Continuing Review – Removing Requirement for Continuing Review

Summary

New studies approved on or after May 1, 2018 and ongoing studies that are minimal risk will be evaluated to assess criteria to remove the requirement for continuing review at the time of the study approval or continuing review occurring on or after May 1, 2018. The determination is based on investigator responses to questions related to study funding, sponsor or regulated status, status of participant interaction and research activities and the criteria outlined below. Removal of the continuing review requirement will be communicated to the study PI in the Review Outcome Letter and documented in the study's electronic IRB record – Continuing Review and Expiration dates will be removed from the Study Outcome tab and Outcome letter.

If the IRB determines continuing review for research that otherwise would not require continuing review as described below, the rationale for conducting continuing review of research will be documented in the IRB records and communicated to the investigator.

Removal of the requirement for continuing review does not impact other IRB submission requirements, e.g., any modifications to the IRB-approved protocol, documents, study personnel, etc. must be submitted for IRB approval prior to implementation of the change. In addition, this does not remove the requirement for reporting to the IRB any Unanticipated Problems (UPs) that increase risk to participants or non-compliance that meet criteria for Prompt Reporting.

If the federal support status of a study reviewed under Geisinger's flexible provisions (described below) changes, it is the responsibility of the Principal Investigator to notify the IRB immediately via amendment/modification so the research can be reviewed under the Common Rule, 45 CFR 46. Under no circumstances will federally supported research be reviewed under these flexible provisions.

Criteria

Ongoing continuing review of research is not required in the following circumstances:

- Research meets the definition of minimal risk, as defined in 45 CFR 46.102
- Research is eligible for expedite review in accordance with 545 CFR 46.110
- Research was reviewed by the IRB in accordance with limited review required for certain exemption determinations

- Research has progressed to the point that it only involves one or both of the following:
    - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    - Accessing follow-up care from procedures that participants would undergo as part of clinical care.
- Additional criteria:
    - Research is not federally supported[1]
    - FDA regulations do not apply to the study
    - No external institutions rely on GIRB for IRB review and ongoing oversight of their engagement in this study, unless all relying institutions have "unchecked" the box on their FWA
    - There are no restrictions imposed by GIRB on the PI
    - The study or PI do not have a history of serious or continuing research non-compliance

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[1] **Federally supported**: This means that the research is supported by federal funding or other type of federal involvement. GIRB staff members rely upon the information provided by the researcher, except when the provided information is inconsistent or ambiguous about federal support. If there is no indication of federal support, the researcher is not asked for confirmation that there is no federal support. "Federal support" includes any of the following:

- Funding from any federal agency. This means:
    - Awards made to directly support the research;
    - No-cost extensions of awards made to support the research;
    - "Flow through" federal funds that are awarded to a non-Geisinger affiliated institution and then awarded to Geisinger or affiliate through a subcontract.
    - Federal funds that may be indirectly supporting the research such as:
        - Federally-funded training grants;
        - Federal scholarships, fellowships, or other training awards such as "K" grants;
        - Federally-funded program project grants.
- Involvement of federal personnel;
- Use of federal equipment or materials;
- Use of federal facilities;
- Any research team member (including students) whose time on the research is paid or supported (whether directly or indirectly) by any federal award.