UNIVERSITY OF MIAMI

WORKSHEET: Determining Common Rule Version at Continuing Rev.		
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HRP-309	03/09/2020	1 of 1

The purpose of this worksheet is to provide support for Designated Reviewers conducting Non-Committee Review OF SUBMISSIONS for Continuing Review. This worksheet is effective on 1/19/19. This worksheet is intended to guide designated reviewers in determining whether to apply the Pre-2018 Common Rule Requirements or the New 2018 Requirements.

FDA Jurisdiction	☐ Yes ***(If checked, apply Pre-2018 Rule flag, ensure continuing review is completed and an expiration date is assigned)***
Funding	☐ Department of Justice***: (If checked, apply Pre-2018 Rule flag, ensure continuing review is completed and an expiration date is assigned)*** ☐ Federal funding other than the Department of Justice ***(If "checked," Complete Risk Level/Study Status)*** ☐ Other funding (industry sponsored, unfunded) ***(If "checked," go to Section 2).***
Risk Level/Study Status	☐ Greater than Minimal Risk open to enrollment ***(If checked, apply Pre-2018 Rule flag and refer to full committee for review)*** ☐ Minimal Risk and open to enrollment ***(If checked, go to Section 1)*** ☐ Minimal Risk and closed to enrollment ***(If checked, transition to 2018 Rule - go to Section 3)***

Section 1 - Consent Process

☐	Waiver of Consent – Determine whether waiver of consent can be granted using January 16 version of HRP 410 Waiver or Alteration of the Consent Process ☐ Meets criteria for wavier under 2018 Common Rule ***(If checked, apply 2018 Rule flag and go to Section 3)*** ☐ Does not meet criteria for waiver under 2018 Common Rule ***(If checked, apply Pre 2018 Rule flag, complete Continuing Review and assign an expiration date.)***
☐	Consent Document is consistent with 2018 Common Rule requirements. **(If checked, apply 2018 Rule Flag and go to Section 3)**
☐	Consent Document is not consistent with 2018 Common Rule Requirements ***(If checked, send a copy of the template to the PI to see if s/he wants to use it to eliminate the need for submitting continuing review report forms. If PI revises consent document so it is consistent with HRP 314B, apply 2018 Rule and go to Section 2. Otherwise apply Pre-2018 Rule, complete continuing review and assign expiration date.)***

Section 2 – Unregulated studies

☐ Greater than Minimal Risk ***(If checked, transition to 2018 Rule, apply 2018 Rule flag and refer to full committee for review)***
☐ Minimal Risk ***(If checked, transition to 2018 Rule, apply 2018 Rule flag, then go to Section 3)***

Section 3 – Removing Expiration Date on a Continuing Review Submission

☐ When completing HRP 402 Checklist Pre-Review, Select "2018 Rule" to the question, which asks which Rule to apply. If consent form revisions are required, submission must be a MOD/CR (Contact RIT if needed)
☐ Select "No" when answering question asking whether continuing review must be completed.
☐ Enter Note to File: "See below Investigator has been notified."
☐ Submit Letter, "Continuing Review no Longer Required."

Note to file:

The purpose of this communication to inform you about the expiration status of this study.

This study was scheduled to expire on _____.

Under the 2018 Common Rule, minimal risk research no longer requires continuing review and will not have an expiration date. Consequently, we are removing the expiration date for this study.

Please remember:

- You must submit FORM HRP-212 Continuing Review Report when you are ready to close this study. As a reminder, you should close studies when:
  - You are no longer interacting or intervening with human subjects to collect data about them; and
  - You are no longer accessing private identifiable information.