New Continuing Review Provisions under Revised Common Rule: Forms & SOP

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Provision for no further continuing review

- 45 CFR 46.109(f)(1) – Unless an IRB determines otherwise, continuing review is not required in the following circumstances:

1. Research eligible for expedited review (as per OHRP guidance, all categories 1-9)
2. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
   A. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or,
   B. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care (i.e., prospective data collection)

Provision for no further continuing review

- NOTE: This provision does not currently apply to FDA-regulated research. It is anticipated that FDA ultimately will harmonize its continuing review requirements with 46.109(f)(1), or create a comparable requirement.

Revised Forms

- OHR-9 (continuing review) – Section A, questions added about study status to determine whether further continuing review is not required
- RQ-1 (reviewer questionnaire for new studies & full CR)– Considerations for continuing review – same as above. Written rationale is required if 109.(f)(1) applies, but IRB/reviewer nonetheless requests continuing review.
- RQ-3 (reviewer questionnaire for expedited CR) – same as above.
- Minutes template – questions added for applicable transactions to document IRB/reviewer determination.

RQ-1

Considerations For Initial Review

Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

1. Research eligible for expedited review
2. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
    a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, and/or;
    b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

If you feel that Continuing Review is still warranted, please provide your written rationale in space provided on the right.

Note: The above cannot be applied to FDA-Regulated Studies

RQ-1

Considerations For Continuing Review

The IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year; however, unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

1. Research eligible for expedited review
2. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
    a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, and/or;
    b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

If you feel that Continuing Review is still warranted, please provide your written rationale in space provided on the right.

Note: The above cannot be applied to FDA-Regulated Studies

Revised Forms

- Letter templates:
  - New expedited – No further CR
  - Full CR – No further CR
  - Expedited CR – No further CR
  - Expedited Amendment – No Further CR

Letters in IRB-2/Letters

Revised Forms

Text added to letters:

As per 45 CFR 46.109(f)(1), this minimal risk research study requires **no further review and approval** by the IRB as long as the study is conducted as proposed. Any proposed revision to this study will necessitate submission of an OHR-12 to the IRB for further consideration prior to implementation.

Please notify the IRB in writing when the study has been completed.

Duties in order of occurrence

1. Research team will submit new studies as usual. For continuing reviews, research team will complete Section A of OHR-9 to be used by IRB in making determination.
2. IRB reviewers will make appropriate determination on RQ-1 for new full and expedited studies and full CRs.
3. Vice Chairs will make appropriate determination on RQ-3 for expedited CR reviews.
4. IRB personnel who handle new studies, amendments, and continuing reviews will use appropriate approval letter template and make appropriate documentation in the minutes. Consent form and other subject materials should be stamped "Approved until end of study."
5. Latesh will enter appropriate transaction in IRB database.

Questions?