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OFFICE OF RESEARCH AND DEVELOPMENT (ORD)
VETERANS HEALTH ADMINISTRATION (VHA)

ORD Guidance on Transitioning VA Human Research Studies to the Revised Federal Policy for the Protection of Human Subjects (the 2018 Requirements)

DATE: February 8, 2019

This is a new guidance document.

For questions on the content of this guidance, email the VHA Office of Research and Development through FIND Pro*.*

BACKGROUND

On January 19, 2017, the Federal Register published a revised Federal Policy for the Protection of Human Subjects, subsequently revised January 22, 2018 and again June 19, 2018. The Department of Veterans Affairs (VA), one of 20 federal departments and agencies that will follow the revised policy, known as a "Common Rule", codified the regulation as 38 CFR Part 16.

This revision presents significant changes from the Common Rule originally published in 1991. For purposes of clarity in this document, "revised Common Rule" or the "2018 Requirements" will refer to the new policy, and "pre-2018 Requirements" will refer to the 1991 Common Rule.

Below are the guidelines for compliance with the transition provisions of the revised Common Rule:

- Studies initially approved by an Institutional Review Board (IRB), or determined to be exempt *before* January 21, 2019 are subject to the pre-2018 Requirements, with the exceptions discussed below (third and fourth bullet).
- Studies initially approved by the IRB or determined to be exempt on or after January 21, 2019 are subject to the revised Common Rule.
- Studies initially approved by the IRB or determined to be exempt between July 19, 2018 and January 20, 2019 and for which one of the two allowable burden-reducing provisions were used must comply with the revised Common Rule as of January 21, 2019.
- Studies subject to the pre-2018 Requirements may choose to transition to comply with the revised Common Rule.

No VA policy or provision requires any study that initially received unconditional approved, or determined to be exempt, by the IRB prior to January 21, 2019 to transition to comply with the revised Common Rule, unless a burden-reducing provision was used during the delay period. The revised Common Rule does, however, include regulatory provisions that may be beneficial and burden-reducing for Investigators and IRBs.

This guidance document reflects the Office of Research & Development's (ORD) position on key issues for Investigators, IRBs and VA research facilities to consider before determining whether to transition research to the revised Common Rule.

SCOPE

This document describes ORD's position regarding transitioning human subjects studies initially approved by an IRB or determined to be exempt prior to January 21, 2019. The majority of this guidance addresses non-exempt human subjects research. Question #2 specifically addresses studies that used one of the allowable burden-reducing provisions during the delay period. ORD offers guidance on the following questions:

1. What does the regulatory text state in the revised Common Rule regarding transitioning studies initially approved by an IRB under the pre-2018 Requirements?
2. Is it mandatory for any studies to transition to the revised Common Rule?
3. Who determines whether a study can be transitioned from the pre-2018 Requirements to the revised Common Rule?
4. What documentation is required if a study initially approved by an IRB prior to January 21, 2019 is transitioned to comply with the revised Common Rule requirements?
5. What are the major applicable regulatory provisions an IRB should consider when it transitions a study from the pre-2018 Requirements to the revised Common Rule?
6. What happens to a VA study that was initially approved by an IRB prior to January 21, 2019 that does not transition to the revised Common Rule?
7. For multisite, non-exempt studies involving multiple IRBs with initial IRB approval under the pre-2018 Requirements, can some sites transition to the revised Common Rule without all sites transitioning?
8. For multi-site, non-exempt studies where some sites have IRB approval prior to January 21, 2019 and other sites have IRB approval on or after January 21, 2019, which regulations apply to each site?
9. Does the VA require subjects from whom informed consent was obtained under the pre-2018 Requirements be reconsented if the study is transitioned to the revised Common Rule?
10. May studies considered non-exempt prior to January 21, 2019 be transitioned as an exempt study under the revised Common Rule?
11. For distinguishing the applicable regulations, what type of tracking is recommended for IRBs subject to both Common Rules?

1. WHAT DOES THE REGULATORY TEXT STATE IN THE REVISED COMMON RULE REGARDING TRANSITIONING STUDIES INITIALLY APPROVED BY AN IRB UNDER THE PRE-2018 REQUIREMENTS?

§.101(l) of the revised Common Rule addresses compliance dates and transition provisions. The exact wording of the regulatory text in this section is as follows:

(l) Compliance dates and transition provisions:

(1) *Pre-2018 Requirements.* For purposes of this section, the *pre-2018 Requirements* means this subpart as published in the 2016 edition of the Code of Federal Regulations.

(2) *2018 Requirements.* For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this subpart. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for §46.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to §46.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under §46.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation through January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 46.102(l) of the 2018 Requirements (definition of research) (instead of §46.102(d) of the pre-2018 Requirements);

(*2*) Section 46.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of §46.103(f) of the pre-2018 Requirements); and

(*3*) Section 46.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of §46.103(b), as related to the requirement for continuing review, and in addition to §46.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019;

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019; and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

2. IS IT MANDATORY FOR ANY STUDIES TO TRANSITION TO THE REVISED COMMON RULE?

Yes. Studies that utilized one of the burden-reducing provisions during the delay period (July 19, 2018 – January 20, 2019) must fully comply with the revised Common Rule on January 21, 2019. For VA Research this is limited to those studies that utilized the burden-reducing provision that eliminated the IRB review of the grant application or contract proposal during initial review §.101(l)(4)(i)(A)(*2*). VA did not allow the burden reducing provision of eliminating continuing review to be implemented.

These studies may not continue to comply with the pre-2018 Requirements after January 20, 2019. January 21, 2019 would be considered the documented date of transition. These studies may require additional IRB review and approval if there are changes required to comply with the revised Common Rule. If a study is found to have used the burden reducing provision and did not fully transition as of January 21, 2019, the institution must report the noncompliance to ORO (and any other applicable offices, e.g., the study sponsor) and take immediate corrective actions to transition the study.

ORD recommends that Investigators and IRBs that used the burden-reducing provisions ensure that all studies now comply with all requirements of the revised Common Rule.

3. WHO DETERMINES WHETHER A STUDY CAN BE TRANSITIONED FROM THE PRE-2018 REQUIREMENTS TO THE REVISED COMMON RULE?

ORD policy in VHA Directive 1200.05 requires that the VA Medical Center (VAMC) Director ensure that a procedure is in place for determining when a human subjects study initially approved by the IRB before January 21, 2019 can transition to the revised Common Rule. ORD created this policy so that a systematic procedure is implemented by the VA facility's HRPP. A VA facility HRPP's policy can be coordinated with its IRB(s) of Record.

There is no ORD policy requirement to transition any human subjects study approved by an IRB prior to January 21, 2019, unless a burden-reducing provision was used between July 19, 2018

and January 20, 2019. However, an Investigator, IRB or HRPP may find it advantageous to transition certain studies to the revised Common Rule. Investigators following procedures outlined by their IRB or Institution may request to transition studies compliant with the pre-2018 Requirements to the revised Common Rule. Only the IRB of Record for a specific study can approve this transition. An Investigator alone is not permitted to decide that his or her study can be transitioned to the revised Common Rule requirements or begin using the 2018 Requirements without IRB approval. IRB records should be clear whether a human subjects study approved prior to January 21, 2019 is subject to the pre-2018 Requirements. An IRB must document whether a study approved prior to January 21, 2019 has transitioned to comply with the revised Common Rule requirements.

Studies initially approved by an IRB on/after January 21, 2019 or studies that have already transitioned to the revised Common Rule MAY NOT request to comply with the pre-2018 Requirements.

NOTE: Any study that used the burden-reducing provision eliminating IRB review of the grant application or contract proposal during the initial IRB review must already have transitioned to the revised Common Rule requirements on January 21, 2019 (see Question 2).

4. WHAT DOCUMENTATION IS REQUIRED IF A STUDY INITIALLY APPROVED BY AN IRB PRIOR TO JANUARY 21, 2019 IS TRANSITIONED TO COMPLY WITH THE REVISED COMMON RULE REQUIREMENTS?

The IRB of Record must provide written study-specific documentation to the Investigator with ample time provided for the Investigator to comply with the revised Common Rule. The IRB has authority over studies for which it has regulatory and ethical oversight. If the IRB decides to allow a study initially approved by an IRB before January 21, 2019 to transition to the revised Common Rule, it must provide written documentation to the Investigator with the date of transition. Investigators should be provided ample time to fulfill all requirements of the revised Common Rule before the study should be transitioned, particularly if there are regulatory requirements that must be met, such as the inclusion of new consent elements.

The IRB must notify all PIs of its desire to transition the study. Institutions may transition studies on a per-protocol basis or with respect to a broader category of research conducted at an institution. An IRB should not send group notifications to Investigators informing them that their studies have transitioned to the revised Common Rule without notifying them of the individual studies that will transition. For example, an IRB should not send notification to Investigators that all studies approved by the IRB prior to January 21, 2019 in data analysis phase only will automatically be transitioned to comply with the revised Common Rule requirements without specifying which studies are affected and the date of transition. Study-specific letters should be sent by the IRB to the Investigator informing the Investigator which studies and the date(s) of transition to the 2018 Requirements.

5. WHAT ARE THE MAJOR APPLICABLE REGULATORY PROVISIONS AN IRB SHOULD CONSIDER WHEN IT TRANSITIONS A STUDY FROM THE PRE-2018 REQUIREMENTS TO THE REVISED COMMON RULE?

The revised Common Rule has made substantial changes to the regulatory requirements, particularly regarding informed consent and continuing review. A study initially approved by the IRB prior to January 21, 2019 (without the utilization of the burden-reducing provisions) cannot automatically transition to the revised Common Rule without an IRB written determination.

A study cannot be partially transitioned. This means that an IRB cannot selectively choose preferred revised Common Rule requirements or provisions to apply while continuing to apply provisions of the pre-2018 Requirements. However, IRBs may implement provisions of the 2018 Requirements that do not conflict with the pre-2018 Requirements at any time, such as additional elements or structure of informed consent. For example, a study approved by the IRB by expedited review prior to January 21, 2019 that is active to subject recruitment cannot choose to apply the provision at §.109(f)(1) eliminating the requirement for continuing review but not apply the informed consent requirements in §.116 at the revised Common Rule. Transition determinations should be made depending upon what study activities will be impacted by transitioning to the revised Common Rule. A study closed to enrollment will be impacted less than a study that initiated enrollment prior to January 21, 2019 and is continuing to enroll subjects.

The following is a list of the major applicable regulatory requirements an IRB should consider when a study initially approved by the IRB prior to January 21, 2019 is proposed to be transitioned to comply with the revised Common Rule requirements. (This is not intended to be an all-inclusive list for purposes of this guidance document):

(a) Compliance with FDA regulations 21 CFR Parts 50 and 56. Several FDA human subject protections provisions in 21 CFR Parts 50 and 56 are not congruent with the revised Common Rule's requirements, particularly regarding exempt categories and continuing review requirements. Consideration should be given to studies that if transitioned to comply with the revised Common Rule requirements may result in noncompliance with the applicable FDA regulations. IRBs and PIs must remember that for studies subject to the FDA regulations, if transitioned the studies must continue to comply with both the revised Common Rule and the FDA regulations. For provisions that differ between both sets of regulations, investigators and IRBs should continue to follow the more stringent requirements. For instance, continuing review must be continued for a study subject to the FDA regulations, even if reviewed via expedited procedures.

(b) §.104 and §.111: Categories of exempt research and limited IRB review. If the study did not meet any of the exemption categories based on the pre-2018 Requirements, the IRB can evaluate whether the study activities now fall into an exemption category under the revised Common Rule. Exempt determinations may be made by the IRB Chair, an experienced IRB member, or qualified administrative staff with expertise in applying human research exempt regulations. Specifically, the individual making the determination should carefully consider prior non-exempt activities which meet exempt categories under the revised Common Rule. As non-exempt activities, many of these studies would have required informed consent; exempt studies do not. The IRB should consider whether a study that initially obtains study-specific consent should transition to

an exempt category under the revised Common Rule, particularly those with primary data collection. Additionally, exemption categories at §.104(d)(2)(iii), §.104(d)(3)(i)(C), §.104(d)(7) and §.104(d)(8) require limited IRB review.

Question #10 in this guidance document addressing transitioning studies previously approved by an IRB to exempt human subjects research under the revised Common Rule.

(c) §.109(f)(1): IRB Review of Research. A study transitioned to the revised Common Rule requirements must follow the continuing review requirements described in this section. Thus, studies eligible for expedited review as well as studies at the final stages of data analysis or clinical follow up will no longer require continuing review by the IRB, unless justification for continuing to conduct continuing review is provided by the IRB.

(d) §.114: Cooperative Research. Compliance with the cooperative research provisions in the revised Common Rule is not required until January 20, 2020.

(e) §.116: General Requirements for Informed Consent. For studies involving informed consent that are open to enrollment, the IRB should consider whether the informed consent is compliant with the revised Common Rule and the level of impact transitioning the study may cause. If a study subject to the pre-2018 Requirements is transitioned to the revised Common Rule and subject recruitment is ongoing, subjects recruited after the date of transition must be consented with an informed consent compliant with the revised Common Rule. For subjects previously consented with an informed consent compliant with the pre-2018 Requirements, it is up to the IRB to determine if these subjects must be re-consented or informed of changes to the consent document or process. Additional information regarding IRB considerations for studies initially approved by an IRB without a waiver of informed consent are described in Question #9 in this guidance document.

(f) §.116(h): General Requirements for Informed Consent: Posting of clinical trial consent form. If a clinical trial subject to the pre-2018 Requirements is transitioned to the revised Common Rule or it is transitioned within 60 days of the last study visit by a subject at all subjected sites, a copy of the clinical trial consent form used to enroll subjects must be posted. Studies transitioned to the revised Common Rule will not be considered out of compliance if the posted consent form remains compliant with the pre-2018 Requirements.

If a clinical trial is transitioned to the revised Common Rule requirements, subject enrollment is complete, and the date of transition is 60 days or greater after the last study visit, ORD does not require a copy of the clinical trial informed consent form approved by the IRB to be posted.

If a study approved by the IRB prior to January 21, 2019 is transitioned to comply with the revised Common Rule requirements, the study will be evaluated for compliance based upon which Common Rule requirements were applicable at the time the activities were conducted. Thus, for ongoing studies subject to continuing review that are transitioned, activities conducted prior to transitioning are subject to the pre-2018 Requirements while activities conducted on or after the date of transition are subject to the revised Common Rule. The decision whether to transition a study to the revised Common Rule for previously approved studies should be

carefully evaluated by the IRB with consideration of both the advantages and disadvantages of transitioning previously approved studies, especially if the transitioned study under evaluation is projected to close within a short period of time.

6. WHAT HAPPENS TO A VA STUDY THAT WAS INITIALLY APPROVED BY AN IRB PRIOR TO JANUARY 21, 2019 THAT DOES NOT TRANSITION TO THE REVISED COMMON RULE?

If a VA study approved by an IRB before January 21, 2019 (without the use of the burden-reducing provisions) does not transition to the revised Common Rule, the study must continue to comply with the pre-2018 Requirements and any other applicable regulations or policies.

7. FOR MULTISITE, NON-EXEMPT STUDIES INVOLVING MULTIPLE IRBS WITH INITIAL IRB APPROVAL UNDER THE PRE-2018 REQUIREMENTS, CAN SOME SITES TRANSITION TO THE REVISED COMMON RULE WITHOUT ALL SITES TRANSITIONING?

ORD's recommendation is that multisite non-exempt studies subject to the pre-2018 Common Rule, should follow the same Common Rule regulations at all sites. The Principal Investigator, Investigators from the multiple sites, and the IRBs of Record at the engaged institutions should communicate about the possibility of transitioning studies, considering all advantages and disadvantages of transitioning a multisite study to the revised Common Rule versus maintaining compliance with the pre-2018 Requirements. Investigators should notify their IRB of Record immediately if they are alerted that a site of a multisite study has transitioned without coordination.

The application of human subjects protections in the conduct of research should be consistent. If a multi-site study is being conducted compliant to different sets of regulations for different sites, inconsistency in the conduct and regulatory oversight of the activity by the applicable Investigators and reviewing IRBs may be introduced. For example, an expedited study that remains compliant with the pre-2018 Requirements at Institution A would require continuing IRB review whereas if another site transitions the study to the revised Common Rule, it would no longer require continuing review at Institution B. Thus, ORD recommends that the investigators and IRBs decide on one set of Requirements for all engaged sites.

For multisite, non-exempt studies with initial IRB approval prior to January 21, 2019, the greatest benefit to transition may be offered to those that have progressed to the point that involve only 1) data analysis [§109(f)(iii)(A)] or 2) accessing clinical data from procedures that subjects would undergo as part of clinical care as described in §109(f)(iii)(B) and thus would no longer require continuing review after transitioning.

Multisite, non-exempt studies that utilized a burden-reducing provision during the delay period must have transitioned to the revised Common Rule on January 21, 2019. This may be specific to the site(s) that used a burden-reducing provision. Investigators learning of a site transition of a multisite study should notify their IRB of Record immediately.

8. FOR MULTI-SITE, NON-EXEMPT STUDIES WHERE SOME SITES HAVE IRB APPROVAL PRIOR TO JANUARY 21, 2019 AND OTHER SITES HAVE IRB APPROVAL ON OR AFTER JANUARY 21, 2019, WHICH REGULATIONS APPLY TO EACH SITE?

The Common Rule requirements that a study is subject to depends on the date of IRB approval. However, for multi-site studies there are several factors that may determine which set of requirements the study and at which site it must comply. Multi-site studies that have IRB approval prior to January 21, 2019 at one or more sites are subject to the pre-2018 Requirements at those sites. If additional sites are added to the study on or after January 21, 2019, the Requirements of the study at those additional sites depends on which IRB provides review and approval. If the additional sites rely on the IRB that previously approved the study prior to January 21, 2019, the study must follow the requirements of the IRB for which it is relying.

For example, a multi-site study received IRB approval at Institution A on December 20, 2018. Institution A decides to keep the study under the pre-2018 Requirements. Institution B is added as a study site on January 30, 2019. If Institution B is relying on Institution A's IRB, the study is subject to the pre-2018 Requirements at both Institutions A and B. Additionally, if Institution A decides to transition the study to the 2018 Common Rule, then the study at both Institutions A and B must comply with the 2018 Requirements.

Alternatively, if additional sites are added to a study after January 21, 2019 and those sites will not rely on a previously approving IRB, instead, relying on their own (or another) IRB, the study at these added sites must follow the revised Common Rule (2018 Requirements). To continue with the above example, Institution C is added as a study site on February 10, 2019 and will use its own IRB to review and approve the study. At Institution C, the study must comply with the revised Common Rule, while at Institutions A and B the study may either continue to comply with the pre-2018 Requirements or transition to comply with the revised Common Rule. If all three sites would like to comply with the same regulations, Institutions A and B must transition the study to the revised Common Rule.

ORD recommends that all sites follow the same Regulations for a given study regardless of number of sites.

9. DOES THE VA REQUIRE SUBJECTS FROM WHOM INFORMED CONSENT WAS OBTAINED UNDER THE PRE-2018 REQUIREMENTS BE RECONSENTED IF THE STUDY IS TRANSITIONED TO THE REVISED COMMON RULE?

The IRB must decide if previously consented subjects must be reconsented or notified of changes under the requirements of the revised Common Rule. Subjects agree to participate in a study based on the information provided and approved by the IRB. The IRB should consider whether changes to the consent form required by the revised Common Rule impact the actual study requirements and participation. Reconsenting subjects who have already agreed through their prior consent to participate in the study may create burden with minimal impact on protecting human subjects, particularly if there are no changes to study participation.

For studies that are closed to enrollment, the IRB must consider whether the additional informed consent requirements at §.116 are significant enough to require revising the informed consent document, particularly if subject participation continues.

For studies that are open to subject enrollment and require informed consent, any subject consented into the study on/after the date of transition must be consented using the informed consent requirements described in §.116 of the revised Common Rule.

For studies that are open to subject enrollment and have subjects who previously consented and are continuing participation, newly enrolled subjects must be consented using the consent form compliant with the revised Common Rule. The decision to re-consent previously enrolled subjects or inform them of the changes caused by compliance with the revised Common Rule is decided by the IRB.

ORD's position regarding reconsenting of subjects enrolled prior to the transition date is that subjects usually should not be reconsented for the *sole purpose* of transitioning the study to the revised Common Rule. However, the IRB makes the final determination whether to require reconsenting or notification of previously enrolled subjects. If after transitioning the study the IRB requires reconsenting of some or all subjects in the study (e.g., a new risk of the research was discovered that required reconsenting as determined by the IRB), those subjects, regardless of whether they are entered into the study using the prior or current Common Rule requirements, must be reconsented using an IRB-approved informed consent compliant with the revised Common Rule requirements in §.116.

10. MAY STUDIES CONSIDERED NON-EXEMPT PRIOR TO JANUARY 21, 2019 BE TRANSITIONED AS AN EXEMPT STUDY UNDER THE REVISED COMMON RULE?

Yes, studies considered non-exempt under the pre-2018 Requirements may transition to an exemption under the revised Common Rule. The transition provisions in §.101 do not prohibit a study initially requiring IRB review and approval from transitioning to an exempt category. The revised Common Rule places many minimal risk human subjects research activities that require IRB approval under the pre-2018 Requirements into an exempt research category. However, ORD does not recommend transitioning studies requiring informed consent under the pre-2018 Requirements to an exemption category under the revised Common Rule if subject enrollment is on-going.

During enrollment, transitioning a study to exempt status can be complicated. For example, a VA researcher is conducting a study consisting of qualitative interviews of Veterans who have experienced traumatic brain injury. Identifiable data are recorded, transcribed and analyzed. Given its regulatory category, under the pre-2018 Requirements, this activity requires IRB review and approval using an expedited process. Most likely the PI is required to obtain informed consent from subjects. It is important to consider that exempt research does not require informed consent. Transitioning a study initially approved by an IRB prior to January 21, 2019 requiring informed consent that will no longer require informed consent for subjects raises ethical considerations for what information is given to newly-enrolled, potentially unconsented subjects participating in the transitioned study. ORD recommends that if such a study is transitioned to an exempt category that all newly enrolled subjects continue to undergo the informed consent process approved by the IRB prior to transition.

Lastly, studies approved by the IRB during the delay period (July 19, 2018 – January 20, 2019) that used a burden-reducing provision must have transitioned to the revised Common Rule as of January 21, 2019. If once transitioned, a study previously considered non-exempt is now considered exempt under the revised Common Rule, the IRB must follow standard operating procedures to transition the study as exempt, this may include a determination of exemption by

an appropriate person and limited IRB review. Additionally, if a previously non-exempt study is transitioned as exempt it will no longer remain under the oversight of the IRB but rather would require continuing review by the R&D Committee according to VHA Directive 1200.01, unless under the oversight of another subcommittee.

For exemption categories at §.104(d)(2)(iii) and §.104(d)(3)(i)(C), there is a require of limited IRB review to determine whether there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. If a non-exempt human subjects study has already been approved by the IRB under the pre-2018 Requirements there should be no need to re-review or conduct a limited IRB review as the corresponding criteria at §.111(7) have already been met and been approved.

11. FOR DISTINGUISHING THE APPLICABLE REGULATIONS, WHAT TYPE OF TRACKING IS RECOMMENDED FOR IRBS SUBJECT TO BOTH COMMON RULES?

Until all studies with initial IRB approval prior to January 21, 2019 have either closed or transitioned to the revised Common Rule, the regulatory community will have to consider two sets of requirements. IRBs, Investigators, and institutions should clearly indicate which set of requirements (pre-2018 Requirements or the revised Common Rule) each study is subject to. There are four major groups of studies that need to be tracked:

- Studies subject to the pre-2018 Requirements: research with initial IRB approval before January 21, 2019.

- Studies that transition to the revised Common Rule: research with initial IRB approval before January 21, 2019 that transition to comply with the revised Common Rule. This includes studies that used a burden-reducing provision during the delay period of July 19, 2018 and January 20, 2019. IRB records of transitioning studies must include the date of transition.

- Studies subject to the revised Common Rule: research with initial IRB approval on or after January 21, 2019.

- Studies that require continuing review and those that do not require continuing review.