

How to Determine if your Study has an Expiration Date and Requires Renewal

There are three types of IRB “approval” correspondence letters: (1) exempt; (2) non-exempt without expiration, and (3) non-exempt with expiration.

1. Review type: Exempt

Expiration date: not applicable

Renewal required: not applicable

Human research determined by the IRB to be exempt will never have an expiration date or any annual reminders as they do not have ongoing/continuing oversight by the IRB.

Therefore, annual renewal submissions are **not applicable**.

Protocol Information Show Less ^			
Review Type Exempt	Status Exempt	Approval Date Mar 11, 2024	Continuing Review Date --
Expiration Date --	Initial Approval Date Mar 11, 2024	Initial Review Type Exempt	

PROTOCOLS kuali

No expiration date

Institutional Review Board
Office of Research and Sponsored Programs
University of Massachusetts Boston
100 Morrissey Boulevard, Boston, MA 02125-3393
P 617.287.5374 | irb@umb.edu
www.umb.edu/research/orosp/institutional-review-board-irb

Monday, March 11th 2024

IRB ID Number: [REDACTED]

PI Name: [REDACTED]

Protocol Title: [REDACTED]

Submission Type: Initial

Type of Review: Exempt

The **Initial** submission for the research study referenced above was reviewed **Exempt** and approved on **Monday, March 11th 2024** by the University of Massachusetts Boston IRB. The UMass Boston IRB expiration date is **no date provided**.

The study has no expiration date, and ongoing IRB review and approval by this organization is not required. This study qualifies as human research that is exempt under the following categories: (2)(iii) Tests, surveys, interviews, or observation (identifiable); and for which limited IRB review was conducted via expedited review

This determination applies only to the activities described in the IRB submission. If you decide to make significant changes to the project or modify the project in such a way that it may no longer qualify for exemption (e.g., changes that add more than minimal risk to subjects, add a vulnerable population, impact privacy and confidentiality, affect design of research, add federal funding, etc.), submit a modification request to the IRB for review prior to implementation of the modified research project.

Exempt

No expiration date

2. Review type: Non-exempt WITHOUT expiration date (most expedited studies)
Expiration date: None
Renewal required: No

Most non-exempt human research approved after 2018 by the expedited review type will have no expiration date per the revised human research regulations.

Annual renewal submissions are **not required**.

However, you will still receive annual reminders (triggered by a “continuing review” anniversary date in Kualu) indicating that the study does not require a renewal submission, but the study has continuing IRB oversight.

All amendments, reportable events, and a closure request are required to be submitted to the IRB.

Protocol Information			Show Less ^
Review Type Expedited	Status Approved	Approval Date Sep 26, 2023	Continuing Review Date Sep 26, 2024
Expiration Date --	Initial Approval Date Sep 26, 2023	Initial Review Type Expedited	

PROTOCOLS **kuali**

No expiration date

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Tuesday, September 26th 2023

IRB ID Number: [REDACTED]
PI Name: [REDACTED]
Protocol Title: [REDACTED]
Submission Type: Initial
Type of Review: Expedited

The **Initial** submission for the research study referenced above was reviewed and approved **Expedited** on **Tuesday, September 26th 2023** by the University of Massachusetts Boston IRB. **The UMass Boston IRB expiration date is no date provided.**

The IRB determined that the research presents/continues to present no greater than minimal risk to children (45 CFR 46.404). Assent is not necessary (45 CFR 46.408), and there are adequate provisions for the permission of the parents (45 CFR 46.408).

The study has no expiration date and does not require renewal (continuing review); however, modification and closure submissions are required. When the research meets the criteria for study closure, you are to submit a closure request (final report) to the IRB.

Continuing review anniversary date in Kualu (not to be confused with an expiration date) triggers an annual reminder to the PI that the study continues to have IRB oversight.

Amendments, reportable events, and a closure request must be submitted to the IRB even though renewals are not required.

No expiration date = No renewal needed

3. Review Type: Non-exempt WITH expiration date (full board; some expedited studies)

Expiration date: Yes

Renewal required: Yes

Some non-exempt human research will have an expiration date. The initial review type could be either expedited (in some cases such as pre-2018 studies) or full board.

Annual renewal submissions are **REQUIRED**.

You will receive annual reminders that indicate that the study REQUIRES a renewal submission at least 30 days prior to the expiration date for IRB review and approval in order to continue IRB oversight.

All amendments, reportable events, and a closure request are also required to be submitted to the IRB.

Protocol Information Show Less ^			
Review Type Expedited	Status Approved	Approval Date Sep 25, 2024	Continuing Review Date --
Expiration Date Sep 24, 2025	Initial Approval Date Nov 29, 2023	Initial Review Type Full Board	

PROTOCOLS kuai

Expiration date

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Wednesday, November 29th 2023

IRB ID Number: [REDACTED]
PI Name: [REDACTED]
Protocol Title: [REDACTED]

Submission Type: Initial
Type of Review: Full Board

The **Initial** submission for the research study referenced above was reviewed and approved **Full Board** on **Wednesday, November 29th 2023** by the University of Massachusetts Boston IRB. The UMass Boston IRB expiration date is **Friday, September 27th 2024**.

The study is subject to continuing review by the expiration date unless closed by that date. Modification submissions are required. You are to submit a renewal or closure request at least 30 days before the expiration date. If renewal approval or closure is not granted by the expiration date, approval of this research expires.

Submit a renewal application at least 30 days prior to expiration.

Courtesy expiration reminder notices are sent to the PI, but the PI is responsible for tracking expiration to avoid a lapse in IRB approval.

Expiration date = Renewal required

Renewals, amendments, reportable events, and a closure request ALL must be submitted to the IRB.