CAMPBELL UNIVERSITY	**IRB SOP:** Determining and Processing "No Continuing Review"		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-155	IRB Chair, IRB Office Campbell University	10/08/2019

1 PURPOSE

1.1. Describe when Continuing Review (CR) of IRB Approved Research is NOT required.
1.2. Describe when Continuing Review (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, REs 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 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 Continuing Review (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.
3.2 CR is NOT required for greater than minimal risk studies once they reach one of the following research milestones:
  3.2.1 Remaining study activities are limited to data analysis, including analysis of identifiable private information or identifiable biospecimens; or (Expedited Category 8c; 45 CFR 46.109(f)); or
  3.2.2 Remaining study activities are limited to long-term follow-up of participants where the research is only accessing follow-up clinical data from procedures the participants would undergo as part of routine clinical care and any research interactions involve no more than minimal risk to participants (e.g., quality of life surveys) (Expedited Category 8a)
3.3 As a general rule, CR of Approved Research is NOT required for studies which meet the following criteria:
  3.3.1 Non-exempt, minimal risk (Note: Exempt studies already do not have an expiration date or CR); and
  3.3.2 IRB determined there was no reason to require the CR.
3.4 CR of Approved Research is required for non-exempt studies that are regulated by the FDA or by another sponsor that requires continuing review.
3.5 CR of Approved Research may be required for studies that meet the criteria under 3.3, may be required, if the IRB determines that the requirement should be maintained for any of the following reasons:
  3.5.1 The study involves additional regulatory oversight (e.g., a conflict of interest (COI management plan).

3.5.2 The study will be conducted internationally or at non-CU sites and the CU IRB decides an annual review will be appropriate.

3.5.3 An amendment (AME) or reportable event (RE) reveals new information that requires additional oversight.

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

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

3.5.6 Studies that have approval as a JIT and must have final approval within the year such as with NSF or DOD funding.

Note: For studies to meet the criteria for CR under 3.5, the IRB must document the reason for maintaining the CR requirement in the comment section of the appropriate Reviewer Checklist (either by Committee or Designated review).

3.6 If a Continuing Review (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 *Approval Intervals Worksheet*.

4. RESPONSIBILITIES

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

4.2. If CR is required, the IRB Office must document in the IRB record that rationale for the CR in the reviewer notes.

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 DETERMINTION:**

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 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 continuing review.

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 Amendment (AME)/Modifications – If the modification of a currently approved study or a study that previously had the CR removed, changes the determination, a new determination needs to 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 electronic protocol file in the comments section of the appropriate reviewer checklist.

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 pre-review note and the CR reviewer note. The rationale will be communicated to the PI in the approval letter.

5.1.4 Reportable Event(s) – If a report of new information changes the determination regarding the CR requirement, the researcher should be directed through the Reportable Event Submission to submit a CR. The rationale for reinstating and expiration date should be documented in the new continuing review. 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 consent documents will be stamped)

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

5.2.2 If CR is not required, the stamp 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 (New Protocol, AME, CR, or RE)

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.

5.3.2. For studies which no longer need a CR, the IRB approval letter will confirm that the continuing review is not required, the study will not expire and that amendment, reportable event, and study closure submissions are still required and the responsibility of the PI.

6 MATERIALS:

6.1 Approval Intervals Worksheet
3.2 Continuing Review/Closure Reviewer Checklist

7 REFERENCES:

7.1 45 CFR 46.109(f)
7.2 45 CFR 46.115(a)(3)(8)
7.3 21 CFR 56.109(f)