Clinical Research Enterprise (CRE)

Standard Operating Procedure Continuing Review IRB Submissions for studies being managed by the CRE regulatory department

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Revision History:	**Version**	**Effective Date**	**Description**

Purpose

The purpose of this SOP is to explain the roles, responsibilities, procedures, and expectations for Continuing Review IRB Submissions for studies being managed by the CRE regulatory department.

Scope

This SOP applies principal investigators (PI), delegates of the PI, CRE regulatory staff, Education and Compliance team members.

Allowable Exceptions

This SOP is meant to be followed without deviation. If there is a reason that this SOP cannot be adhered to it is the responsibility of the PI to reach out to the head of compliance Dr. Cynthia Joiner, cirwin@uabmc.edu with a justification for this exception along with an action plan no longer than 15 days prior the study's expiration date. Failure to follow this process will be considered non-compliance and the study will be placed on hold until at which point the PI is able to correct the issue and provide the requested information to complete and submit the study renewal.

I. Background regarding IRB Renewal Notices and Timelines

A. For protocols that require a convened (full) board review, the IRB expects the continuing review to be submitted 4 to 6 weeks prior to study expiration to avoid a lapse in approval.

B. Protocols are subject to continuing review if subjects are still being enrolled, being followed, in long-term follow-up, or if the study is in data analysis.

C. The IRB expects findings to be included for all studies that have been ongoing for 5 or more years.

D. PI needs to ensure proper delegate access has been granted for the regulatory coordinator to submit and receive correspondence to the IRB on the protocol.

E. For protocols that fall under expedited review or Expedited Status Update (ESU), the IRB will require a status update at least every 3 years. The IRB or Expedited reviewer will determine and document the need for ongoing continuing review. The PI will be contacted directly by the IRB for reviews that fall into the ESU category.

II. Roles, Responsibilities, Procedures and Expectations are outlined below for Continuing Review IRB submission for PIs, delegates of the PI, and CRE regulatory staff.

III. CRE Regulatory Staff

A. Upon receiving the 60-day Renewal Notice from the IRB for the study in question the CRE Regulatory staff member will reach out to the PI and/or delegate of the PI if previously identified to receive updated recruitment numbers and demographics as required for the continuing reviews.

B. If no response is received within 14 days (2 weeks) a second reminder email/prompt will be sent to the PI and/or identified delegate.

C. Upon receiving the 30-day Renewal Notice from the IRB for the study, if no response has been received from the previous two queries a 3rd reminder email will be sent to the PI and/or identified delegate with the education/compliance team cre-education@uabmc.edu cc'd.

D. If no response is received by the date of the 14-day Renewal Notice from the IRB a 4th and final email reminder will be sent to the PI/and identified delegate (if applicable) with the education/compliance team cre-education@uabmc.edu cc'd. A response to this email is expected within 1 business day.

E. If no response is received from the PI within 1 business day of the 4th and final reminder email, the CRE regulatory coordinator will notify the education/compliance team and the regulatory team will cease all work on this protocol until further instructed to do so by the education/compliance team.

F. Once this matter has been resolved and needed information provided to the CRE Regulatory staff will submit the renewal and notify the PI and any identified delegates once this renewal has been approved and research activities can be resumed.

IV. CRE Education/Compliance Team

A. The CRE Education/Compliance team will assist the regulatory staff in ensuring timely PI communication for continuing reviews.

B. Upon receiving notice of non-response to 30-day and 14-day renewal notices the CRE Education/Compliance team will reach out to the PI and PI delegate (if applicable) and instruct them to cease all study activities until this matter has been resolved.

C. The PI will be instructed to set a meeting time with the CRE Education and Compliance team to discuss reason for non-compliance, to provide necessary enrollment numbers and demographic information, and discuss a corrective action plan to prevent further non-compliance in the future.

D. If no response is received to this correspondence within 5 business days, escalation will occur with Vice Chair of Department of Medicine (DOM) reaching out to further assist with compliance and resolution.

E. The study will remained paused until all IRB approvals have occurred.

V. PI and/or Delegate of the PI

A. It is the PI's responsibility to provide the CRE regulatory team with the needed enrollment numbers and patient demographics to complete the IRB continuing review process. They may delegate this task to another member of the research team (i.e. sub-investigator, research coordinator, research assistant, etc.), however the ultimate responsibility to provide this information in a timely manner is theirs.

B. Failure to provide this information in a timely manner can lead to IRB study approval lapsing and necessitate the need to pause all study related activities until which time this matter can be resolved

C. This new SOP has been put in place to ensure that we are providing the appropriate resources and support to enable our new investigators to be successful and remain in compliance with IRB, FDA, and GCP guidelines.