Board Determinations

Purpose

The purpose is to outline the policy and procedures for human research determinations and approval by the Institutional Review Board (IRB) or Exempt Review Committee (ERC).

Definition

Approval of research is the determination of the IRB or ERC that the research has been reviewed and may be conducted within the constraints set forth by the IRB or ERC and by other institutional and federal requirements.

Modifications required or ***deferred*** are both determinations that research has been reviewed, but will require change or additional information before approval may be granted. They differ in who will provide review, as follows:

- "Deferred" Determination – This is reviewed by all original reviewers, or at a convened IRB meeting if the original had undergone full review.
- "Modifications Required" Determination – This is reviewed by staff, or by a volunteer member outside of a convened IRB meeting if the original had undergone full review.

Policy

The IRB and ERC make determinations to approve, require modifications in (to secure approval), disapprove, monitor, suspend or terminate research. Both notify investigators and the institution (where applicable) in writing of the decision about the research activity.

In its approval, the IRB or ERC will:

- Determine which projects require more than annual review based on degree of risk and document it in its decision letters
- Determine which projects need verification from sources other than the investigator that no material changes have occurred since previous review
- Ensure prompt reporting to the IRB or ERC of proposed changes in a research activity
- Ensure that changes during the approval period are not initiated without IRB or ERC review and approval except when necessary to eliminate apparent immediate hazards to the subject

NOTEApproval of research does not end an investigator's responsibilities concerning the IRB or ERC. Closure reports are mandatory, as is reporting of other events throughout the life of a project. Please see our Mandatory Reporting, Continuing Review and Closure policies for further information.

Disapproval and Appeal

If the IRB or ERC decides to disapprove a research activity, it includes in its written notification a statement of the reasons for its decision. An investigator has an opportunity to respond in writing or in person at a convened IRB meeting.

Expiration of Approval

Federal regulations concerning the protection of human subjects under 45 CFR 46 (The Common Rule) have been revised and became effective on January 21, 2019. As a result, approval periods have changed for certain types of research. Unless an investigator completes a study within a year from the approval date, continuing review must be sought or a check-in report filed annually. See the Continuing Review policy for details.

When does approval expire?

	Full	Expedited	Exempt
If approved prior to 1/21/19	1 year from approval, unless IRB determines sooner	1 year from approval	1 year from approval (One time only)
If approved on or after 1/21/19	1 year from approval, unless IRB determines sooner	No expiration, unless IRB determines and documents otherwise	No expiration

Review by Institution

Research that has been approved by the IRB or ERC may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by the IRB or ERC [45 CFR 46.112].

Procedures

1. Upon approval, an IRB or ERC staff member imprints documents which are part of the consent process (informed consent/parental permission/assent forms and scripts, and any advertisements) with Marywood University's official IRB or ERC approval stamp and uploads the stamped copies into IRBNet. The staff member also creates and publishes an official approval letter in IRBNet.
2. The IRBNet system sends the Principal Investigator (PI) and all individuals who have been granted full project access automated e-mail notices about

the document publication and determination, and a staff member sends an email notice with detailed instructions.
3. The PI logs into IRBNet to access the official determination letter and stamped documents, which must be used in the implementation of the project.
4. The approval letter communicates the approval date, investigator responsibilities, reporting requirements, and the expiration date for the research project, if one applies.

Related Policies

- Continuing Review
- Closure or Withdrawal
- Mandatory Reporting
- Revisions to Approved Research
- Suspension or Termination

History

06/13/2013 - Updated

07/19/2013 - Updated

12/10/2013 - Updated

06/13/2017 - Updated with regulatory language

06/28/2019 - Updated as a result of the Revised Common Rule

07/01/2019 - Updated title