IRBIS changes, effective 12:00 AM, October 19, 2021

IRBIS System Update:

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New Safety Information is now Promptly Reportable Information

“New Safety Information” and “NSI” has been replaced with “Promptly Reportable Information” and “PRI” on the investigator home screen and in the PRI submission form to align with the OHRE SOP 1401 update.
Update to PRI form

In order to better collect information in the initial submission and decrease the return for more information, there are some new questions on the Promptly Reportable Information form.

A new section will address submissions where the information is related to an Investigator’s Brochure update.

Section A has four additional questions to address privacy and noncompliance events.
**Exemption section display**

The exemption section has been updated so that the responses associated with each exemption category are contained within a box. We hope that this provides better visual cues to the investigator and assists in completing the correct responses.

<table>
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<th>Category 1</th>
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<td>The research is to be conducted in established or commonly accepted educational settings. Note: This applies to the location where education research will actually be conducted (e.g., public schools) and not to your location at a university. And the research specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction, such as:</td>
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<td>Research on regular or special education instructional strategies</td>
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<td>Research on the effectiveness or the comparision among instructional techniques, curricula, or classroom management methods.</td>
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| Category 2 |
| Does your study involve minors under the age of 10? |
| Yes | No |

| Category 3 |
| Does the research involve secondary uses of identifiable private information or identifiable biospecimen. |
| And one of the following is true: |
| The identifiable private information or identifiable biospecimen are publicly available. |
| Information, which may include information about biospecimen, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects; the investigator does not contact the subjects, and the investigator will not re-identify subjects. |
| The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for nonresearch activities. |

**Display of analyst on PM and AR submissions for investigator**

Once an analyst is assigned to Personnel Modification and Administrative Review submissions, the analyst’s name will display on the submission screen.
Liaison selection in Personnel Mods

Study teams will now have the ability to update the IRB liaison in personnel mods. There is a new required question on the personnel entry.

When adding a new investigator who will be the liaison, an alert is displayed indicating that the former liaison designation will be removed.

If attempting to remove the liaison when no other investigators are listed, an alert is displayed indicating this is not allowed.
When other investigators are available, the alert box will provide the list to replace the liaison.

**AR Past Due hard stop for investigators**

In order to ensure that institutional requirements are up to date, a hard stop has been added when the Administrative Review Due Date has passed. When a study team attempts to create a modification for a study where the Admin Review is overdue, they will receive a hard stop alert to submit an AR. They can still submit a PRI or a Closure.

Once the Administrative Review is submitted to routing, a modification can be drafted and submitted.

**Department Administrators CC’d on expiration notices**

In order to assist department leadership with ongoing oversight of studies within their department, administrators listed as IRB approvers for the administering department will be copied on all expiration notices for both Continuing Review and Administrative Review. This will be especially helpful in cases when the PI has left UNC to prompt the department to take action when necessary. In the example below, only the OHRE administrators, Mike Matamoros and John Roberts, will receive the expiration notices.
Expiration notices are emailed as follows:

Continuing Review where a Renewal is required: 60 days, 30 days, 1 day

Administrative Review: 60 days, 44 days

These notices do not apply to studies where UNC is relying on another IRB.

Reminder: If your study has received Administrative Review, the Administrative Review due date is included in all approval letters.

If Continuing Review is required for your study, your approval letters will include an expiration date.