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| 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]](#footnote-2) 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 e-IRB.  NOTE: Studies deemed to be Non-Human Research or qualify for Exempt Review do not require either a Status Report or Continuing Review. | | |
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| 1. Identify The Rationale Of Requiring A Continuing Review (Select All That Apply Under A and B) | | |
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| 1. 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.** |
| 1. 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]”. |

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.

1. [↑](#footnote-ref-2)