1 PURPOSE

1.1 Describe when Continuing Review (CR) of IRB Approved Research is NOT required.

1.2 Describe when CR of IRB Approved Research is required.

1.3 Establish the process for making, documenting, and communicating the determination of when a CR is required.

1.4 The process begins at the time of Initial Review when the determination regarding the CR requirement is made.

1.5 The process or assessment of the CR requirement continues through the lifecycle of a study because modifications, new information reports (RNI) and the changing status of a study (reported in a CR) may affect the initial determination.

1.6 The process ends when the approved research is closed with the IRB using the designated closure process.

2 PREVIOUS VERSION

2.1 Revised from previous version dated 06/01/2023

3 POLICY

3.1 **The determination for CR of Approved Research** is required for:

3.1.1 All Greater than Minimal Risk studies, and

3.1.2 Non-exempt studies *regulated by the FDA* (the study involves drugs, devices, assays or biologics) or by another sponsor that requires continuing review.

3.2 **CR of Approved Research is NOT required** for studies which meet the following criteria (as a general rule) unless the IRB determines otherwise:

3.2.1 Non-exempt, minimal risk studies that met an expedited category;
This includes:

3.2.1.1 Non-FDA regulated studies that are reviewed at a panel initially and are determined to be No Greater than Minimal Risk by the panel, An expedited category or categories should be determined by the panel. If a category is not determined, then continuing review will occur and at the full panel meeting.

3.2.1.2 Exempt studies already do not have an expiration date or CR.

3.3 CR of Approved Research that meet the criteria under 3.2 may be required, if the IRB determines and documents* that the requirement should be maintained for any of the following reasons:

3.3.1 The study involves additional regulatory oversight (e.g., a conflict of interest (COI) management plan, NSF, DOD)

3.3.2 The study will be conducted internationally or at non-Northwestern University (NU) sites and the NU IRB determines whether an annual review will be appropriate.

3.3.3 A modification or incident report (RNI) reveals new information that requires additional oversight.

3.3.4 The investigator has previous serious non-compliance or a pattern of continuing non-compliance that is of concern.

3.3.5 IRB or designated reviewer determines a CR is needed and documents the rationale.

*Note: For studies to meet the criteria for CR under 3.3, the IRB (full board or expedited method) must document the reason for maintaining the CR requirement in the “Submit Review” activity (either by Committee or Designated review).

3.4 **CR is NO LONGER required**

3.4.1 ***Post*-2018 OHRP-Regulated Studies:**

For greater than minimal risk studies *regulated by ORHP and* approved after 1/21/2019 when they reach one of the following research milestones, unless an IRB determines otherwise:

3.4.1.1 Remaining study activities are limited to data analysis, including analysis of identifiable private information or identifiable bio specimens (45 CFR 46.109(f)(1)(iii)(A)"); or

3.4.1.2 Remaining study activities are limited to accessing follow-up clinical data only from procedures the participants would undergo as part of routine clinical care [45 CFR 46.109(f)(1)(iii)(B)]")

***Pre*-2018 Non-FDA Regulated Studies:**

For non-FDA regulated studies approved prior to 2018, the study may be **transitioned** to a status where Continuing Review is not required, provided there are no other ongoing research activities and the study meets one of the following conditions:

3.4.2.1 Remaining study activities are limited to data analysis, including analysis of identifiable private information or identifiable bio specimens (45 CFR 46.109(f)(1)(iii)(A)"); or

3.4.2.2 Remaining study activities are limited to accessing follow-up clinical data only from procedures the participants would undergo as part of routine clinical care [45 CFR 46.109(f)(1)(iii)(B)]")

3.4.3 **Process for Transitioning Studies from CR to No CR:**

3.4.3.1 For eligible **non-FDA regulated, pre-2018 studies**, reviewers should take the following steps to transition the study to **No Continuing Review (No CR)**:

3.4.3.2 Confirm via the Pre-Review or Reviews tab that the study is not FDA regulated. FDA-regulated studies are not eligible for transition to No CR under these pathways.

3.4.3.3 During pre-review, update the **Common Rule/OHRP regulatory requirements** from **"Pre-2018" to "2018."**

3.4.3.4 Document the following language in the **designated review**, modifying a appropriate based on the applicable milestone:

"This study is being transitioned to the 2018 provisions of No Continuing Review, as remaining activities are limited to data analysis or accessing follow-up clinical data from routine clinical care procedures only."

3.4.3.5 Select **"No CR"** for **Question 6** in the designated review and complete the reviewer form.

3.4.3.6 Ensure **No CR language** appears in the **approval letter**.

3.5 **CR can be reviewed by the expedited method** for all other greater than minimal risk studies when they reach one of the following three research milestones, otherwise it remains reviewed by the convened panel (FDA; and OHRP studies approved before 1/21/2019):

3.5.1 Where:

3.5.1.1 (i) the research is permanently closed to the enrollment of new subjects;

3.5.1.2 (ii) all subjects have completed all research-related interventions; ***and***

3.5.1.3 (iii) the research remains active only for long-term follow-up of subjects; ***or***

3.5.2 where no subjects have been enrolled and no additional risks have been identified (neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source); ***or***

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

3.6 If a CR is required, the CR submission should be submitted no more than 60 days and no less than 30 days prior to the expiration date determined by the IRB at the time of initial review (not to exceed 1 year minus one day) – See HRP-302 – Approval Intervals.

4 RESPONSIBILITIES

4.1 IRB Office must determine when CR of IRB approved research is required.

4.2 When the IRB determines that CR is required, the IRB Office must document in the IRB minutes the rationale for the CR.

4.3 If CR is required, the IRB Office or Reviewer will determine the IRB approval period for which CR is required to secure approval again.

4.4 The Principal Investigator or proxy is responsible for submitting the CR application (when required) 60 - 30 days prior to the end of the IRB approval period.

5 PROCEDURE

5.1 MAKING THE DETERMINATION:

5.1.1 Initial Review:

5.1.1.1 For Policy 3.1 studies when CR is required, the convened IRB or designated reviewer and the rationale determines the IRB approval period that dictates when the first CR is required.

5.1.1.2 For Policy 3.2 and 3.3 studies, the convened IRB or designated reviewer will determine that the criteria are met for the designation of no CR. The removal of the requirement of an expiration date and CR for non-exempt minimal risk studies is presumed and will be documented in the reviewer note/minutes when the study is either initially approved or when an existing study is transitioned to the no CR status. There will be an approval date but no expiration date attached to studies and the respective documents with no CR.

5.1.1.3 For studies that fall under 3.2 or 3.3, the convened IRB or designated reviewer will determine and document the reason for maintaining the CR requirement when the study otherwise meets the criteria for removal of the CR.

5.1.1.4 For other studies that are no greater than minimal risk but do not meet the 3.3 criteria, the CR requirement remains and the designated reviewer determines the IRB approval period which dictates when the first CR is required.

5.1.2 Modifications – If the modification changes the determination of a currently approved study or a study that previously had the CR removed, a new determination will be made by the IRB or designated reviewer. The new determination will be documented in the pre-review note and the reviewer note of the modification. The rationale for resuming the CR will be documented in eIRB+ in the reviewer note.

5.1.3 CR for existing approved studies – At the time of CR, a determination regarding whether future CRs are needed will be made. For minimal risk non-exempt studies, the presumption is no CR. If a study is eligible for no CR and the IRB or designated reviewer determines a CR will continue to be needed, the rationale must be included in the CR reviewer note. The rationale will be communicated to the PI in the approval letter.

5.1.4 Reports of New Information – If a report of new information changes the determination regarding the CR requirement, the researcher should be directed through the RNI to submit a CR. The rationale for reinstating an expiration date should be documented in

the new CR. The new expiration date will be established at the time of the CR and should reflect time approval period determined by the IRB or designated reviewer.

5.2 FINALIZING DOCUMENTS (only protocols and consent documents will be watermarked)

5.2.1 If a CR is required, the documents will be finalized with the IRB Approval watermark containing the approval period established in the review.

5.2.2 If CR is not required, the watermark will only contain the approval date and not an expiration date.

5.3 COMMUNICATION TO THE PI: The IRB Office will communicate to the Principal Investigator the determination regarding if a CR is required in the Approval/Determination Letter (Initial Review, Modification, CR, or RNI)

5.3.1 If a CR is required, the IRB approval letter will contain the study's approval period and the IRB's expectation for submission of the CR prior to the end of the IRB approval period.

5.3.2 In addition, for Policy 3.3 studies, the rationale for maintaining the CR requirement will be communicated to the PI in the approval letter.

5.3.3 For studies which no longer need a CR, the IRB approval letter will confirm that the CR is not required, the study will not expire and that modifications, reports of new information, and study closure submissions are still required and the responsibility of the PI.

6 MATERIALS

6.1 WORKSHEET: Approval Intervals (HRP-302)

7 REFERENCES

7.1 45 CFR 46.109(f)
7.2 45 CFR 46.110
7.3 45 CFR 46.115(a)(3)
7.4 21 CFR 56.109 (f)
7.5 21 CFR 56.110
7.6 21 CFR 56.115(a)(3)