RUTGERS UNIVERSITY
Office for Research

WORKSHEET: Extended Approval Intervals		
NUMBER	DATE	PAGE
3.212 (HRP-349b)	5/1/24	1 of 3

The purpose of this worksheet is to provide support for IRB staff when determining whether an IRB-approved study qualifies for an Extended Approval Interval. This worksheet is to be used. It does not need to be completed or retained.

Except for studies determined to be exempt from IRB oversight, all human research studies are subject to approval intervals appropriate to the degree of risk of harm, as follows:

- For studies that must comply with the *old* Common Rule (pre-2018), all non-exempt projects require review at intervals not less than once a year until such time as they meet the qualifying criteria for an 'Expanded Approval Interval' (see below).

- For studies that must comply with the *revised* Common Rule (rCR):
  - All greater-than-minimal risk projects require review at intervals not less than once a year until such time as they meet the criteria for an 'Expanded Approval Interval.
  - Minimal risk projects that qualify for Expedited Review do not require continuing review intervals unless otherwise required by the IRB or institutional policy. [See **4.205 (HRP-349a) WORKSHEET: When CR Applies to Minimal Risk Research per Revised Common Rule**.]
    - IRB requires a continuing review interval (interval specified by IRB may be 1-2 years).
    - Per Rutgers Policy a Progress report is required at 2-year intervals.

- For studies that are not required to comply with the Common Rule:
  - All greater-than-minimal risk projects require review at intervals not less than once a year until such time that the remaining study activities meet the qualifying criteria for an 'Expanded Approval Interval'.
  - Minimal risk projects that qualify for Expedited Review, must follow regulations that apply to their project. If none apply, follow the rCR rules for Expedited Review rules outlined above.

Expanded Approval Interval Criteria

Research projects that meet ***all*** of the following criteria are eligible for the approval interval to be expanded (lengthened) [See **3.204 (HRP-302) WORKSHEET: Approval Intervals**]:

- The research activities that remain must present no more than minimal risk to human subjects as determined by the Rutgers IRB (convened or designated reviewer).
- The project does not include federal and non-federal funding, including federal training and program project grants, federal no-cost extensions, federal flow-through funding, etc.
- The project does not include FDA (Food and Drug Administration) regulated components (i.e., food products or additives, dietary supplements, medical devices—including activity monitors—drugs, vaccines, biologics).
- The research has not enrolled prisoners as subjects unless the study is eligible for exemption or review via expedited procedures.
- Findings of serious or continuing noncompliance related to the study or the PI within the past 2 years have not occurred.
- Incidents that meet the definition of an unanticipated problem involving risks to subjects or others within the past 2 years have not occurred.
- The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects and/or
- The remaining research activities are limited to data analysis, including analysis of identifiable private information or identifiable biospecimens.
- The PI is not a student or a resident. [NOTE: The approval interval for student- or resident-led research remains 12-months until study closure.]

During an extended approval interval, the study must remain unchanged from that reviewed and approved by the IRB except for amendments approved in accordance with Rutgers IRB policies. For any amendment proposed during an extended year approval period, however, the convened IRB (or the Chair or designee in the case of expedited review) shall determine whether the

amendment makes changes that are compatible or incompatible with an extended approval of the study and whether such extended year approval should or should not be continued. The IRB reserves the right to require continuing approval intervals more frequently, as necessary, to provide appropriate oversight of the research.

During the approval period, the PI is responsible to (a) report to the IRB any changes in funding or sponsorship that involve federal sources; (b) obtain approval for any change(s) to the IRB-approved protocol, prior to implementation of the change(s), unless the change is necessary to eliminate apparent immediate hazards to subjects; and/or (c) report any unanticipated problems or serious adverse events to the IRB.

NOTE: Studies deemed to be Non-Human Research or qualify for Exempt Review do not require either a Progress Report or Continuing Review.

Check Eligibility for Extended Approval:

For studies that are eligible for extended continuation approval, the IRB administrator must review the study history to confirm the eligibility below before proceeding to process a 24-month approval.

- **Does the study have Federally funding**, including federal training and program project grants, federal no-cost extensions, federal flow-through funding, etc.?
  - **YES: STOP- since the study is federally funded, then continuation is not eligible for 24-month progress report request. Process continuation with an annual review.**
  - **NO: If it's not federally funded, then proceed with next question.**

- **Does the study include FDA-regulated components** (i.e., food products or additives, dietary supplements, medical devices [including activity monitors], drugs, vaccines, biologics)?
  - **YES: STOP- since the study has FDA-regulated components, then continuation is not eligible for 24-month progress report request. Process continuation with an annual review.**
  - **NO: If the study does not include FDA-regulated components, then proceed with next question.**

- **Does the study involve Prisoners as subjects?**
  - **YES: STOP- since the study has prisoners as subjects, then continuation is not eligible for 24-month progress report request. Process continuation with an annual review.**
  - **NO: If the study does not include prisoners as subjects, then proceed with next question.**

- **Is the PI of the study a graduate student or resident**?
  - **YES: STOP- Since the PI is a graduate student or resident, then continuation is not eligible for 24-month progress report request. Process continuation with an annual review.**
  - **NO: If the PI is not a graduate student or resident, then proceed with next question.**

- **Does the PI of the study have any findings of serious or continuing noncompliance** related to the study or the Principal investigator **within the past two years**?
  - **YES: STOP- Since the PI and/or the study has had non-compliance issues within the past 2 years, then continuation is not eligible for 24-month progress report request. Process continuation with an annual review.**
  - **NO: If the PI and/or the study does NOT include any non-compliance issues within the past 2 years and then proceed with next question.**

- Does the study **involve any incidents that meet the definition of an unanticipated problem involving risks to subjects** or others within the past two years?
  - **YES: STOP- Since the study has had unanticipated problem involving risks to subjects within the past 2 years, then continuation is not eligible for 24-month progress report request. Process continuation with an annual review.**
  - **NO: If the study has NOT had unanticipated problem involving risks to subject within the past 2 years and all above questions were "NO", then proceed with processing 24-month progress report request.**

If all the above questions are "NO", then process an **extended continuation approval notice in eIRB+.** Please see the Frequently Asked Questions (FAQs) below.

Frequently Asked Questions (FAQs):

1. **Question:** Would this apply to all pre-2018 studies in data analysis as well or would those be subject to annual review?
    a. **Answer:** If the study is not federally funded, then we can include studies under the pre-2018 regulations (i.e., Old Common Rule) and studies approved under the limited exceptions in the Revised Common Rule (i.e., those studies that need to undergo continuing review) under this extended policy.
2. **Question**: If the status of the study is in data analysis and the answer to question: 3.80 Progress Report - Private Identifiable Information (PII) / DATA Management / Record Retention 1.0* Do you have PII for this study? is No. Should the PI consider submitting a final report in that case?
    a. **Answer:** This policy is specifically for long-term follow-up and including analysis of identifiable, private information or identifiable biospecimens. If the data/specimens are de-identified, then other IRB guidance-policies prevail that note a closure request in eIRB+ is appropriate.
3. **Question:** If an extended approval is granted but the PI later submits a modification to open enrollment again. Would the extended approval period no longer be applicable or remain the same?
    a. **Answer:** Once enrollment is opened, then the study no longer qualifies for Expedited approval under Categories 8a-c. Therefore, the extended approval period would be removed upon amendment approval. Keep in mind that the amendment approval would prevail with respect to the Committee member or convened board's determination/approval (e.g., it is possible that the board can deem the amendment as expedited under categories 6 & 7, which an amendment approval establishes a new approval-expiration date.