Grand Valley State University Institutional Review Board (IRB)	
Title: *Continuing Review and Approval of Selected Non-Exempt Protocols*	
Section: 910.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 10/29/2013 Revisions approved: 01/14/2014 Revisions approved by HRRPPC: 04/24/2018 Revisions approved by IRBPPC: 10/29/2019 Revisions approved by IRBPPC: 03/29/2022	Approved by RIO/HRPA: 02/10/2014 Revisions approved by AIO/RIO: 05/23/2018 Revisions approved by AIO: 11/5/2019 Revisions approved by AIO: 04/12/2022
Effective Date: 04/12/2022	
Related Sections: 121: Review Standards for Research Not Covered by FWA 901: IRB Protocol Review: Expedited Protocols 902: IRB Protocol Review: Full Board Protocols 911: Exemption Determinations and Research Ethics Standards 1030: Research Noncompliance 1060: Closure of Approved Research Studies	

Policy

1. All non-exempt protocols approved prior to January 21, 2019, are required to undergo continuing review, until a determination has been made by the IRB that the research can be transitioned to the Revised Common Rule and continuing review is no longer necessary.

2. Non-exempt protocols approved after January 20, 2019 are not required to undergo continuing review unless specifically required by 45 CFR 46, 21 CFR 56, or the IRB determines that continuing review is required per *IRB Policy 901: IRB Protocol Review: Expedited Protocols* or *IRB Policy 902: IRB Protocol Review: Full Board Protocols*.

3. The IRB shall follow the written procedures below for determining which projects need verification from sources other than the investigators that no material changes have occurred since the previous IRB review.

Procedures

1. Requests for continuing review must be submitted by the Principal Investigator (PI) using the appropriate form in the Office of Research Compliance and Integrity's (ORCI's) electronic database management system.

2. When conducting continuing review, the IRB must evaluate whether the research continues to satisfy the criteria for IRB approval of research. The IRB should start with the working presumption that the research, as previously approved, does satisfy the criteria for IRB approval. The IRB should focus on whether there is any new information provided by the investigator, or otherwise available to the IRB, that would alter the IRB's prior determinations or necessitate revision of the protocol and/or informed consent document. In particular, the IRB should pay particular attention to the following aspects of the research:

    a. Risk assessment and monitoring

    b. Adequacy of the process for obtaining informed consent

c. Investigator and institutional issues; and

d. Research progress

3. Protocols approved after January 20, 2019 (i.e., protocols approved after the implementation of the revised Common Rule)

    a. The federal regulations require that human subjects research be reviewed at least annually under certain circumstances (e.g., federally-funded studies that are greater than minimal risk, research subject to FDA oversight, etc.). The IRB will communicate such instances to the PI upon approval of the protocol.

    b. Many research studies under the oversight of the IRB pose no more than minimal risk to the subjects. Thus, it is unlikely that IRB determinations about potential benefits, informed consent, or risks to subjects would be affected by new information gathered directly from the research interim results or from other sources if the approval period were lengthened beyond one year. Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:

        i. Research eligible for expedited review in accordance with §46.110;

        ii. Research reviewed by the IRB in accordance with the limited IRB review described in §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);

        iii. 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:

            1. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

            2. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care. (§46.109 (f)(1)).

    c. If continuing review is determined to be necessary by the IRB upon initial approval of the research (*IRB Policy 901: IRB Protocol Review: Expedited Protocols* or *IRB Policy 902: IRB Protocol Review: Full Board Protocols*), the IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, not less than once per year. The following criteria should be considered by the IRB, as applicable, when determining the continuing review interval of the proposed research: the nature of the study; the degree of uncertainty of the risks involved; the vulnerability of the subject population; the experience of the investigator; the IRB's previous experience with the investigator and/or sponsor; the projected rate of enrollment; and whether the study involves novel therapies.

4. Protocols approved prior to January 21, 2019 (i.e., protocols approved prior to the implementation of the revised Common Rule)

    a. The existing approval period for studies approved under the expedited review process prior to January 21, 2019, will be retained.

b. When a study is submitted for continuing review or for a change in approved research, the Chairperson or designated reviewer(s) may determine that the revised Common Rule regulations apply and that continuing review is no longer required. This determination can only be made if the research complies with all applicable elements of the revised Common Rule. If any part of the research is not in compliance with the revised Common Rule, the research must remain under the previous version of the Common Rule (i.e., the version of the Common Rule that was in effect when the protocol was originally approved) or it must be amended to bring it into compliance with the revised Common Rule. (e.g., if participants are still being enrolled in the research, the consent document must be updated to include any additional elements required in the revised Common Rule.)

c. It is not required that all existing research comply with the revised Common Rule. If the researcher chooses to remain under the previous version of the Common Rule, this will be permitted. In these cases, the IRB may approve a non-exempt study for a two-year approval period following the previously established guidelines below.

    i. To qualify for two-year approval studies ***must***:

        1. Pose *no more than minimal risk* to subjects (initial review may be expedited or full board), and

        2. Receive the recommendation for a two-year approval from all IRB reviewers, **and**

        3. ***Must not*** include any of the following:
            a. Federal funding or federal training grants
            b. FDA-regulated components
            c. Sponsor or other contractual restrictions
            d. Prisoners as subjects

    ii. IRB protocols granted a two-year approval period will need to be revised if the study receives federal funding. The PI must contact the ORCI for instructions if federal funding is anticipated.

5. Tracking Study Approvals

   The ORCI tracks active protocols in the electronic database management system. Additionally, the ORCI typically sends out reminder emails to the PI at 90, 60, 30, and 7 days prior to a protocol's expiration date, and another notice one day after protocol expiration. However, it is the PI's responsibility to ensure that the continuing review request is submitted in a timely manner.

6. Lapse in IRB Approval

    a. IRB protocols must remain active until the protocol is closed by the IRB (see *IRB Policy 1060: Closure of Approved Research Studies*). Note that the PI can request closure prior to the expiration date of the protocol.

    b. If the protocol requires continuing review, and the approval period expires (i.e., a protocol lapse), all research activities must stop until IRB approval has been re-established. During

a protocol lapse, no recruitment and enrollment may occur, no data may be collected, and data analysis must stop.

i. If the PI believes that current participants are at risk of harm from stopping the research procedures, the PI will submit the following to the IRB:

1. A list of participants who may be harmed, using their participant ID only

2. Identify the research procedures that need to continue and explain the reasons why

ii. The IRB Chairperson, or qualified IRB member(s) designated by the Chairperson, will determine in consultation with the PI if it is in the best interests of enrolled participants to continue. This determination can be made for all enrolled participants as a group or for each individual participant.

iii. If the IRB determines it is not in the best interests of enrolled participants to continue to participate in research during the lapse in IRB approval, the PI must stop all human subjects research activities.

c. If the lapse is no more than one month in duration, the PI may submit a continuing review form to request re-approval. If the lapse is greater than one month in duration, the IRB may require a new protocol be submitted.

7. Protocols Requiring Additional Verification

a. The IRB may determine that it needs verification from sources other than the PI that no material changes have occurred since the last IRB review. The verification process may be initiated at any time and due to information derived from any source, including both immediate concerns related to the research study and broader concerns that may affect the research (e.g., recalls, lawsuits, cutting edge technologies, etc.). The IRB may consider independent assessment for situations including, but not limited to:

i. When concerns have been raised, through IRB review or from other sources, about possible material changes occurring without IRB approval

ii. Complex projects involving unusual levels or types of risks to participants (e.g., multi-site studies, large number of research assistants, etc.)

iii. Protocols or investigators with previous compliance issues

iv. Other circumstances for which the IRB deems independent verification is needed

b. The IRB Chairperson, assigned reviewer, or a convened IRB may request that an independent agent review the protocol documents or observe the conduct of the research and/or consent process to verify the accuracy of the information presented to the IRB and to ensure that no material changes have been instituted without IRB approval. The individual requesting the verification shall indicate the specific reason for the request and the information to be verified. Individuals who may conduct the verification include, but are not limited to:

i. ORCI staff

ii. IRB members

iii. Authorizing Official

iv. Other protocol personnel (co-investigators, research assistants, project managers, etc.)

v. Any other individual associated with the completion of the project or other stakeholder, as appropriate

c. The type of verification needed will depend on the nature of the study and may be obtained from one or more potential sources including, but not limited to, the following:

i. Research records

ii. Literature searches

iii. Observation of the consent process

iv. Data Safety Monitoring Boards

v. Grant applications

vi. Sponsors

vii. The ORCI, as part of Post-Approval Compliance Review (*IRB Policy 1040: Post-Approval Compliance Review*) or other compliance review

d. The individual performing the verification will provide a written summary of the verification to the IRB. This summary will be attached to the study in the ORCI's electronic database management system. The findings may also be shared with the following individuals, as appropriate:

i. A convened IRB or designated reviewer when the verification is requested during the course of reviewing an amendment, continuing review, or reportable event

ii. The IRB Chairperson

iii. ORCI staff

iv. Institutional Official

e. If the IRB determines material changes have been made without prior IRB approval, the incident will be reviewed for potential noncompliance according to *IRB Policy 1030: Research Noncompliance*. If applicable, the PI will be instructed to submit an amendment request in ORCI's electronic database management system.

8. Determination of Approval Date and Approval Period

    a. Continuation approved at a convened meeting or via expedited review

        i. If a continuing review submission for a protocol is approved at a convened meeting, the approval date is the date of the meeting and the approval period is calculated based on this date.

        ii. If a continuing review submission for a protocol is approved via expedited review, the approval date is the date of the Chairperson's approval following the designated reviewers' completion of the review process, and the approval period is calculated based on this date.

        iii. Examples:

            1. If the protocol was reviewed on 11/1/2019 and approved for one year, the approval period is 11/1/2019 – 10/31/2020.

            2. If the protocol was reviewed on 11/1/2019 and approved for six months, the approval period is 11/1/2019 – 4/30/2020.

    b. Continuation *conditionally* approved at a convened meeting or via expedited review

        i. If a continuing review submission for a protocol is conditionally approved for one year at a convened meeting, the approval date is the date of the meeting. However, the approval is not effective until the Chairperson or designee confirms the approval conditions have been satisfied.

        ii. If a continuing review submission for a protocol is conditionally approved for one year via expedited review, the approval date is the date of the Chairperson's conditional approval following the designated reviewers' completion of the review process, and the approval period is calculated based on this date. However, the approval is not effective until the Chairperson or designee confirms the approval conditions have been satisfied.

        iii. Examples:

            1. If the protocol was reviewed on 11/1/2019 and was conditionally approved for a period of one year, and the conditions were satisfied and approved by the Chairperson or designee on 11/15/2019, the approval period is 11/1/2019 – 10/31/2020 with an approval effective date of 11/15/2019.

            2. If the protocol was reviewed on 11/1/2019 and was conditionally approved for a period of six months, and the conditions were satisfied and approved by the Chairperson or designee on 11/15/2019, the approval period is 11/1/2019 – 4/30/2020 with an approval effective date of 11/15/2019.

            3. If the protocol expired on 10/15/2019 and was reviewed and conditionally approved for a period of one year on 11/1/2019, and the conditions were satisfied and approved by the Chairperson or designee on 11/15/2019, the

approval period is 11/1/2019 – 10/31/2020 with an approval effective date of 11/15/2019. Because there is a lapse in approval, no work can be done on the protocol until the conditional approval has been satisfied.

9. The IRB's determination regarding the date of approval and continuing review interval will be communicated to the PI in writing.