RUTGERS UNIVERSITY
Office for Research

WORKSHEET: When CR Applies to Minimal Risk Research Per Revised Common Rule		
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4.205 (HRP-349a)	11/22/2024	1 of 1

The purpose of this worksheet is to provide support for Designated Reviewers or a convened IRB when determining whether a Minimal Risk Study requires Continuing Review rather than a Status Report. This worksheet is to be used. It does not need to be completed or retained.

Continuing Review is **not** required under the following select minimal risks of harm circumstances for studies regulated under the Revised Common Rule[1] or for unfunded studies not regulated by any outside agency or institution.

- Research eligible for expedited review;
- Research reviewed by the IRB in accordance with limited IRB review;
- Research that has progressed to the point that it only includes one or both of the following:
  - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
  - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

When submission of Continuing Review is not required, the PI must submit a Status Report in eIRB+ every 2 years.

However, institutional policy or IRB discretion may require the submission of a *Continuing Review* report for research that otherwise qualifies for a *Status Report*.

This worksheet lists scenarios when continuing review is required per Rutgers policy or when a continuing review may be indicated. When a Designated Reviewer or IRB requires a continuing review of research that otherwise qualifies for a Status report, the rationale for requiring continuing review must be documented in eIRB+.
NOTE: Studies deemed to be Non-Human Research or qualify for Exempt Review do not require either a Status Report or Continuing Review.

1 Identify The Rationale Of Requiring A Continuing Review (Select All That Apply Under A and B)

A.	**Required Per Rutgers IRB Policy**	
☐	**Research Repository**	For projects established solely to maintain an IRB-approved research repository--Data and/or Specimens--that will be used by a single investigator or shared with multiple investigators for future research not yet defined. (This option does not apply to research that proposes to store data/specimens in an established IRB-approved Research Repository).
☐	**International**	For research that will be conducted with individuals who reside in international settings, research data that will be collected in international settings, and/or research will be conducted at sites located internationally.
☐	**Non-Rutgers Investigators / Institutions**	For research engaging non-Rutgers Investigator(s) and/or Non-Rutgers Institution(s).
☐	**Student Research**	For research involving students as PI or as lead Investigator with a Faculty Advisor serving as the PI.
B.	**Required At the Discretion of the Reviewer**	
☐	**Other** possible justifications for requiring a Continuing Review (must be documented in eIRB+):	
	Vulnerable Populations	"This study involves particularly Vulnerable Populations which requires closer monitoring through the Continuing Review Process". (**Note**: The inclusion of a vulnerable population in the research does not automatically require a CR submission).
	Additional Oversight	"Research involves additional oversight, such as a Conflict of Interest (COI) Management Plan."
	Revealing New Findings	"A research modification or reportable event reveals new findings that require additional oversight".
	Previous Non-Compliance	"Investigator has had previous serious non-compliance or a pattern of non-serious non-compliance which requires closer monitoring".
	Other Justification	"This study requires closer monitoring through the Continuing Review Process because **[Provide Justification]**".

[1] The Revised Common Rule changed the requirements when submission of Continuing Review of research is required (45 CFR 46.109(f)). These changes do **not** apply to: (a) federally-funded studies approved prior to the implementation date of January 21, 2019 and have not transitioned to the Revised Common Rule; (b) studies regulated by the Food and Drug Administration (FDA); or (c) any research sponsored by a Federal Department that has not signed on to the Revised Common Rule, such as the US Department of Justice (DOJ), Environmental Protection Agency, etc.