IMPORTANT ANNOUNCEMENT FROM THE OFFICE FOR THE PROTECTION OF HUMAN SUBJECTS (OPHS)

IRBear Submissions Will be Administratively Withdrawn (Closed) after 60 Days of Inactivity

Effective after 6 p.m., Friday, December 18, 2015, any submission in IRBear that requires a response from a PI will be Administratively Withdrawn if a response has not been submitted within sixty (60) days of the initial request. This means that the submission will be closed. The PI must create a new submission if (s)he is still seeking approval or acknowledgement from the IRB. Submissions include:

- New study applications
- Amendments
- Continuing reviews
- Reportable events

PIs may receive requests for changes or clarifications to their submission. These requests require action on the part of the investigator. Requests may come from any of the following:

- IRB/IRB staff
- Division or Research Center reviewer (new studies only)
- Ancillary reviewer

To avoid the administrative withdrawal of a submission, you must submit a response (even if incomplete) to any outstanding requests within 60 days. This will reset the clock for another 60 days and give you more time to respond fully, if needed.

What happens when a submission is Administratively Withdrawn?

When a submission is Administratively Withdrawn within IRBear, it is effectively closed. The PI and study team can no longer make changes to it or respond to requests for changes. A new submission must be created by the study team and submitted by the PI. The new submission must go through the entire review process even if some of the steps were completed for the previous submission before it was administratively withdrawn.

Example: If an amendment was submitted and the IRB staff requested changes to the SmartForm, the PI must submit a response to the IRB within 60 days of the request or the amendment will be administratively withdrawn. Once it has been administratively withdrawn, a new amendment must be created and submitted for IRB review. (Note: Administrative withdrawal of the amendment does not affect the state of the approved study.)

How does this affect my approved studies?

- A study that was already approved remains open until its expiration date, even if an amendment, continuing review, or reportable event is Administratively Withdrawn.
- If an amendment is Administratively Withdrawn, the changes proposed in the amendment may not be implemented.
- If a continuing review is Administratively Withdrawn and the expiration date is reached, all research activities must stop. This includes subject recruitment, data and specimen collection, follow up, and data analysis.
How will I know when I am expected to respond to a reviewer?

PIs and other members of the study team receive ample notification when a response is required.

- IRBear sends an Outlook email from irbear@childrensnational.org that notifies the PI and other study team members when a response is first requested.
- Frequent reminders that a response is required are sent to the PI and study team via Outlook email.
- A link to the submission is listed in the IRBear inboxes of the PI and other study team members until a response has been submitted.

In addition:

- The “Current State” of the submission indicates that a response is required from the PI. (See the attached table for a complete list of states which require a response.)

  ![Example](image)

- The submission’s History log records each Outlook notification and the date and time that it was sent.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Author</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI Changes Required Reminder</td>
<td>Administrator, System</td>
<td>11/5/2013 2:22 AM</td>
</tr>
<tr>
<td>PI Changes Required Reminder</td>
<td>Administrator, System</td>
<td>11/3/2013 2:22 AM</td>
</tr>
<tr>
<td>PI Changes Required Reminder</td>
<td>Administrator, System</td>
<td>11/1/2013 2:22 AM</td>
</tr>
</tbody>
</table>

- Letters sent to the PI after a submission has been reviewed by the convened IRB (full board review) or a designated expedited reviewer outline any contingencies (requests for changes) and instruct the PI to respond within 60 days of the date of the letter.
- You will continue to receive reminders in Outlook and the submission will remain in your IRBear inbox until you submit your response.

I responded to the requests for changes but I am still receiving reminders in Outlook and the submission has not left my IRBear inbox. The “current state” of the submission still shows Changes Required or PI Response Pending. What’s going on?

If you responded to the requests but continue to receive reminders and the submission is still in your IRBear inbox, you most likely did not submit the response. Your response has not transitioned to the person who requested the changes. You must click on the Submit Changes activity to move the submission to the next state. (Only the PI can submit changes for new study applications. The PI, study coordinators, and co-investigators can all submit changes to amendments and continuing review forms.)

What if I don’t have the information I need to complete my response to the IRB within 60 days?

If you cannot complete a response to the IRB within 60 days (e.g., you are waiting for information from the study sponsor), submit a response explaining the situation. The IRB Analyst will return the submission to the study team, and the clock will be reset for another 60 days.

If you have questions, please contact the Office for the Protection of Human Subjects (OPHS) at 301-565-8452.
In IRBear, the Current State indicates the submission’s status in the IRB review process. It appears in the orange box in the upper left corner of each workspace, and in the ‘State’ column under the ‘Inbox’ tab on your ‘My Home’ page.

The table below lists the states when action by the PI or study staff is required. Submissions remaining in these submission states with no activity for 60 days will be Administratively Withdrawn by the system.

<table>
<thead>
<tr>
<th>Current State</th>
<th>What Do I Need to Do?</th>
</tr>
</thead>
</table>
| Changes Required by Ancillary Reviewer | • Click Edit Study [Button] to make requested changes and/or provide clarification.  
  ○ PI must click Submit Changes [Activity] to move the submission back to Awaiting Ancillary Review [State]. |
| Changes Required by IRB OR Changes Required by IRB Staff | • Review the requests for changes or clarifications and respond:  
  ○ Click Reviewer Notes [Tab]. Then click the ‘Jump To’ link.  
  ○ Make the requested changes or add clarifications to the completed SmartForm (submission form), if applicable. Once the changes are made, respond to the clarification.  
  ○ Once you have addressed all of the requests for changes or clarifications, the PI must click Submit Changes [Activity] to move the submission back to IRB Staff Review [State]. |
| Clarification Required (Division Review) | • Click Edit Study [Button] to make requested changes or provide clarification.  
  ○ PI must click Submit Changes [Activity] to move the submission back to Division Review [State]. |
| Contingencies Pending | • Review the requests for changes or clarifications and respond:  
  ○ Click Reviewer Notes [Tab]. Then click the ‘Jump To’ link.  
  ○ Make the requested changes or add clarifications to the completed SmartForm (submission form), if applicable. Once the changes are made, respond to the clarification.  
  ○ Once you have addressed all of the requests for changes or clarifications, the PI must click Submit Changes [Activity] to move the submission back to IRB Staff Review [State]. |
| In Exempt Review: PI Response Pending | • Review the requests for changes or clarifications and respond:  
  ○ Click Reviewer Notes [Tab]. Then click the ‘Jump To’ link.  
  ○ Make the requested changes or add clarifications to the completed SmartForm (submission form), if applicable. Once the changes are made, respond to the clarification.  
  ○ Once you have addressed all of the requests for changes or clarifications, the PI must click Submit Changes [Activity] to move the submission back to IRB Staff Review [State]. |
| In Expedited Review: PI Response Pending | • Review the requests for changes or clarifications and respond:  
  ○ Click Reviewer Notes [Tab]. Then click the ‘Jump To’ link.  
  ○ Make the requested changes or add clarifications to the completed SmartForm (submission form), if applicable. Once the changes are made, respond to the clarification.  
  ○ Once you have addressed all of the requests for changes or clarifications, the PI must click Submit Changes [Activity] to move the submission back to IRB Staff Review [State]. |