

IBC Policy on Renewals, Suspensions, and Terminations of Protocols

Adopted (10/25/2018) Updated (8/18/2022)

DEFINITIONS

CLOSED: This designation indicates a project is completed or that the investigator requested closure of a protocol. The research covered under a closed protocol will no longer be pursued: data collection is finished, the biological work is completed, or the laboratory will be closed. No further work related to the closed protocol may be performed.

SUSPENDED: This designation indicates a temporary hold on biological or recombinant research activities (all or a subset) associated with an approved protocol. **Protocols may be suspended due to failure of the investigator to secure approval on a renewal in advance of the expiration date** or any noncompliance that does not result in immediate termination of the protocol. Upon suspension of a protocol, the Administrator or Chair of the Institutional Biosafety Committee (IBC) will send a notification letter and/or email to the Department/Division Head/Director in addition to the principal investigator (PI), identifying the protocol and thus defining the associated activities that shall be SUSPENDED until IBC approval is obtained. The suspension period is determined by the IBC and will not be extended beyond 60 days. Suspended protocols that are not resolved to the satisfaction of the IBC with the 60-day window will be TERMINATED.

TERMINATED: This designation indicates that a protocol was actively terminated by the IBC. A previously approved protocol can be terminated due to noncompliance with university or federal government policies, resulting in serious or unexpected risks to an

individual, the public, or the environment from recombinant or biohazardous materials or failure to complete a renewal within 60 days of suspension due to expiration.

Termination is defined as a permanent withdrawal of protocol approval, and explicitly mandates all related activity must cease immediately. The Vice Chancellor for Research, Research Dean, Department/Division Head/Director, appropriate university committees, the MU Office of Sponsored Programs Administration, the National Institutes of Health and other approval agencies (if applicable) may be notified, in addition to the PI, of protocols terminated by the IBC. Continued use of materials or procedures that pose a risk to an individual, the public, or the environment will result in reporting to the MU Office of Research for further disciplinary action.

CONTINUATION: In rare cases, a request for continuation may be submitted by a PI who has extenuating circumstances for missing a protocol submission deadline. Continuation requests will be reviewed by the IBC Chair and Biological Safety Officer (BSO) and shared with the IBC at the next scheduled meeting. Continuation requests must be submitted within 72 hours of protocol expiration and will not be extended for more than the greater of 60 days or 2 IBC meeting cycles. If a protocol is not approved by the end of the continuation period, it will be TERMINATED.

SUBMISSION OF RENEWALS

The PI is responsible for submitting, in a timely manner, a renewal protocol for activities that will continue beyond the currently approved term. Protocol renewals must be received, reviewed, and approved by the IBC before expiration of the current protocol. Four months before a protocol expires, the IBC will send a reminder notice requesting submission of a renewal by email to the PI. If necessary, a second notice will be sent two months prior to protocol expiration and a SUSPENSION notice will be sent on the date of expiration. Investigators who fail to submit a renewal protocol form with

sufficient time to allow IBC approval will have their protocol SUSPENDED on the date of expiration, pending completion of IBC review and approval. It is recommended that protocol renewals are submitted for review at least 3 months prior to the date of the meeting during the month of protocol expiration. Good faith requests for temporary CONTINUATION will be considered by the IBC Chair and BSO.