IRBIS changes, effective 6:00 PM, May 30, 2018

**IRBIS 5.09.10 Update:**

**A.2.4 text has been revised:**

<table>
<thead>
<tr>
<th>A.2.4 Original:</th>
<th>Do you have specific plans to enroll subjects from these vulnerable or select populations:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Do not check if inclusion of a group is purely coincidental and has no bearing on the research. For example, you should check &quot;Pregnant women&quot; if you specifically intend to recruit women who are pregnant. Do not check if you are conducting a survey of the general public, not aimed at pregnant women. See SOP 1201: Vulnerable subjects in research.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>A.2.4 Revised:</th>
<th>Do you plan to enroll subjects from these vulnerable or select populations:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If you will include children, prisoners or nonviable neonates or neonates of uncertain viability, please check the appropriate category below and complete the additional sections.</td>
</tr>
<tr>
<td></td>
<td>You should check &quot;Pregnant women&quot; if you specifically intend to recruit women who are pregnant or are not excluding pregnant women in biomedical research that is greater than minimal risk. Do not check if you are conducting a survey of the general public or conducting secondary data analysis or chart review not aimed at pregnant women.</td>
</tr>
<tr>
<td></td>
<td>Only check UNC-CH Student athletes, athletic teams, or coaches if you have specific plans to enroll these subjects. This is not applicable for intramural or club sports. For definitions and guidance see SOP 1201: Vulnerable subjects in research.</td>
</tr>
</tbody>
</table>

**A.2.5 text has been revised:**

<table>
<thead>
<tr>
<th>A.2.5 Original:</th>
<th>Based on your recruitment plan and target sample population, are you likely to include any of the following as subjects? Select all that apply.</th>
</tr>
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<td>Based on your responses, the consent form builder will insert the required text into your consent form template.</td>
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<th>A.2.5 Revised:</th>
<th>Based on your recruitment plan and target sample population, are you likely to include any of the following as subjects? Select all that apply. This is not applicable to secondary data analysis or chart review.</th>
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Screening Question #6

Screening Question #6 must be listed as Yes if external or independent Investigators are listed on the project. Warning messages have been updated:

Revised FWA Language

In the multisite section, the site detail pop-up window text has been revised to note that CVs and Medical Licenses are not required if the personnel are from an organization or institution which holds an FWA.
C.1 has been revised to home that the Research Disclosure Form should be sent to Health Information Management (HIM) when medical records of fewer than 50 patients are accessed.

D.3 Waiver of Consent Guidance revision

Following the existing statement: “To justify a waiver of the requirement for informed consent, you must provide a complete explanation for how each of the following items that apply to this study.” We have added a request to provide an explanation. This links to a new guidance document.
Modification Warning for pending Expiration

To prevent users from submitting a modification when a study is nearing expiration (expiring in less than 30 days), a new warning box has been added:

Study Patient Payments to Non-Resident Aliens

The incentive tag has been updated to include: “any payment provided for participation in this study may be subject to applicable tax withholding obligations.”
COI Training

COI Training has been added to the Training and COI grid:

If you hover over the training, it will show the expiration date (4 years after the date of training completion). This was required as all staff are required to complete COI Training, regardless of whether an annual COI disclosure is required (role based).

Expedited review Checklist color coding

The Expedited Checklist has been updated to better match the Stipulation Confirmation process.

Criterion Met is red, Criterion not met is green...
... and when confirmed, the criterion are blue.

5.2 Multisite Revision
Question 2 has been updated, similarly to Question 1 to note that:

The Lead Site/Coordinating Center addendum is not required if you are relying on an external IRB. In the attachments section, click Lead Site/Coordinating Center addendum and select the Not Yet Available / Not Applicable checkbox.
NSI Letter Templates – Reference IDs

The Reference ID has been added to all New Safety Information (NSI) Letter templates. As multiple NSI submissions can exist per project, this should better clarify correspondence regarding a particular report.

NSI Permissions Update

NSI submissions have been revised to use the same roles as other IRBIS submissions. Access is now read-only for Research Assistant, Other, etc.
NSI Researcher-View Navigation Update

NSI Submission process from the researcher view has been revised to make navigation and routing requirements clearer. This change removes the tabs and adds a left hand navigation, similar to other IRBIS submissions.

Yellow triangles indicate where additional information is needed:

Additional improvements have been made regarding NSI Attachments and certification requirements. Additional changes are planned for the near future.

2-Step Authentication + Osprey

As a reminder, 2-Step Duo Authentication is now required for IRBIS2 as of May 30, 2018 and will be required shortly for IRBIS1.

COI for Hospital Affiliates (Osprey Risk Manager) will be displayed in IRBIS beginning on June 5, 2018. Additional details are forthcoming.