AAH RSPP GUIDANCE

Non-responsiveness to RSPP/IRB requests for information/action

PURPOSE
This document outlines the RSPP policy related to non-responsiveness by research teams to AAH RSPP Office/IRB requests for information, follow-up or actions, up to and including actions related to IRB required condition(s) of approval. Failure to respond to the AAH RSPP/IRB after 45 calendar days will result in the package being administratively withdrawn from RSPP/IRB review.

This policy is enacted to ensure an efficient review process by the RSPP/IRB. It applies to submissions of new studies (studies to be overseen by the AAH IRB or an external IRB of record), Changes, Continuing Review applications, reportable events, and Human Subject Research (HSR) Determinations.

It should be noted that multiple requests for information/follow-up or action may occur during the RSPP/IRB’s review of the submitted package. Each request for information/action will follow this same process.

The RSPP does not ‘remind’ submitters that action is necessary after the initial request has been made via IRBNet. It is the responsibility of the study team/submitter to monitor their emails or the IRBNet program, and to take action where needed.

NOTE that this policy does not apply to notifications/requests for Continuing Review. IRBNet automatically sends reminders to the PI/study team when Continuing Review is required per federal regulation or the AAH IRB. Failure to provide the Continuing Review application to meet AAH IRB or regulatory requirements will result in a lapse of IRB approval.

It is important to remember that no study may be conducted or any change in an approved study be implemented without RSPP authorization/IRB approval.

GUIDANCE
What are the consequence for a lack of responsive to AAH RSPP/IRB requests for information/follow-up or action?

The failure of the research team to respond to the RSPP/IRB’s request for information/follow-up or action after 45 calendar days from the request will result in the administrative withdrawal of the submission/package from RSPP/IRB review. (See below for the process related to inactivity.)

It is important to note that once a package is withdrawn it cannot be reactivated. Instead, a new package must be submitted.

An extension beyond 45 calendar days may be granted by the RSPP Director or IRB if the PI provides sufficient cause. Note there is no guarantee of an extension. (See process below for requesting an extension.)
What packages are affected by this policy?

Any package submitted to the AAH RSPP/IRB in IRBNet that requires a response, follow-up, or action from the submitter/PI is included in this policy.

The requests for more information or follow-up can occur at any point during the RSPP/IRB review cycle: package intake, Research Compliance Analyst (RCA) review, IRB Primary Reviewer (PR) review, conditions of approval issued as part of the IRB's review.

- Packages included in this policy include: new submission applications, requests to rely on an external IRB, Continuing Review applications, Change forms, reportable events, and HSR Determinations.

- Note that a lack of response to a request for information, follow-up, or actions related to a Continuing Review submission may result in a lapse of IRB approval should the package containing the continuing review application be administratively withdrawn. See the RSPP Guidance: IRB approval dates and Expiration of Approval for more information on a lapse in IRB approval.
  - No research activities may be conducted if there is a lapse of IRB approval.

What is the process for notifying submitters that information or action is needed?

- Following submission intake, RCA/Primary Reviewer review, or issuance of conditions of approval by the IRB, a project email will be generated in IRBNet by the RSPP Office outlining what is required of the PI/submitter.
  - This is the only communication that will be sent.
    - No email will be sent directly to the personal email address of the submitter/PI by the AAH RSPP office.
    - Those individuals with Full Access in IRBNet will receive the email generated in the IRBNet system.
      - It is important that the PI have Full Access to the IRBNet package so that s/he is aware of the request.
      - The submitter/PI should monitor their emails for communications sent via the IRBNet system.
  - A due date will not be included in the request for information/action. However, it is expected that a response be provided as soon as possible but in no case later than 45 calendar days of the date the request is sent.
    - No action on the part of the RSPP or IRB will occur until the PI/submitter completes the requested action.
• It is important to remember that no study may be conducted or any change in an approved study be implemented without RSPP authorization/IRB approval.

What is the process for notifying submitters of impending withdrawal of the package due to lack of response?

• If there is no response within 45 days of the request for information/follow-up or action, an email will be generated by the RSPP Office team member who requested the information/action.

• This email will be sent in both IRBNet (project email) and to the personal email of the submitter/study PI. This is the only time that an email will be sent to a personal email address.

• The email will notify the individual that the administrative withdrawal of the submission/package will occur in three (3) working days.
  
  o If the submitter/PI provides the requested material or asks for a formal extension (see below) by the end of the third working day, the RSPP office will take needed action.

  o If the follow-up/information is not provided in IRBNet by the end of the third working day, the package will be marked as ‘administratively withdrawn’ in IRBNet.

  ▪ A package that has been administratively withdrawn cannot be re-opened by the study team or the RSPP. A new package must be submitted in IRBNet.

How can I request a formal extension of the original 45 day response period?

• The submitter/PI will need to provide to the RSPP Office team member who requested the action/new information a written request (an email is sufficient) for an extension to the 45 day response period.

  o The extension request must include a rationale for the extension, and a plan of action to respond to the requested information/action.

• The request for an extension will be considered by the RSPP Director, and is not guaranteed.

• The extension period, if granted, will NOT exceed an additional 45 days.

• An extension will only be granted once.
• If there is no response/action after the extension period (the second 45 day period), the IRBNet package will be administratively withdrawn without further communication with the submitter/PI.

APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS

• RSPP GUIDANCE: *IRB approval dates and Expiration of Approval*

• RSPP GUIDANCE: *IRB Decisions*