data must be handled and stored securely, in compliance with University policy.
- Access to research data must be limited to study team members and other authorized personnel.
- All members of the research team must be current on human subjects training and must have a current conflict of interest disclosure.

Each exempt category is described below. The regulatory text is in [blue](#), and clarifications follow.

## **EXEMPT CATEGORY 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.](#)

Most educational research on regular and special educational instructional strategies, and research on the effectiveness of, or comparison among, instructional techniques, curricula, or classroom management methods may be exempt under this category.

Changes to this exempt category include the caveat that there must not be any impact on the subjects’ opportunity to learn or any negative impact if the research involves an evaluation of the instructors. If the research involves diverting significant time and attention away from the delivery of the regular curriculum or withholding of standard educational content, this exemption would not apply. Also, there must be protection against negative impact on employment if instructors are being evaluated. Research involving randomization to an unproven educational technique, or research conducted by supervisors involved in employment decisions may not be approvable under this exemption.

*Applicability to vulnerable populations:*

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.

## **EXEMPT CATEGORY 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 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, educational advancement, or reputation; or
- (iii) 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*.

This exemption category involves several changes from pre-2018 rules. The wording of this exemption was changed to clarify that the category applies to research that *only* involves interactions. Additionally, the use of potentially sensitive information might be allowable if appropriate protections are in place and the IRB conducts a new process called '*limited IRB review*.'

This category involves interactions (verbal and written responses) and data collection only. The data collection can include audio or video recordings. Research involving "interventions" would not be approvable under this category. Interventions include manipulation of the environment or physical procedures to collection information, such as a cheek swab.

### *Applicability to vulnerable populations*

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption only when it relates to educational tests or observations of public behavior in which the investigators don't participate in the activities being observed. Additionally, children are not eligible for this exemption if the project requires limited IRB review.

## **EXEMPT CATEGORY 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:

- (i) 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;
- (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, educational advancement, or reputation; or
- (iii) 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*.

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.

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.

This exempt category is completely new in the 2018 revisions to the federal regulations. There are limits on the interventions considered ‘benign’ and requirements on IRB review of this type of research. Please refer to the [Guidance for Research Involving Benign Behavioral Interventions](#).

*Applicability to vulnerable populations:*

- Pregnant women who are adults *may* be included in this type of research
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research that could include children is *not* eligible for this exemption.
- Research involving decisionally-impaired persons is *not* eligible for this exemption.

#### **EXEMPT CATEGORY 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, 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 non-research 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 applicable federal privacy standards found in the E-Government Act, Privacy Act and the Paperwork Reduction Act.

The 2018 changes significantly broaden the type of secondary research that can be done under this exemption category:

- The requirement that all study data be existing at the time of IRB submission has been eliminated. Data under this exemption may be both retrospective and prospective.
- As noted in the regulatory definition above, informed consent is not required for this category of research.
- The requirement that the study involves data only has been eliminated. This exemption category may also involve the use of specimens *if the specimens are publicly available or provided to the researcher in a coded/de-identified manner*.
- If the investigator uses identifiable specimens for the research, it will not qualify for this exemption category; however, it may be approvable under an Expedited review process.
- Creating a de-identified dataset for analysis is still an approvable option and continues to be the most straight-forward approach.

- If investigators need to retain data that contains any HIPAA elements or need to retain a linking list, then appropriate HIPAA protections could make the project approvable. Depending on the circumstances of the data, the HIPAA protections might include a Data Use Agreement or a waiver of HIPAA authorization with accounting of disclosures.
- Certain sources of publicly available data require the recipient to sign an agreement outlining restrictions on access, use, security and transfer. Most often, those agreements will need review by the university's general counsel.
- Collaborations with non-KUMC researchers who are not members of a HIPAA covered entity or covered component will add data protection requirements and move the project outside of this exemption category.

It is important to note the Exemption Category 4 only applies to the *re-use* of data and specimens that were or will be collected for non-research purposes or from research studies other than the proposed research study. The research materials typically will be publicly available materials, medical records or existing repositories of clinical specimens. *No contact between investigator and subject is allowed.* If an investigator wants to collect information/specimens directly from research subjects, then another approval path would be required.

*Applicability to vulnerable populations:*

- Data/specimens from pregnant women would be allowed
- Data/specimens from prisoners could be allowed as long as the research wasn't designed to recruit prisoners and prisoners were only incidental subjects of the research.
- Data/specimens from children would be allowed
- Data/specimens from persons with decisional impairment would be allowed

### **EXEMPT 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 otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. 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.

The scope of this category has been broadened. Prior rules required that the Federal demonstration projects be conducted by the Federal agency. This category has been updated to allow projects that are simply funded by a Federal agency. The scope has been expanded to include purposes not only to study and evaluate but also to improve these programs. Note that projects eligible for this exemption will be posted on a Federal website. Investigators who have a project in this category are asked to consult with [IRB staff](#) prior to submission.

### **EXEMPT CATEGORY 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 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.

This exemption category was not changed in the revised Common Rule. Note that it is the only exemption that is allowable for FDA-regulated research.

#### *Applicability to vulnerable populations:*

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.
- Research involving decisionally-impaired persons could be allowed if their inclusion was justified.

### **EXEMPT CATEGORY 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 determinations required by § .111(a)(8).

This exemption is new with the 2018 Common Rule and is not being implemented at KUMC. It may be implemented in the future, if capacity to meet technical and regulatory requirements is confirmed.

### **EXEMPT CATEGORY 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
- (ii) §\_\_ .116(a)(1) through (4), (a)(6), and (d);
- (iii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §\_ .117;
- (iv) An IRB conducts a limited IRB review and makes the determination required by
- (v) §\_ .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 479
- (vi) 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 any legal requirements to return individual research results.

This exemption is new with the 2018 Common Rule and is not being implemented at KUMC. It may be implemented in the future, if capacity to meet technical and regulatory requirements is confirmed.

# **RESEARCH INVOLVING BENIGN BEHAVIORAL INTERVENTIONS (Exempt Category 3)**

**This guidance applies only to research that is federally funded or supported.  
Minimal risk research that is not federally funded or supported is reviewed under  
[SOP 20: Flexible IRB Review](#)**

Beginning January 21, 2019, the federal government changed the types of human subjects research that are considered “exempt.” A new category of exempt research is those projects involving benign interventions (**Exempt Category #3**). This guidance document aims to provide examples of interventions that are considered ‘benign’ and to outline the limitations on the use of the exemption category.

## **How do the federal regulations describe this exemption category?**

“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:

- (i) 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;
- (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, educational advancement, or reputation; or
- (iii) 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).

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. The interventions are limited to communication or interpersonal contact with the subject; performance of cognitive, intellectual, educational or behavioral tasks; or manipulation of the subject’s environment.

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 are the limits on the use of Exempt Category 3?**

- Participants must be adults who are able to prospectively agree to the research. Children and subjects who require a surrogate decision-maker may not be enrolled.
- The overall duration of the intervention must be brief. It should occur in a single day and not exceed more than a few hours.
- The research activities must be behavioral in nature; they cannot include medical interventions, even if those interventions are low risk.
- Data collection must only be through verbal and written responses by the subject, data entry by the subject or observation of the subject. The data collection can include audio or video recordings.
- Data from electronic sensors or devices would not be approvable in this exemption category.
- Changes to the subject’s physical environment are allowed, provided they do not involve extremes of heat, cold, noise or light.
- Appropriate privacy protections are required.

## What are examples of ‘benign interventions?’

Example*	Benign Intervention, Yes or No?
<p>Graduate business students are asked to participate in research examining the influence of surfing a social media site on measures of self-control. Students were randomly assigned to browse a popular social networking site or a popular news site and then, as a measure of self-control and persistence, were timed in their efforts to solve a complex word puzzle (for which there was no solution). No identifiable information is recorded.</p>	<p>Yes. Subjects will be agreeing to participate, and the data will be anonymous.</p>
<p>To study the influence of restaurant gratuity policies on overall satisfaction, customers calling for reservations are asked to take part in a research study involving the completion of an anonymous survey following their meal. Those who agree are randomly assigned to either a suggested service charge group or a group where there are no suggested gratuity amounts identified. Individuals are informed about a survey but not about the subject of the survey or assignment to one of these groups. All are told that certain aspects of the research will only be revealed to them at the conclusion of their involvement.</p>	<p>Yes. The study involves deception, and subjects are informed of this aspect in advance. Also, the intervention is brief and not expected to have negative impact.</p>
<p>Adult learners agree to be videotaped while reading a passage from a standard text while alone in a quiet room. Ratings of vocal inflection and tone are assessed as predictors of comprehension and compared with the results of a written test of the subject’s ability to understand the same reading material. The procedures take 90-120 minutes.</p>	<p>Probably yes. Subjects are alone in the room, so the potential for embarrassment in public speaking has been avoided. A limited IRB review might be required if the study involved a population who could be negatively impacted by an unintended disclosure of results.</p>
<p>Nursing home staff interview patients to complete a brief self-report scale measuring mood and anxiety at baseline and two weeks after music is played nightly in patient rooms on half of the wards. All subjects are informed that a study of the effect of music is planned, and music is played only the rooms of those patients who agree to the intervention and ratings.</p>	<p>No. Although the changing of the subjects’ environment is allowed and intervention is likely benign, the two-week duration of the intervention would not qualify as ‘brief’ for this exemption category. This project would require review as Expedited research.</p>

<b>Example*</b>	<b>Benign Intervention, Yes or No?</b>
<p>Healthy adult subjects are asked to take part in two, two hour-long assessments of memory, attention and information processing speed before and after 1 hour of cognitive enhancement exercise using specially designed computer software. The procedures are conducted during a single visit, and subjects are encouraged to take breaks when desired.</p>	<p>Yes. The intervention is completed in a single day and the study is not likely to be seen as offensive or harmful.</p>
<p>Recordings of blood pressure and pulse are obtained along with the collection of a saliva specimen for the measure of cortisol level from adult subjects in a study linking physiological arousal to cognitive performance on a standard series of computer games. The procedures last 75 minutes.</p>	<p>No. The intervention is brief, but the study involves collection of blood pressure, pulse and saliva samples. This exemption category does not allow medical interventions; also, the study data would involve more than oral or written responses. This project would require review as Expedited research.</p>
<p>College students take part in a study involving computer simulation of an online dating app in which each student is ultimately rejected by a prospective date who in fact is a member of the study team. The students are asked to agree to the research and are told that aspects of the research goals and methods are being withheld from them until after their participation.</p>	<p>No. Although subjects are informed of the deception, the aim of the study is to simulate rejection and elicit an emotional response. The experience of rejection may cause distress and embarrassment. Therefore, the intervention would not be considered benign.</p>
<p>A study seeks to measure how individuals attend to visual stimuli with different emotional meaning. Each subject places his head on a chin rest in front of a computer monitor while being shown a matrix of 6 magazine photos of people with mildly sad, happy, surprised, frightened, and worried expressions. Subject eye movements and fixation are recorded by a digital camera. No identifying data are recorded.</p>	<p>Yes. The intervention is brief. The mild emotions in the photos are unlikely to be disturbing or elicit a strong negative response.</p>
<p>Clients at a health club are asked to participate in a study looking at the impact of a two-hour session on the benefits of exercise. Clients are provided with a free Fitbit and then asked to come to the club every other day to have a reading taken of their daily steps as recorded on the Fitbit.</p>	<p>No. The study data would involve more than oral or written responses because a Fitbit is being used. This project would require review as Expedited research.</p>
<p>*Examples and recommended answers are abstracted from guidance by the <a href="#">Secretary's Advisory Council on Human Research Protections</a></p>	

## LIMITED IRB REVIEW

**This guidance applies only to research that is federally funded or supported.  
Minimal risk research that is not federally funded or supported is reviewed under  
[SOP 20: Flexible IRB Review](#)**

Revised federal regulations governing human subjects research, effective January 21, 2019, require a new type of review called “limited IRB review” for certain exempt and expedited protocols.

The new provision for limited IRB review allows certain research to be categorized as exempt, even when the identifiable information might be sensitive or potentially harmful if disclosed. To qualify for exemption, the study must meet the standards of the limited IRB review.

If the information is both identifiable and sensitive or potentially harmful, the safeguards offered by the limited IRB review may allow the IRB to make an exemption determination.

### ***Limited IRB review is required in the following circumstances:***

1. Exempt category 2 (educational tests, surveys, interview or observations of public behavior) When the information is recorded by the investigator in an identifiable manner and disclosure of the subject’s responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement or reputation.
2. Exempt category 3 (benign behavioral interventions)  
When the information is recorded by the investigator in an identifiable manner and disclosure of the subject’s responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement or reputation.

### ***Reviews Related to Privacy and Confidentiality***

The purpose of limited IRB review is to assure adequate protections for the privacy of subjects and adequate plans to maintain the confidentiality of the data. To assure these protections, the limited IRB review may consider the following topics:

- The nature of the identifiers associated with the data
- The justification for needing identifiable materials to conduct the research
- The feasibility of conducting the research with fewer identifiers (to lower the risk of a breach)
- Characteristics of the study population
- The proposed use of the information
- The overall sensitivity of the data being collected
- Persons or groups who will have access to study data
- The process used to share the data
- The likely retention period for identifiable data
- The security controls in place
  - Physical safeguards for paper records
  - Technical safeguards for electronic records
  - Secure sharing or transfer of data outside the institution, if applicable
- The potential risk for harm that would occur if the security of the data was compromised.

Additional information about adequate protections is outlined in guidance issued by the HHS Secretary.

### **Individuals Performing the Limited IRB Review**

Limited IRB review must be performed by the IRB Chair or by an experienced IRB member. The review can occur on an expedited basis and does not require consideration by a convened board. The reviewer may require modifications to the proposal prior to approval. Disapprovals must be made by the convened board. If the limited IRB review does not result in approval under the exempt categories, then the IRB can evaluate whether or not approval is appropriate under expedited categories. Expedited research must meet all the approval criteria under 45 CFR 46.111, including either informed consent or waiver of consent.