

IRBIS changes, effective 6:00 PM, February 27, 2018

IRBIS 5.09.06 Update:

Finalized PDF view for Admin and Researchers has remove the Department and COI WebID Columns to ensure that all required information is displayed appropriately on the PDFs.

| University of North Carolina at Chapel Hill (UNC-CH) | | | | | | | |
|--|------------------------|--------------|----------------|--|--------------------|--------------------|-------------------|
| Full Name | Role | IRB Training | GCP COI Number | Initial COI Disclosure | Potential Conflict | COI Review Process | COI Review Result |
| Marcus Hannah | Principal Investigator | ✗ | ✗ 18-01449 | ✗ | | Unsubmitted | |
| ★ Laura Cowan | Co-investigator | ✓ | ✓ 18-01460 | ✓ | | Completed | No Conflict |
| Kelley Hollowell | Co-investigator | ✗ | ✗ 18-01448 | ✗ | | Unsubmitted | |
| 🏠 Valentine Williamson | Research Assistant | ✗ | ✗ n/a | n/a | | | n/a |
| John Slattery | Other | ✗ | ✗ n/a | n/a | | | n/a |
| UNC REX Healthcare | | | | | | | |
| Full Name | Role | IRB Training | GCP COI Number | Initial COI Disclosure | Potential Conflict | COI Review Process | COI Review Result |
| 🏠👤★ Caitlin Hollowell | Co-investigator | ✗ | ✗ | Responsibility of affiliate site (check Attachments for a current COI Validation Form) | | | |

The removed information will still be available via the PI view Personnel tab or the HTML QuickView.

The time of the COI disclosure is now displayed in the hover over in addition to the date of disclosure. This is available from the PI view Personnel tab or the admin Options COI/Training section.

The screenshot shows a window titled "View Training and COI" for IRB NO: 17-1325. It contains a table with columns: Full Name, Role, Department Name, IRB Training, GCP, COI WebID, COI Number, Initial COI Disclosure, Potential Conflict, COI Review Process, and COI Review Result. A tooltip is visible over the "Initial COI Disclosure" cell for Kelley Hollowell, stating "COI disclosure was submitted on 12/21/2017 at 03:10 PM".

| Full Name | Role | Department Name | IRB Training | GCP | COI WebID | COI Number | Initial COI Disclosure | Potential Conflict | COI Review Process | COI Review Result |
|------------------|------------------------|--|--------------|-----|-----------|------------|------------------------|--------------------|--------------------|-------------------|
| Marcus Hannah | Principal Investigator | Office of Research Information Systems | ✗ | ✗ | 237840 | 17-49440 | ✓ | | Completed | No Conflict |
| Kelley Hollowell | Co-investigator | Office of Research Information Systems | ✗ | ✗ | 237839 | 17-49439 | ✓ | | | |
| ★ Laura Cowan | Other | Office of Human Research Ethics | ✓ | ✓ | | n/a | n/a | | | n/a |
| John Slattery | Other | Office of Research Information Systems | ✗ | ✗ | | n/a | n/a | | | n/a |
| John Stephenson | Other | Office of Research Information Systems | ✓ | ✗ | | n/a | n/a | | | n/a |

This is useful when troubleshooting COI related issues.

The OCT Audit/Monitoring weekly report has been updated to include the PI department. This was requested by Diane Towle so that she could distinguish Network Entity specific projects.

The submission flags have been updated to include the name and date of the person who set the flag.

This is useful to know who to contact re: why the flag was set and if it can be removed. We also capture who removed the flag, but that information is not displayed.

Additional explanatory text has been added to the end of question 5.1.: The International Research Guidance and Worksheet is not required if you are relying on an external IRB. In the attachments section, click International Research Guidance and Worksheet and select the Not Yet Available / Not Applicable checkbox.

IRB and GCP training will always be displayed for Independent Investigators in the COI/Training table:

| External Institution | | | | COI Policy | | | | Assurance Letter | Management Plan | |
|-----------------------------|--------------------|------------------|--------------|----------------------------|-----------|------------|------------------------|---------------------|--------------------|-------------------|
| - University of Mississippi | | | | Policy Undetermined (edit) | | | | + | + | |
| Full Name | Role | Department Name | IRB Training | GCP | COI WebID | COI Number | Initial COI Disclosure | Potential Conflict | COI Review Process | COI Review Result |
| Eli Manning | External Site PI | | -- | -- | | | | Policy Undetermined | | |
| Michael Oher | Other | Offensive Tackle | -- | -- | | | | Policy Undetermined | | |
| - Independent Investigators | | | | | | | | | | |
| Full Name | Role | Department Name | IRB Training | GCP | COI WebID | COI Number | Initial COI Disclosure | Potential Conflict | COI Review Process | COI Review Result |
| Kevin Hart | Co-investigator | | ✗ | ✗ | 288026 | 18-00156 | ✗ | | Unsubmitted | |
| Steve Austin | Research Assistant | | ✗ | ✗ | | n/a | n/a | | | n/a |
| Bon Jovi | Research Assistant | | ✗ | ✗ | | n/a | n/a | | | n/a |

Key: Faculty | Zero Salary | Inactive Status | Hospital Employee Only | External Personnel | Liaison

Search by PI name now is working in the Waiting Triage bucket:

| Notes | Reference ID | IRB Number | Title | PI | Submission Type | Date Routing Complete | IRB | Analyst | Expiration | Chair |
|-------|--------------|------------|---|------------------|---|-----------------------|----------------|--------------|------------|------------------|
| | 184411 | 15-1109 | Pain Coping Skills Training for African Americans with Osteoarthritis | | Modification | 3/6/2017 | Non-Biomedical | Towle, Diane | 6/6/2017 | Matthews, Robert |
| | 184419 | 13-1550 | Evaluation of Youth in Transition (YIT) Initiative in Forsyth County | Duncan, Dean | Renewal | 3/6/2017 | Non-Biomedical | | 3/15/2017 | |
| | 184415 | 16-0750 | Deforestation, Conservation, and Socio-ecological impacts in Kenya: a Comparative, Multidisciplinary, Multiscalar Study | Bertalan, Margit | Renewal | 3/6/2017 | Non-Biomedical | | 4/4/2017 | |
| | 182852 | 17-0313 | Assessing the Online Services for ARS Students at UNC | Eckstrand, Tom | Initial | 3/6/2017 | Non-Biomedical | | | |
| | 183736 | 17-0610 | Corporate Social Initiative Types and Corporate Social Responsibility Communication Strategy | Kim, Seoyeon | Initial (Exempt Request) | 3/6/2017 | Non-Biomedical | | | |
| | 183098 | 15-0958 | Large-Scale Psychometric Assessment of the ECERS 3 | Early, Diane | Renewal (NHISR Request) (Data Analysis) | 3/6/2017 | Non-Biomedical | | 4/17/2017 | |
| | 183732 | 16-2663 | Multi-University Study of Student Perspectives on Campus Diversity | Ryan, Timothy | Modification (Exempt Request) | 3/6/2017 | Non-Biomedical | | | |

If the application indicates Screening Question 1 as No, and 1.A as Yes, the COI hard stop will not apply.

[The first question is whether this is RESEARCH \(click for details\)](#)

1. Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above. *

Yes No

1.A Are you using a Humanitarian Use Device (HUD), Expanded Access IND or IDE, or an Emergency use of an investigational drug or device? *

Yes No

New Macro: DOD Funded

This study is supported by DoD funding and was reviewed under additional DoD federal regulations [32CFR219] and Directive 3216.02 "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research."

New Macro - COI – Full Board

COI disclosure(s) for **[investigator(s)]** has/have not been submitted **AND/OR** COI review(s) for **[investigator(s)]** is/are pending.

Please note that if a COI determination is not yet available for review at this committee meeting, any complex Administrative

Considerations or FCOI management plans will need to be reviewed at the next available meeting.

- The status of COI disclosures can be viewed on the "Personnel" tab on the "Application Status" screen.
- Do not resubmit to the IRB until all COI disclosures are submitted **AND** the review process is **complete**.
- If there are questions about COI disclosures, contact the COI Office at (919) 843-9953 or coi@unc.edu.

Updated Letter Templates re: standalone HIPAA Authorization forms:

- Network Entity-Permission to Register
- UNC Only-Permission to Register
- Rely on External IRB

Updated NSI Letter Templates: NSI – Minor Stips via F/U report
