

# IRBIS changes, effective 6:00 PM, May 28, 2020

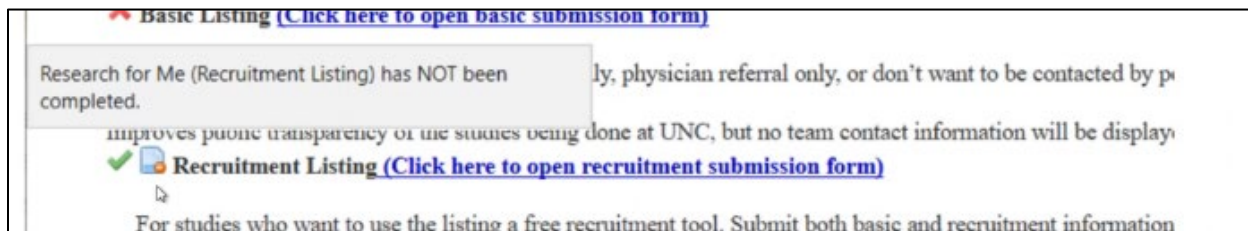
## IRBIS System Update: 6.01.07

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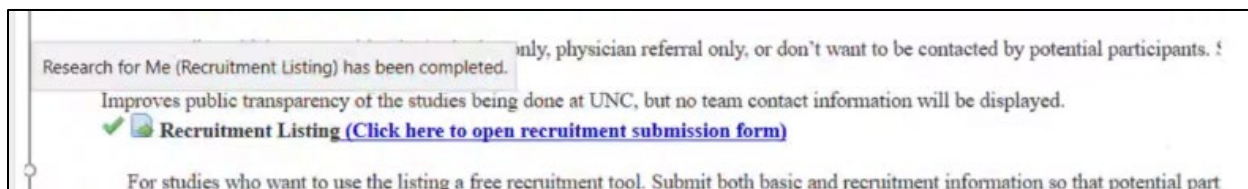
### 29824 – ADMIN – Research for Me Icon

In the admin review section, an icon will be displayed to indicate if the researcher has submitted the RedCap research for me form. Hover over text will serve as a reminder as to the icon meaning.

The form with the red x will be displayed icon will be displayed if the researchers have not yet submitted the RedCap form:



The form with the green arrow icon will be displayed if the researchers have submitted the RedCap form:



This should not be confused with the Recruitment Listing PDF Attachment, which is a required attachment if the research selects the Recruitment Listing option.

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### 30420– NSI CAPA Question Update

Revisions have been made to the NSI CAPA section:

**Update to the “Corrective Action” Header:**

Update header to “Root Cause Analysis and Corrective and Preventative Action (CAPA) Plan.”

**Update to CAPA questions:**

**E1) Root Cause Analysis:** Please identify and describe the root cause of the problem and your process for identifying the root cause (i.e., brainstorming, the 5 Whys, Flowcharting, fishbone diagrams and affinity diagrams). The root cause is the initiating, most basic cause of a problem that may or may not lead to a chain of causes or other problems. Once the root cause is identified, a CAPA plan to eliminate the root cause can be established.

**E2) Corrective and Preventative Actions:** Please provide a numbered list of any taken or planned actions to correct the problem and prevent the problem from recurring. For each action include the date(s) on which the actions were taken or are planned, and the personnel responsible for implementing each action. Note: Immediate actions to eliminate/mitigate a hazard to participants do not require prior approval but must be reported promptly.

**E3) Plan for Effectiveness Check:** Please describe your procedures for evaluating effectiveness of the CAPA plan, the personnel who are responsible for the evaluation, the timeframe for the evaluation, and your process by which the CAPA plan will be amended if it is found to be ineffective.

**Statement added after the CAPA questions:**

For additional information about completing a root cause analysis or establishing, please refer to OHRE SOP 1401: <http://ohresop.web.unc.edu/>

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### 29792– Department Level IRBIS Access NSI View

For users with the following departmental Backbone roles:

- IRB Submission Access
- IRB Submission Approver
- IRB Submission Reviewer

They are now able view NSI submissions related to projects they have access to.

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### 30446 – Research for Me Submission Form RedCap Link

If a researcher submits their IRB prior to opening the customized RedCap link for the Research for Me submission form, it is available via the submission HTML quickview.

### 30470– ADMIN – NSI Attachments, Remove View Deleted Documents

The IRBIS Admin view of NSI Attachments has been updated to remove attachments from the admin view that have been deleted by the researcher prior to certification.

### 30443 – ADMIN – Finalization Hardstop Regarding Department Approvals

Previously, OHRE staff encountered a hardstop when selecting Approved and a Departmental Approval was still pending. This has been added to Exempt.

The routing on this submission is incomplete. **Letters cannot be created until routing is complete.** Please review the Submission Routing History within [View Routing](#) in the Options menu to view what PI/FA certifications and/or department approvals are needed.

This scenario sometimes occurs if the department had been updated during response to stipulations.

### 30131 – Current Study Personnel Explanatory Text

On the IRB study management screen, when you click the Current Study Personnel link, a new text box has been added to the pop-up window which clarifies the information displayed in the personnel table below:

The screenshot shows the IRB Study Management interface. A pop-up window titled "Current Personnel for IRB Number 16-1465" is displayed. The pop-up contains the following text:

This table represents the **most recently approved** version of the study staff at the time the study was last approved.

To monitor the CITI training or COI status of a **current or prior personnel change request**, click the submission reference ID, and then click the Personnel tab on the Application Status screen.

Below the text is a table titled "Training and Conflict of Interest entered for this Submission" for the University of North Carolina at Chapel Hill (UNC-CH). The table has the following columns: Full Name, Credentials/Role, Department Name, IRB Training, GCP, COI Training, COI Number, Initial COI Disclosure, Potential Conflict, COI Review Process, and COI Review Result.

Full Name	Credentials/Role	Department Name	IRB Training	GCP	COI Training	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
---	Principal Investigator	Orthopaedics - Sports Medicine	✓	✓	✓		✓		Completed	No Conflict
---	Study Coordinator	Orthopaedics	✓	✓	✓	1	✓		Completed	No Conflict
MD	Research Assistant	Emergency Medicine	✓	✓	✓		✓		Completed	No Conflict
---	Research Assistant	Medicine Administration - Commitments	✓	✓	✗	n/a	n/a			n/a

## CITI Training Related Updates:

To support the OHRE policy regarding the Collaborative Institutional Training Initiative (CITI Program) Human Subjects Protection (HSP) and Good Clinical Practice (GCP) as announced on February 14, 2020, the following changes have been made. Click [here](#) for more information about this policy.

### 30302 – New IRBIS Question Regarding Observational Activities

A new IRBIS questions has been added: Does your study ONLY include observational activities? This question appears following the Funding Sources, 4. Is this a Clinical Study? Question if you answer yes.

If your study is a clinical study and does not only include observational activities, CITI GCP training is required for all personnel listed on the project.

### 29975 – CITI Training Icons Update

Previously, if had not yet been completed, a red X was displayed, and a green check indicated completion. This has been expanded to the following:

- Red X = user has not completed CITI training (or is unlinked to institution)
- Red Check = user has completed CITI training requirements but is outside the three year window. Display expiration date below or via hover over
- Yellow check = user has completed CITI training requirements, but training is due to expire in the next thirty days. Display expiration date below or via hover over
- Green check = user has completed all CITI training requirements and expiration does not expire in the next thirty days. Display expiration date below or via hover over

Because expiration dates have been updated on a rolling basis (based on month and year of completion), users may have their CITI training display as valid (green check) through June 1, 2021.

Full Name	Credentials	Role	Department	IRB Training	GCP	COI Training	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
Kelley Hollowell	--	Principal Investigator	Office of Research Information Systems	✖	✖	✖	407326	20-14468	✖		Unsubmitted	Pending
	--	Co-investigator	Anesthesiology - Research	✔	✔	✔	336001	19-13371	✔		Completed	No Conflict
	--	Co-investigator	Emergency Medicine	✔	✔	✔	335992	19-13362	✔		Completed	No Conflict
	--	Study Coordinator	Anesthesiology - Research	✔	✔	✔	335996	19-13366	✔		Completed	No Conflict
	--	Study Coordinator	Anesthesiology - Research	✔	✖	✔	336000	19-13370	✔		Completed	No Conflict
	--	Study Coordinator	Anesthesiology - Research	✔	✔	✔	335994	19-13364	✔		Completed	No Conflict
	--	Study Coordinator	Anesthesiology - Research	✔	✔	✔	339930	19-17295	✔		Completed	No Conflict
	--	Study Coordinator	Anesthesiology - Research	✔	✔	✔	335998	19-13368	✔		Completed	No Conflict
	--	Study Coordinator	Anesthesiology - Research	✔	✔	✔	335999	19-13369	✔		Completed	No Conflict
	--	Study Coordinator	Anesthesiology	✔	✔	✔	335990	19-13360	✔		Completed	No Conflict
	--	Study Coordinator	Anesthesiology - Research	✔	✔	✔	335997	19-13367	✔		Completed	No Conflict
	--	Research Assistant	Anesthesiology - Research	✔	✔	✔	407433	20-14574	✖		Unsubmitted	Pending

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## 30305– ADMIN – CITI Training Soft-Stop at Submission Finalization

When a submission is being finalized, if the CITI HSP or GCP training, or both, has not yet been completed, a soft-stop alert will be displayed.

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