Implementing the Revised Common Rule
10 Ways to Get Started

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1. **Engage leadership in key decisions that will inform implementation of the rule and budget and resource needs,** for example:

    - Will your organization apply the Common Rule (in part or in full) to all research, only to research subject to the rule, or establish different rules for unregulated research?
      (See **Thinking Points – Appendix A**)
    - Will your organization adopt the option for broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens?
      (See **Thinking Points – Appendix B**)
    - Begin decision-making and planning for management of pre-existing studies – will the IRB re-review current studies to comply with the new rule (if so all, or just studies funded or supported by Common Rule agencies?), or continue pre-existing studies under existing regulations?
      (See **Thinking Points – Appendix C**)
    - How will your organization ensure that it is aware of and able to fulfill its obligations to oversee research reviewed by external IRBs, and to fulfill obligations that may vary based upon who is serving as the IRB of record? Is there a need for a reliance office or reliance administrator? For QA/QI staff? For a separate tracking system?
    - Are there circumstances that would make the organization unwilling to cede review to an external IRB or that would require additional evaluation? (e.g., planned emergency research, research targeting a specific population)
    - The updated regulations now require that the IRB have written procedures *"… for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval"* (.108(a)(3)(iii)), how will the organization fulfill this obligation? Are additional resources needed (e.g., QA/QI staff)?
    - Identification and planning for additional budgetary and resource allocation needs.

2. **Engage stakeholders in planning for changes that will utilize or require resources outside of the HRPP/IRB,** for example:

    - Internal IT
    - Electronic system vendors (e.g., IRB platform, Electronic Health Records)
    - External IRBs (e.g., what are their plans for implementation of rule, how do they intend to manage pre-existing studies, do agreements and/or procedures for reliance need to be modified, what are their plans for dissemination of updates?)
    - Training platforms (e.g., CITI)
    - Website administrators
    - Registrar's office
    - Health Information Management
    - Legal counsel
    - Grants and Contracts or Sponsored Programs

3. **Identify rules and regulations that apply to your current research and evaluate where requirements would be the same or different from the revised Common Rule,** for example:
    - FDA
    - HIPAA
    - DOJ
    - DoD
    - VA
    - FERPA
    - PPRA
    - State law
    - Organizational policies
    - Grant requirements (e.g., NIH policies)

4. **Flag your existing materials to identify where changes are or may be needed,** for example:
    - Policies and procedures
    - Application forms
    - Reviewer checklists
    - Determination letters
    - Guidelines and resources
    - Training materials
    - Website materials

5. **Begin drafting revisions to your materials**, consider prioritizing based upon whether revisions are straight-forward (e.g., updated and new definitions) versus revisions that require decision-making or further evaluation (e.g., broad consent).

6. **Develop (or review & update as needed) reliance procedures, templates, and tools.**

7. **Review existing reliance agreements for consistency with requirements of revised rule, revise if needed** (only essential when the reliance agreement applies to research subject to revised Common Rule and, for existing NIH awards, with renewal applications).

8. **Draft or update consent templates:** consider whether you will use universal templates or will have templates specific to the rules or guidelines that apply to different categories of research (Common Rule, FDA, FDA + ICH-GCP E6, NIH, unregulated, etc.).

9. **Consider early implementation of changes that don't conflict with current Common Rule**, for example:
    - Reliance agreements/procedures
    - Consent – Design consents to begin with a concise and focused presentation of key information and so that consent is organized and presented in a way that facilitates comprehension (.116(a)(5)(i) and (ii)). Consider early adoption of additional elements called for in .116(b) and .116(c). If not already in place, consider adjusting policies and procedures to accommodate electronic consent, including electronic signatures and provision of a written copy of the consent to the signee.

10. **Develop dissemination and training plan, begin to develop materials.**

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Appendix A

Thinking Points: Applicability of the Common Rule, Changes to Federal Wide Assurances (FWAs)

Effective Date: January 21, 2019 **Compliance Date:** January 21, 2019

Current Rule:

45 CFR 46.101(a) Footnote: *"Institutions with HHS-approved assurances on file will abide by provisions of Title 45 CFR part 46 subparts A-D…"*

45 CFR 46.103(b)(a): *"…Assurances applicable to federally supported or conducted research shall at a minimum include: (1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation [emphasis added]."*

Current FWAs:

Include the following term: *"All of the Institution's human subjects research activities, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution [emphasis added]."*

Provide an option for organizations to voluntarily elect to apply the Common Rule or the Common Rule and subparts B, C, & D to all non-exempt human subjects research regardless of the source of support.

Changes:

- 45 CFR 46. 101(a) "To what does this policy apply…"
  - Removed footnote: "institutions with HHS-approved assurances on file will abide by provisions of Title 45 CFR 46 subparts A-D"
- 45 CFR 46.103(b)(a) and Terms of FWA – Eliminates the requirement to have a statement of ethical principles applicable to all human subjects research activities.
- Terms of FWA - Eliminates the options for an organization to voluntarily elect to extend their FWA so that all non-exempt human subjects research must abide by the Common Rule or the Common Rule and subparts B, C, & D.

Interpretation:

The Common Rule will now apply only to non-exempt human subject research activities conducted or supported by federal agencies that have signed on to the Common Rule. There will not be an option for "checking or unchecking" the box on your FWA. *10/15/2018 Update: OHRP has recently commented (informally) that they may delay eliminating the voluntary elections due to feedback received regarding the potential impact on research in certain states.*

As noted in the Preamble to the revised Common Rule: "*We note the concern expressed by commenters that a gap in federal oversight will remain for nonfederally funded research... **We recognize that institutions may choose to establish an institutional policy that would require IRB review of research that is not funded by a Common Rule department or agency (and indeed, as commenters noted, almost all institutions already do this), and nothing in this final rule precludes institutions from providing protections to human subjects in this way.** As a result, the final rule continues to allow institutions the same wide degree of flexibility that they currently have with regard to making other similar determinations regarding ethical oversight of research not regulated by the Common Rule. [emphasis added]*"

Federal Agencies now signed on to the revised Common Rule:

Department of Homeland Security
Social Security Administration
Department of Labor
Consumer Product Safety Commission
Department of Agriculture
Department of Energy
National Aeronautics and Space Administration
Department of Commerce
Agency for International Development
Department of Housing and Urban Development
Department of Defense
Department of Education
Department of Veterans Affairs
Environmental Protection Agency
Department of Health and Human Services
National Science Foundation
Department of Transportation

Note: Department of Justice, a current signatory, has not yet signed on to the revised Common Rule.

Institutional Decisions:

Organizations will need to decide whether to:

1. Apply the principles of the Common Rule to all research regardless of funding,
2. Apply the Common Rule only to research conducted or supported by Common Rule agencies, or
3. Apply the Common Rule to research conducted or supported by Common Rule agencies and apply other rules to research that is not covered by the Common Rule.

Thinking Points:

1. How will your organization ensure the protection of human subjects in research not subject to oversight by federal agencies (e.g., Common Rule, FDA)?
    - Will you establish institutional policy requiring IRB review and oversight for all non-exempt human subjects research?
    - Will you apply the principles of the Common Rule to all human subjects research, identify alternative standards and requirements, or some combination of each (e.g., adopt Common Rule criteria for approval of research but have standards other than those specified in Subpart B for research involving pregnant woman)?
    - Will your organization be comfortable allowing some human subjects research to be conducted without IRB review or any other institutional oversight? If so, how will you ensure that other applicable regulations or requirements are addressed (e.g., HIPAA, FERPA, state law, tribal law, accreditation standards, policies)?
2. Would you comfortable knowing that, for example, you may have very similar studies being conducted, and you would have IRB review and oversight of some, but not all? What if the research involves vulnerable populations or sensitive data or topics?
3. Does state law, accreditation standards (e.g., AAHRPP, Joint Commission, Magnet, etc.) or policy dictate requirements for IRB review and oversight that might restrict or inform decision-making about your organizational approach to research not subject to the Common Rule or FDA regulations?
4. Given your overall organizational responsibilities for the activities of faculty, employees, medical staff, students, etc. and for activities that take place within your facilities or using your data, how would your organization maintain knowledge of human subject research activities if you did not require IRB review and oversight? (volume of research, types of research, whose conducting research, etc.). If something were to happen; e.g., harm to a subject, lawsuit, etc., would your organization be able to demonstrate sufficient oversight of the research?

5. If unfunded research later receives funding from a Common Rule agency, what mechanisms would you have in place to ensure that the IRB will be notified and will review the research before any funded activities take place?
6. If unfunded research involves the use or disclosure of Protected Health Information (PHI), and your organization does not require IRB review and oversight of such research, who will be responsible for review of requests for waivers or alterations of the requirement for HIPAA authorization for research? Is a Privacy Board available or will the IRB review such requests but not the research in its entirety?
7. When similar research is subject to different requirements, how would you ensure and support researcher, IRB, and staff ability to understand and properly apply varying standards?
8. Are additional resources needed for training and education needed?
9. Are additional resources to conduct quality monitoring of research and IRB activities needed?
10. Are additional materials needed to support understanding or requirements (e.g., decision trees, FAQs, etc.)?
11. Is a mechanism other than the IRB needed to oversee unregulated research?

Operationalizing:

Policies and Procedures:

If your organization decides not to apply the Common Rule to unfunded studies, or to apply alternative standards, your policies and procedures must describe the pathways for organizational and/or IRB oversight. For example: Studies subject to the Common Rule or FDA regulations will be submitted for IRB review, studies not subject to these rules will…

Because the FDA regulations for the protection of human subjects and for informed consent at 21 CFR 50 and 56 will not be consistent with the revised Common Rule, if your organization conducts FDA regulated research, or your IRB reviews such research, your policies and procedures will need to reflect the requirements for the review and conduct of FDA-regulated research.

Likewise, because agencies that have not adopted the Common Rule may have requirements for IRB review and oversight, if your organization conducts such research, your policies and procedures will need to reflect the requirements for the review and conduct of such research.

Other Materials:

Existing materials will need to be reviewed and updated as needed, new materials may need to be created, for example:

- Operating procedures and manuals
- Submission forms and reviewer checklists
- Internal guidance documents
- Electronic systems
- Websites
- Training and instructional materials
  Quality assessment/monitoring tools & templates

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Appendix B

Thinking Points: Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.

Effective Date: January 21, 2019 **Compliance Date:** January 21, 2019

Current Rule:

The current rule does not include provisions for broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. Study-specific consent must be obtained unless the criteria for a waiver of consent are satisfied.

Changes:

The revised Common Rule has added regulations providing an option for the use of broad consent for the storage, maintenance and secondary use of identifiable biospecimens and related requirements and restrictions.

A summary of the pertinent regulations is provided at the end of this document.

Interpretation:

The revised Common Rule provides researchers and organizations a new option for broad consent which is intended to facilitate secondary research. The use of broad consent as a replacement for standard consent is permissible only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. When broad consent is obtained, so long as secondary research uses of data and/or specimens satisfy certain requirements (such as being within the scope of the broad consent), the need for study-specific consent or a waiver of consent is obviated. Much secondary research with broad consent will be eligible for exemption with limited IRB review.

However, this new option comes with certain requirements designed to protect the rights of potential subjects, that may not be desirable or feasible for all researchers and organizations. For example, if a person declines broad consent, this decision must be respected and waivers of consent are not allowed. This necessitates a tracking mechanism so that researchers know which records and/or specimens are not available to them for secondary research. Further, the process for broad consent must satisfy the updated general requirements for consent, including that

consent will only be sought under circumstances that provide potential subjects with the information that a reasonable person would want to have to make an informed decision, an opportunity to discuss and consider the information and whether to participate, and that minimizes the possibility of coercion or undue influence. In other words, consent must be meaningful and cannot be sought in circumstances where potential subjects might feel rushed or pressured.

The preamble to the revised rule contains the following explanation:

> *The final rule strengthens the element of broad consent proposed in the NPRM regarding the need to provide a general description of the types of research that may be conducted with identifiable private information and identifiable biospecimens. It does this by requiring that this description must include sufficient information to allow a reasonable person to expect that the broad consent would permit the types of research conducted. This "reasonable person" standard is consistent with the interpretation that the Office for Civil Rights provided for authorization obtained from an individual for the use or disclosure of protected health information for future research purposes. In addition, the final rule has been strengthened to require that when subjects will not be informed about the details for any specific research studies that might be conducted using their identifiable private information or identifiable biospecimens, the broad consent must disclose this fact and inform subjects that they might have chosen not to consent to some of those specific research studies. It is envisioned that for certain types of research, such as research for which there is reason to believe some subjects will find the research controversial or objectionable, a more robust description of the research will be required in order to meet this "reasonable person" standard. This requirement has been included in the final rule in recognition of the concerns raised by some public commenters that broad consent would not be meaningful because it will not provide detailed information about specific research studies that might be conducted with the individual's identifiable private information or identifiable biospecimens.*
>
> *As proposed in the NPRM, the final rule permits broad consent to be sought for either a narrow type of research to be conducted in the future (e.g., cancer research), or a broader scope of research. Given this flexibility, while the final rule includes an exemption for secondary research for which broad consent is required, the exemption is contingent on several criteria being satisfied, including that an IRB determines that the research to be conducted is within the scope of the broad consent (§__.104(d)(8)). This exemption is further discussed in Section V. For research that is not exempt, the IRB is expected to assess whether the description of the research included in the broad consent form is adequate to permit a reasonable person to expect that they were providing consent for the currently proposed secondary research study.*

Institutional Decisions:

1. Will your organization adopt the option for broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens?

Thinking Points:

- Who would be approached for broad consent for secondary research? Patients, students, faculty, employees, others?
- Will you attempt to seek consent 100% of the selected populations (e.g., all patients or all students) or a subset (e.g., only those already being approached for participation in other research, only those with a certain disease state, only students in a certain program, etc.)?
- Who will obtain broad consent? How will you ensure that persons obtaining consent are appropriately trained and able to explain the research and respond to questions?
- How will you ensure compliance with the basic requirements for informed consent? (See .116 (a) below – including that potential participants must be provided sufficient opportunity to discuss and consider participation)
- How/where will you store consents (consent repository, medical records, investigator records, etc.)?
- Since records/specimens cannot be used for secondary research when someone has declined broad consent, how will you track who has been approached and their responses? How will you "flag" data and/or specimens to identify which records/specimens may and may not be used for research.
- Will you release data and/or specimens to external researchers who can demonstrate that they obtained broad consent? Who will review and approve such requests and ensure that any necessary agreements (materials transfer, data use, etc.) are in place?

Operationalizing:

- Developing broad consent form templates.
- Developing policies and procedures to address the above.
- Developing systems for tracking consents and flagging data and/or specimens.
- Developing training for researchers, IRB members, and staff.
- Developing procedures to monitor compliance and to address any noncompliance.

Summary of Revised Common Rule Regulations Pertinent to Broad Consent:

Definitions .102

This section includes the definitions necessary to interpret and apply the regulations, including the following definitions relevant to broad consent:

> ***Private information*** *includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).*
>
> ***Identifiable private information*** *is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.*
>
> *An* ***identifiable biospecimen*** *is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimens.*

Exemptions .104

This section describes the categories of studies that qualify for exempt status, including two exemptions that are only available when broad consent will be or has been obtained:

> *(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) [emphasis added].*
>
> *(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 part of the study plan. This provision does not prevent an investigator*

from abiding by any legal requirements to return individual research results [emphasis added].

Criteria for IRB approval of research .111

This section describes the basic criteria for IRB approval of research, including what must be assessed when limited IRB review is required.

.111(7) must be assessed for exempt category 8:

When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

.111(8) must be assessed for exempt category 7:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §46.116(a)(1)-(4), (a)(6), and (d);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §46.117; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

General requirements for informed consent .116(a)

This subsection addresses the general requirements for informed consent, and specifies that the following requirements also apply to broad consent:

*(1) **Before** involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.*

*(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative **sufficient opportunity to discuss and consider** whether or not to participate **and that minimize the possibility of coercion or undue influence.***

(3) The information that is given to the subject or the legally authorized representative ***shall be in language understandable*** *to the subject or the legally authorized representative.*

(4) The prospective subject or the legally authorized representative must be provided with the information ***that a reasonable person would want to have in order to make an informed decision*** *about whether to participate****, and an opportunity to discuss*** *that information…*

(6) ***No informed consent may include any exculpatory language*** *through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.*

Elements of Broad Consent for the storage, maintenance and secondary research use of identifiable private information or identifiable biospecimens .116(d)

This subsection addresses the use of broad consent, and specified elements, as a permitted alternative to the use of the standard elements for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.

- .116(d)(1) specifies the basic elements from .116(b) and (c) that must still be included (risks, benefits, confidentiality, voluntary, commercial profit, and whole genome sequencing).
- .116(d)(2) requires a general description of the types of research that may be conducted.
- .116(d)(3) requires a description of the identifiable information or identifiable biospecimens that might be used in future research; whether sharing might occur; and, the types of institutions or researchers that might conduct research.
- .116(d)(4) requires a description of the length of time that the identifiable information or identifiable biospecimens may be stored, maintained and used.
- .116(d)(5) unless subjects will be provided details about specific studies, this element requires a statement that subjects will not be informed of the purposes or details of any specific research studies that might be subsequently conducted, and, that they might have chosen not to consent to some studies.
- .116(d)(6) unless it is known that clinically relevant research results will under all circumstances be disclosed to subjects, this element requires a statement that research results **may not** be disclosed to subjects.
- .116(d)(7) requires contact information to be provided for questions about rights, questions about storage and use, and in the event of a research-related harm.

Waiver or alteration of consent in research involving public benefit and service programs conducted by/subject to the approval of state or local officials .116(e)

- Specifies that if an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable information or identifiable biospecimens and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use for this individual.
- Specifies that IRB's may not omit or alter any of the requirements of consent (.116(a)). If a broad consent procedure is used, an IRB may not omit or alter any of the required elements at .116(d), i.e., alteration is not permitted.

General waiver or alteration of consent .116(f)

- .116(f)(1) cautions that if an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable information or identifiable biospecimens and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use for this individual.
- 116(f)(2) addresses alterations of informed consent. Two new conditions/restrictions are included. An IRB may not omit or alter any of the .116(a) general requirements for informed consent. If a broad consent procedure is used, an IRB may not omit or alter any of the required elements at .116(d), i.e., alteration is not permitted.
- .116(f)(3) includes the four existing waiver conditions with the following addition: for research that involves using identifiable private information or identifiable biospecimens, it is a requirement that the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

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Appendix C

Thinking Points: Management of pre-existing studies once the revised Common Rule goes into effect.

Effective Date: January 21, 2019 **Compliance Date:** January 21, 2019

Introduction:

The revised Common Rule establishes that all studies approved, waived under .101(i), or determined exempt before January 21, 2019 will be subject to the old rule through the close of the study. All protocols approved or determined exempt on or after January 21, 2019 will be subject to the new rule. However, institutions have the flexibility to transition studies and agree to comply with the new rule if they so choose.

10/22/2018 Update: OHRP has provided the following resources.

- Revised Common Rule Implementation Timelines - These pictorial representations seek to clarify the transition provision in the revised Common Rule, and should be used together with the transition provision Q&As.
  https://www.hhs.gov/ohrp/sites/default/files/Webinar-supplements-July-2018.pdf

- Transition Provision Q&As
  https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html#transition-provision

  - Are studies initiated before January 21, 2019 subject to the revised Common Rule as of that date?
  - 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?
  - Do institutions have to transition studies to comply with the revised Common Rule one at a time?
  - Can my institution implement the entirety of the revised Common Rule before January 21, 2019?
  - What are the three burden-reducing provisions of the revised Common Rule and how can institutions take advantage of them before January 21, 2019?
  - What are the primary considerations for an institution that plans to transition to the revised Common Rule during the delay period?

Institutional Decisions:

1. Will pre-existing studies (approved or determined exempt before Jan 21, 2019 and not transitioned to a burden-reducing provision) comply with the revised rule or continue under the old regulations? Please note that institutions may make the voluntary determination for studies what were initiated before January 21, 2019 to comply with the revised Common Rule **on a per-study basis or for a group of studies.** Also, note that the **IRB must document** the institutional decision to comply with the new rule (which necessitates re-review of the study to ensure that the study does in fact comply with the new rule).

2. How will you support investigator and IRB compliance with two sets of active rules, and presumably two sets of policies and procedures, for "old rule" studies and "new rule" studies?

3. For institutions that adopt the three less burdensome provisions between July 19, 2018 and January 20, 2019, SOPs must also address compliance during this period as well as full compliance with the revised rule on January 21, 2019.

Thinking Points:

- What criteria will you establish to determine which studies, if any, to transition to the new rule?
- How will you manage pre-existing studies that aren't subject to the revised Common Rule? Will they continue under existing policies and procedures or will they be transitioned to comply with updated policies and procedures?
- Who will be responsible for the institutional decision? How will the decision be communicated to the IRB? To investigators?
- Keeping in mind that the effective and compliance dates of the new rule are currently the same, if you do choose to transition and re-review studies, when will you do so (e.g., within an established time frame (after the new rule goes into effect)? with the next submission for the study? at continuing review?)? How about for exempt studies?
- How will you operationalize the administration of at least two active sets of policies and procedures, forms, workflows, etc.?
- How will you manage studies that are subject to rules that are no longer harmonized (e.g., an NIH-funded FDA-regulated study)?
- How will studies be "flagged" so that researchers, IRB members, and staff know which rules a study falls under?

- If you have an electronic system, will updates be needed (e.g., to indicate which studies fall under the current regulations and which studies fall under the revised Common Rule? How will you indicate which studies will receive continuing review and which studies will not? Can the system accommodate more than one version of certain forms and checklists?)?
- How will you manage modifications that may need to be made to existing studies to comply with the new rule (e.g., what if a study no longer qualifies for exempt status? If a consent form needs to be updated, will existing subjects be reconsented? What if a study no longer qualifies for a waiver or alteration of consent? etc.)?

Operationalizing:

- Process development for study-by-study decisions, support tools
- Pre- and post- revised rule versions of policies and procedures, submission forms and reviewer checklists, consent templates, guidelines, etc.
- Electronic system revisions
- Training researchers, IRB members, staff
- QA reviews of pre- and post- studies, and IRB reviews, to monitor compliance and make corrections if needed