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THE REVISED COMMON RULE: WHAT HAPPENS NOW AFTER THE COMPLIANCE DATE?

2019 SRA MIDWEST/NORTHEAST SECTION MEETING
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INTRODUCTIONS

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TODAY'S PRESENTERS

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LEARNING OBJECTIVES

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LEARNING OBJECTIVES

1. List the major changes in the revised Common Rule and implementation examples.
2. Identify best practices when working within both sets of rules.

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REVISED COMMON RULE: DISCLAIMER

The material presented today should be considered a work in progress, based upon our current understanding of the Revised Common Rule.

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REVISED COMMON RULE
TERMINOLOGY

Terms	Definition
Pre-2018 Rule	Current set of Common Rule regulations that IRBs followed prior to January 21, 2019
2018 Rule; 2018 Requirements; Revised Rule; Revised Common Rule	Updated Common Rule, effective January 21, 2019 (except for collaborative research, effective January 20, 2020)
Interim Final Rule	Formal rulemaking which delayed the 2018 Rule until July 19, 2018
Final Rule	Final Rule to Delay for an Additional 6 Months the General Compliance Date of Revisions to the Common Rule While Allowing the Use of Three Burden-Reducing Provisions; delayed compliance date to January 21, 2019

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REVISED COMMON RULE CHANGES

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REVISED COMMON RULE BACKGROUND

- The U.S. Department of Health and Human Services and 15 other federal agencies have issued a final rule to update the "Common Rule" regulations that safeguard individuals who participate in research

- This update to the Common Rule follows the September 2015 publication of the Notice of Proposed Rulemaking (NPRM). In response to concerns raised during the public comment period and extensive subsequent review processes, the final rule contains a number of significant changes from the originally-proposed rule

- Original effective and compliance date was January 19, 2018; was first delayed until July 19, 2018; delayed a final time until **January 21, 2019**

- Final delay allowed implementation of three (3) burden-reducing provisions prior to compliance date

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REVISED COMMON RULE TIMELINE

1/19/17

- Release of Final Rule from Office of Human Research Protections (OHRP)
- First major update to the Common Rule since the 1990s

1/25/18

- Effective Date for the NIH Single IRB (sIRB) of Record Policy

1/21/19

- Revised Effective and Compliance date for the Final Rule
- All research approved on or after this date must follow the Final Rule

1/20/20

- Compliance Date for the Final Rule Single IRB of Record Requirement

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REVISED COMMON RULE
SUMMARY OF CHANGES

- Key changes to existing Common Rule regulations include:
  - Requires use of a single IRB for most Federally funded multi-institution research studies (effective January 2020)
  - Elimination of grant congruency review by the IRB
  - New/revised definitions including “clinical trial,” “human subject,” and “research”
    - IMPACT: Update applicable IRB SOPs, review tools, etc.
  - Requires additional content in informed consent documents
    - IMPACT: Update informed consent templates and review tools

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REVISED COMMON RULE
SUMMARY OF CHANGES

- Key changes to existing Common Rule regulations include (continued):
  - New options for the use of “broad consent” documents for research involving identifiable data or identifiable bio-specimens
    - IMPACT: Institutions should decide whether or not they want to allow use of broad consent; if so, develop a broad consent template, tracking mechanism and review tools
  - New categories of “exempt” human research
    - IMPACT: Update review tools and possibly eIRB system
  - New criteria for limited IRB review required for certain exempt categories.
    - IMPACT: Update review tools and possibly eIRB system

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REVISED COMMON RULE
SUMMARY OF CHANGES

- Key changes to existing Common Rule regulations include (continued):
  - Elimination of continuing review requirements for certain human research studies
    - IMPACT: Update review tools and possibly eIRB system; consider instituting an alternate process for the organization to maintain oversight over the research
  - Required posting of consent documents for certain federally-funded trials to a public website
    - IMPACT: Identify party responsible for ensuring compliance and develop process

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2018 RULE COMPLIANCE DATE

- Through this final rule, the general compliance date for the 2018 Requirements was **January 21, 2019**
- The regulations are still referred to as “pre-2018” and “2018” even though the compliance date is January 21, 2019; the text of the revised Common Rule is unchanged
- Any study initiated on or after January 21, 2019 is required to comply with the 2018 Requirements. Any study initiated before January 21, 2019 is required to comply with the pre-2018 Common Rule, unless an institution voluntarily elects to transition such studies to comply with the 2018 Requirements.
  - This election to transition a study must be documented and dated by the institution or an IRB.

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IMPLEMENTATION GUIDANCE

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ELIMINATION OF INSTITUTIONAL REVIEW BOARD (IRB) REVIEW OF RESEARCH APPLICATIONS AND PROPOSALS: 2018 REQUIREMENTS DRAFT GUIDANCE

- Issued July 19, 2018

The pre-2018 Requirements require an FWA institution to certify to HHS that each application or proposal covered by an OHRP-approved assurance and by 45 CFR 46.103 has been reviewed and approved by the IRB

The 2018 Requirements eliminate the requirement in the pre-2018 Requirements that grant applications or proposals for research undergo IRB review and approval for the purpose of certification.

- IMPACT: Even though draft guidance, it states what is in revised Common Rule. Since IRB does not need to review the grant anymore, IRBs do not need to request a copy of the grant for this purpose.

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SCHOLARLY AND JOURNALISTIC ACTIVITIES DEEMED NOT TO BE RESEARCH: 2018 REQUIREMENTS DRAFT GUIDANCE

- Issued July 19, 2018
- The 2018 Requirements explicitly clarify that a category consisting of certain scholarly and journalistic undertakings are not included in the definition of "research", and do not fall within the scope of the regulations.
  - Examples cited include oral history, journalism, biography, literary criticism, legal research, and historical scholarship
- In contrast, if the activity involves collecting and using information about individuals for the purpose of drawing generalizations about such individuals or a population of which they are members, then the activity does not fit the parameters of this exception, and the activity may fall within the definition of “research” under the 2018 Requirements.
- Studies using methods such as participant observation and ethnographic studies, in which investigators gather information from individuals in order to understand the beliefs, customs, and practices, not only of those individuals, but also of the community or group to which they belong, would not meet the category found at 45 CFR 46.102(*l*)(1). The purpose and design of such studies or activities is to reveal something about the community or group – that is, to develop generalizable knowledge.

IMPACT: None because guidance is DRAFT. Likely no change as IRBs have historically not considered these activities human subjects research.

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ACTIVITIES DEEMED NOT TO BE RESEARCH: PUBLIC HEALTH SURVEILLANCE 2018 REQUIREMENTS DRAFT GUIDANCE

- Issued November 7, 2018
- Public health surveillance activities are deemed not to be research.

The activity must be a public health surveillance activity	The activity must be conducted, supported, requested, ordered, required, or authorized by a public health authority	The activity must be limited to that necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance
• OHRP views surveillance activities that are not undertaken for the purpose of directly informing public health decision making or action generally not to be public health surveillance, even if they might be considered surveillance for other purposes.	• The definition of a "public health authority" extends to government entities at all levels, within the United States and abroad, that are responsible for public health matters. It also extends to anyone acting on such an entity's behalf, for example, through a grant of authority or contract. Examples include ministries of health, state and local health departments, CDC, FDA, OSHA.	• To satisfy the "limited to those necessary" condition of this provision, OHRP considers only the component parts of an activity that address one or more of these objectives to appropriately constitute a public health surveillance activity.

IMPACT: None because guidance is DRAFT. When final, IRBs may want to update non human subjects research criteria to include information to assist with decision making

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REQUIREMENT FOR CONTINUING REVIEW UNDER REVISED COMMON RULE

(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) 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 part of clinical care.

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REQUIREMENT FOR CONTINUING REVIEW UNDER REVISED COMMON RULE

Specifically, for *(i) Research eligible for expedited review in accordance with 45 CFR 46.110*; in 45 CFR 46.110(a) it states, "The Secretary of HHS has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure." In the Federal Register, the list of research categories eligible for expedited review include:

8. Continuing review of research previously approved by the convened IRB as follows:

a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

b. where no subjects have been enrolled and no additional risks have been identified; or

c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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QUESTION POSED TO OHRP

Question: Are categories #8 and #9 included under 45 CFR 46.109 (f)(1)(i) as research that does not require continuing review or is 45 CFR 46.109 (f)(1)(i) applicable only to categories 1-7 in the Federal Register?

a. If the IRB reviews, at a convened meeting, a study not conducted under an IND or IDE where categories two (2) through eight (8) do not apply and determines that it is no greater than minimal risk, would this study require continuing review?

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OHRP RESPONSE
INCLUDED IN OHRP 2018 REQUIREMENTS FAQS

OHRP notes that eliminating the requirement for continuing review of research eligible for expedited review effectively reduces administrative burdens, but this must be weighed against the goal of providing meaningful protections for research subjects. In the case of research eligible for expedited review categories 8(b) and 9, continuing review is likely to provide such meaningful protections. For example, studies that qualify for expedited category 8(b) may involve interactions, interventions, or procedures that might present more than minimal risk to subjects.

Similarly, continuing review of studies that qualify for expedited category 9 provides IRBs with the opportunity to evaluate the progress of ongoing research activities otherwise not included in the list of permissible expedited review categories. In both instances, OHRP believes that continuing review provides meaningful protections for human subjects, such as the opportunity to evaluate the most current risk-benefit analysis and to reapprove informed consent documents for research activities that have not been completed.

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OHRP RESPONSE (CONTINUED)

Therefore, OHRP recommends that IRBs use their discretion "to determine otherwise" under §46.109(f)(1) to determine that continuing review of research should be conducted at intervals appropriate to their degree of risk, but not less than once per year for research that is subject to the 2018 Requirements in the following circumstances:

1. Where no subjects have been enrolled and no additional risks have been identified (expedited review category 8(b)); and

2. Where (i) the research is not being conducted under an investigational new drug application or investigational device exemption, (ii) categories two (2) through eight (8) of the OHRP Expedited Review Categories (1998) do not apply, and (iii) the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified (expedited review category 9).

IMPACT: IRBs should conduct continuing review for studies that qualify for expedited review categories 8(b) and 9

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MINIMAL RISK & EXPEDITED REVIEW UNDER REVISED COMMON RULE

In the Federal Register it states:

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

However, the revised 45 CFR 46 states:

Under the final rule, a study is deemed to be minimal risk and thus eligible for expedited review if the study only involves activities on the Secretary's list, unless the reviewer determines and documents that the study involves more than minimal risk (§__.110(a) and (b)(1)). Thus, we anticipate that more studies that involve no more than minimal risk will undergo expedited review, rather than full review, which will relieve burden on IRBs. Further, IRBs will be required to document their rationale when they override the presumption that studies on the Secretary's expedited review list involve greater than minimal risk (at §__.115(a)(8)). §__115(a)(8) states "The rationale for an expedited reviewer's determination under §__.110(b)(1)(i) that research appearing on the expedited review list described in §__.110(a) is more than minimal risk."

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CORRESPONDENCE WITH OHRP

Question:
Under the final rule, is it expected that IRBs should presume that the activities listed on the Federal Register are minimal risk and therefore are not required to also document that a research activity presents no greater than minimal risk when reviewed via expedited review (if the procedures include those listed in the Federal Register)?

OHRP Response:
The answer is “No”, the reviewer does not need to document a confirmation that the research is not greater than minimal risk.

IMPACT: IRBs can remove documentation that research is also not greater than minimal risk when conducting expedited review

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IMPACT OF CERTAIN PROVISIONS OF THE REVISED COMMON RULE ON FDA-REGULATED CLINICAL INVESTIGATIONS

FDA GUIDANCE ISSUED OCTOBER 2018

- For studies that are subject to FDA regulations AND the 2018 Requirements (because they are federally funded), where the regulations differ, the regulations that offer the greater protection to human subjects should be followed
- Provisions of the 2018 Requirements related to the content, organization, and presentation of information included in the consent form and process as well as the basic and additional elements of informed consent are not inconsistent with FDA's current policies and guidances
  - IMPACT: One consent form with the additional 2018 Requirements for consent can be used

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IMPACT OF CERTAIN PROVISIONS OF THE REVISED COMMON RULE ON FDA-REGULATED CLINICAL INVESTIGATIONS

FDA GUIDANCE ISSUED OCTOBER 2018

- FDA recognizes that under the 2018 Requirements, an IRB may use the expedited procedures for research appearing on the expedited review list, unless the IRB reviewer determines that the study involves more than minimal risk. Because FDA has not revised its regulations, IRBs must continue to comply with FDA's regulation at 21 CFR 56.110(b)
  - IMPACT: The IRB must find that the research on the expedited list involves no more than minimal risk in order for the IRB to use the expedited review procedure
- Because FDA has not revised its regulations, IRBs must continue to comply with current requirements for IRB continuing review at 21 CFR 56.109(f) and conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year
  - IMPACT: IRB must be able to identify when a study is subject to FDA regulations and ensure that continuing review is conducted

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TRANSITIONING STUDIES PRE-2018 TO 2018 RULE

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TRANSITION OF STUDIES

- As a default, studies initiated (i.e., initially approved by an IRB, or determined to be exempt) before January 21, 2019 will continue to be subject to the pre-2018 Requirements
- Research initiated (i.e., initially approved by an IRB, or determined to be exempt) on or after January 21, 2019 must be conducted in compliance with the 2018 Requirements
- Any pre-2018 studies that transition to comply with the 2018 Requirements on or after January 21, 2019 must be conducted in compliance with the 2018 Requirements beginning on the transition date (i.e., the date the transition determination is documented, on or after January 21, 2019) for its duration

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3 BURDEN REDUCING PROVISIONS
ALLOWED BETWEEN JULY 19, 2018 THROUGH JANUARY 20, 2019

- Could use the 2018 definition of “research”
  - Includes the description of activities that are deemed not to be research
- Could apply the revised certification requirement that eliminates IRB review of grant applications/proposals
  - No IRB grant congruency review
- Could apply the 2018 Requirements that remove the requirement for continuing review for certain studies
  - Studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care
- Use of these provisions were optional

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THOSE WHO APPLIED THE BURDEN REDUCING PROVISIONS

- If you applied the 3 burden-reducing provisions to any studies, those studies must now be compliant with the 2018 Requirements
- For those studies that used the provision of not requiring continuing review, if the additional 2018 Requirements were not applied at the time of initial review, those studies must be re-reviewed to ensure 2018 compliance

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TRANSITION FAQS

- *What type of documentation is necessary if an institution makes the determination to transition a study that was initiated before January 21, 2019 to comply with the revised Common Rule?*
  - The institution or IRB must document and date the institution's determination to transition a study to the revised Common Rule. Beyond that requirement, the transition provision does not prescribe how institutions must document these decisions as long as the decision is dated. For example, this institutional determination could be documented in IRB meeting minutes or in an IRB reviewer checklist (if an institution uses a checklist system and maintains checklists). The determination also could be documented in an institution's existing electronic system, if it has one, or in a spreadsheet created and maintained by the institution or IRB to keep track of which studies have been transitioned to the 2018 Common Rule.

https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html

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TRANSITION FAQS

- *If an IRB approves a study with conditions before January 21, 2019, but verification that the conditions are satisfied occurs after January 21, 2019, is that study subject to the pre-2018 Common Rule?*
  - The date the IRB approves the research with conditions is the date of IRB approval. The effective date of the IRB's approval is the date that it is verified that the investigator has satisfied all conditions related to the approval. This is also the date on which the research may actually begin.
  - For the purposes of determining whether a study is subject to the pre-2018 Common Rule or the 2018 Common Rule, the date that the IRB voted to conditionally approve the study is the date that should be used.
  - For example, assume that a study is approved with conditions on January 15, 2019. Verification that all conditions have been satisfied occurs on February 1, 2019. This study would be subject to the pre-2018 Common Rule because the date of conditional approval is before January 21, 2019.

https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html

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THE REVISED COMMON RULE COMPLIANCE DATES AND TRANSITION PROVISION
DRAFT GUIDANCE

- Issued January 2019
- **Transition Principles**
  - When an institution transitions studies initiated before January 21, 2019, an IRB need not review IRB actions or research-related activities that occurred prior to the transition date in order to ascertain whether those actions or activities meet the 2018 Requirements.
    - In other words, the 2018 Requirements apply only to future actions or activities (i.e., prospectively) beginning on or after the transition date.
    - For example, there is no need to seek reconsent after the transition date from already-enrolled subjects using a consent process consistent with the 2018 Requirements. However, any subject enrolled in the study on or after the transition date must be enrolled using a consent form that complies with the 2018 Requirements.
  - Voluntarily applying provisions of the 2018 Requirements to research subject to the pre-2018 Requirements does not constitute transitioning a study.
    - An example is a decision to implement the new elements of informed consent. Without transitioning a study, it is permissible to incorporate these new elements of consent because the pre-2018 Requirements do not prohibit including such information in an informed consent document.

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THE REVISED COMMON RULE COMPLIANCE DATES AND TRANSITION PROVISION
DRAFT GUIDANCE

- Institutions may transition studies on a per-protocol basis or with respect to a broader category of research conducted at an institution.
- Institutions are not required to transition research. Only studies initiated before January 21, 2019 may be transitioned; studies initiated on and after January 21, 2019 are required to comply with the 2018 Requirements.
- A decision to transition a study may not be reversed.
- As a general rule, protocol amendments must be reviewed and evaluated under the version of the Common Rule to which a study is subject, regardless of when the amendment is made. For example, if a study is subject to pre-2018 Requirements, any amendment to that study must be evaluated under the pre-2018 Requirements regardless of when the amendment is made.
- If an institution transitions a study that was issued a waiver of consent under pre-2018 Requirements, is the new waiver of informed consent criterion in the 2018 Requirements applicable to that study?
  - If subject enrollment is ongoing on or after the study's transition date, an IRB must ensure that such enrollment complies with all of the waiver criteria outlined in the 2018 Requirements

IMPACT: None because guidance is DRAFT. When final, likely update SOPs and review tools

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GUIDANCE STILL NEEDED

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EXEMPTION 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.
- *How should IRBs interpret the condition that the normal educational practices studied "are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction"?*

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EXEMPTION CATEGORY 1

- SACHRP* recommends:
  - If the intent of the exemption is to cover research that would also be covered by FERPA, this should be made explicit in guidance. In making this determination, OHRP may wish to consider the impact of imposing restrictions on an exempt category that historically has been interpreted broadly, without any well documented issues regarding its use.
  - OHRP issue guidance that describes any limitations on what may be considered “established or commonly accepted educational settings” and “normal educational practices” for the purpose of the exemption.
  - OHRP issue guidance to clarify the limits on methods or content of data collection, if any.

* Secretary’s Advisory Committee on Human Research Protections

https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-november-13-2018/index.html

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EXEMPTION CATEGORY 2

- Research th**at 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 t**hat 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)**.

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EXEMPTION CATEGORY 2

- SACHRP recommends:
  - Guidance specify that category 2 cannot serve as the basis for a determination that interventions with research subjects are exempt.
  - OHRP issue guidance on the use of limited IRB review to support a determination that a proposed activity is exempt under category 2.

https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-november-13-2018/index.html

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INFORMED CONSENT – KEY INFORMATION

- Informed consent must begin with a **concise and focused presentation of the key information** that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one 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.
- Topics that generally would encompass the key information required to satisfy this requirement (in Preamble):
  1. The fact that consent is being sought for research and that participation is voluntary
  2. The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research
  3. The reasonably foreseeable risks or discomforts to the prospective subject
  4. The benefits to the prospective subject or to others that may reasonably be expected from the research
  5. Appropriate alternative procedures or courses of treatments, if any, that might be advantageous to the prospective subject.

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INFORMED CONSENT – KEY INFORMATION

- Questions posed by OHRP to SACHRP:
  1. How does "key information" vary depending on the clinical trial design being used, the specific research questions being asked, and the populations being asked to participate?
  2. Please consider whether the elements of consent listed in the preamble generally should be considered to encompass key information. Should all of the listed elements of informed consent be considered "key information," or, depending on the design and context of the study, would some of this information not necessarily be "key"? Are there additional recommendations regarding what should also be considered "key," beyond the listed elements of consent, depending on the design and context of the study?
  3. Are there criteria, thresholds, or standards that can be identified to determine what information should be included as "key" and what are the underlying justifications or principles supporting them?

https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-november-13-2018/index.html

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INFORMED CONSENT – KEY INFORMATION

- Questions posed by OHRP to SACHRP:
  4. Given the wide variety of types and complexities of studies, and drug/device/biologics considerations, what tool(s) or strategies do you recommend to assist investigators and IRBs in determining the key information to be presented up front (e.g., developing a table or algorithm, general points-to-consider)?
  5. Assuming risk and benefit information must be included, what considerations are relevant and what strategies can be used to determine which reasonably foreseeable risks and potential benefits should be included as key information, and how should they be discussed as key information? Specifically, how do different study designs affect: (1) which reasonably foreseeable risks and potential benefits should be included in the discussion of key information, and (2) how such risks and benefits should be described in the discussion of key information?
  6. Under what circumstances should key information presented up front be repeated in the core sections of the consent form (recognizing that there is no requirement that any such information that is already presented at the front of the consent form needs to be repeated elsewhere in the consent form)?

https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-november-13-2018/index.html

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IN SUMMARY

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SO WHAT SHOULD YOU MAKE SURE YOU ARE DOING?

- Decide if you will be transitioning any pre-2018 studies to the 2018 Requirements
  - If so, what are the criteria for deciding which studies transition?
  - Decide how you will document those studies that transition (e.g., minutes, checklist)
  - Create a checklist for those studies that transition to ensure all new criteria addressed
  - How will you identify those studies that are under pre-2018 and those that are under 2018?
  - Ensure you still have access to pre-2018 review tools for those applicable studies
- If you applied any of the burden-reducing provisions, ensure that all of those studies meet all of the 2018 Requirements
- Incorporate any OHRP FAQ information into your updated policies and procedures

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Q&A

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