

# 1.27.4 Minor Configuration Release Items: September, 2026

Icons below indicate the application(s) impacted by the enhancement.



ESTR-IRB



Agreements-DUA



Data Safety



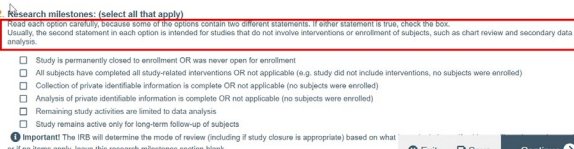
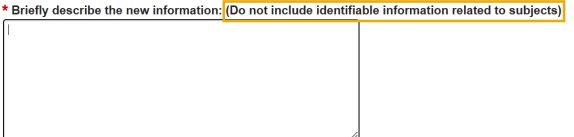
OAIR

## Cross-Suite Enhancements

| What has changed...                                                                                            | What it means...                                                                                                                                        | How it looks (as applicable) ... |
|----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| <b>Guidance Updates</b>                                                                                        |                                                                                                                                                         |                                  |
| Links to the new Research Compliance website documents have been added to the Help Section of all applications | When a user clicks on the Help Center tab, all the links to the guides now direct you to the new Research Compliance page where they can be downloaded. |                                  |

## ESTR-IRB Enhancements

| What has changed...                                                                                               | What it means...                                                                                                                                                                                                                                   | How it looks (as applicable) ...                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Notifications</b>                                                                                              |                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Send message to PI and Primary Contact when their study is added to an IRB meeting agenda                         | When an IRB study is assigned to an IRB meeting, the PI and Primary Contact receive an email notification letting them know.                                                                                                                       |  <b>HARVARD</b><br>Human Research Protection Program<br><br><b>To:</b> Carolyn Evan (Dev)<br><b>Subject:</b> Assigned to meeting<br><b>Study Link:</b> <a href="#">IRB26-0306</a><br><b>Study Title:</b> Formula 1 Testing Protocol<br><b>Principal Investigator:</b> <a href="#">Lewis Hamilton (pi)</a><br><br>This submission has been assigned to committee review.<br><br>This is an automated notification email from <a href="https://irb.harvard.edu">https://irb.harvard.edu</a> . Please do not reply to this email.<br><br><a href="#">University Area IRB</a> <a href="#">cuhs.harvard.edu</a><br><a href="#">Longwood Area IRB</a> <a href="#">hsph.harvard.edu/orarc/irb</a> |
| Faculty Sponsor was added to IRB Approval letters for protocols with student PIs (for Initial and Modifications). | When there is a study which has a student PI and a faculty sponsor on the study team, the Faculty Sponsor will be listed on the approval letter, for Initial and Modification submissions. <i>(Note: CR Letters will be added at a later time)</i> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

| What has changed...                                                                           | What it means...                                                                                                                                                                                                                                                                                                                                                                                                                                                         | How it looks (as applicable) ...                                                                                                                                                                                                                                                                                                                                                                                                                            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| SmartForm                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                             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| Tool Tip on Continuing Review SmartForm has been changed to Help Text.                        | When completing item # 2 on the Continuing Review SmartForm, there is no longer a Tool Tip associated with that question. Instead, there is Help Text which starts with “Read each option carefully...”                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                         |                                                                                                                                                                      |                                |                                                    |                                 |                                    |                                           |                                                                                                     |                                          |                            |                                            |                                                                                                               |                                        |                                                                                     |                                    |                                                                      |                                     |                                                                                                   |                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| RNI SmartForm Tool Tip language has been changed to Help Text for Item 4 per Huron’s request. | When completing an RNI, Item 4 now has helper text instead of a Tool Tip.                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                             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| Options under Q3 of the RNI SmartForm Q3 have changed per Huron’s request.                    | When completing an RNI, one will no longer see the following under question 3: <ul style="list-style-type: none"><li>• “Protocol violation that harmed subjects...”</li><li>• “VA-SAE” (For Department of Veterans Affairs research)</li></ul>                                                                                                                                                                                                                           | <div><p>“Protocol violation that harmed subjects” no longer appears as item “d”:</p><p>Information that indicates a new or increased risk, or a safety issue. For example:</p><ul style="list-style-type: none"><li>a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.</li><li>b. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or to describe a new risk.</li><li>c. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.</li><li>d. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.</li><li>e. Any changes significantly affecting the conduct of the research.</li></ul></div> <div><p>“VA-SAE” is no longer an option here:</p><table><tr><td><input type="checkbox"/> Non-compliance</td><td>Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.</td></tr><tr><td><input type="checkbox"/> Audit</td><td>Audit, inspection, or inquiry by a federal agency.</td></tr><tr><td><input type="checkbox"/> Report</td><td>Written reports of study monitors.</td></tr><tr><td><input type="checkbox"/> Researcher error</td><td>Failure to follow the protocol due to the action or inaction of the investigator or research staff.</td></tr><tr><td><input type="checkbox"/> Confidentiality</td><td>Breach of confidentiality.</td></tr><tr><td><input type="checkbox"/> Unreviewed change</td><td>Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.</td></tr><tr><td><input type="checkbox"/> Incarceration</td><td>Incarceration of a subject in a study not approved by the IRB to involve prisoners.</td></tr><tr><td><input type="checkbox"/> Complaint</td><td>Complaint of a subject that cannot be resolved by the research team.</td></tr><tr><td><input type="checkbox"/> Suspension</td><td>Premature suspension or termination of the research by the sponsor, investigator, or institution.</td></tr><tr><td><input type="checkbox"/> Unanticipated adverse device effect</td><td>Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.</td></tr></table></div> | <input type="checkbox"/> Non-compliance | Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance. | <input type="checkbox"/> Audit | Audit, inspection, or inquiry by a federal agency. | <input type="checkbox"/> Report | Written reports of study monitors. | <input type="checkbox"/> Researcher error | Failure to follow the protocol due to the action or inaction of the investigator or research staff. | <input type="checkbox"/> Confidentiality | Breach of confidentiality. | <input type="checkbox"/> Unreviewed change | Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject. | <input type="checkbox"/> Incarceration | Incarceration of a subject in a study not approved by the IRB to involve prisoners. | <input type="checkbox"/> Complaint | Complaint of a subject that cannot be resolved by the research team. | <input type="checkbox"/> Suspension | Premature suspension or termination of the research by the sponsor, investigator, or institution. | <input type="checkbox"/> Unanticipated adverse device effect | Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects. |
| <input type="checkbox"/> Non-compliance                                                       | Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                             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| <input type="checkbox"/> Audit                                                                | Audit, inspection, or inquiry by a federal agency.                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                             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| <input type="checkbox"/> Report                                                               | Written reports of study monitors.                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                             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| <input type="checkbox"/> Researcher error                                                     | Failure to follow the protocol due to the action or inaction of the investigator or research staff.                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                             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| <input type="checkbox"/> Confidentiality                                                      | Breach of confidentiality.                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                             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| <input type="checkbox"/> Unreviewed change                                                    | Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                             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| <input type="checkbox"/> Incarceration                                                        | Incarceration of a subject in a study not approved by the IRB to involve prisoners.                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                             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| <input type="checkbox"/> Complaint                                                            | Complaint of a subject that cannot be resolved by the research team.                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                             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| <input type="checkbox"/> Suspension                                                           | Premature suspension or termination of the research by the sponsor, investigator, or institution.                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                             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| <input type="checkbox"/> Unanticipated adverse device effect                                  | Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects. |                                                                                                                                                                                                                                                                                                                                                                                                                                                             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| What has changed... | What it means... | How it looks (as applicable) ... |
|---------------------|------------------|----------------------------------|
| <b>Activity</b>     |                  |                                  |

Items 1 and 2 of the Submit/Edit Pre-Review activity page have wording changes per Huron’s request.

Item 1 on the Submit/Edit Pre-Review page now includes “HIPAA” along with “OCR.” Item 2 has a checkbox which has been changed from “Cognitively impaired adults” to “Individuals with impaired decision making.”

1. **\*Regulatory oversight:** (check all that apply)

☐ DOD (Department of Defense)
☐ DOE (Department of Energy)
☐ DOJ (Department of Justice)
☐ ED (Department of Education)
☐ EPA (Environmental Protection Agency)
☐ FDA (Food and Drug Administration)
☐ GDPR (General Data Protection Regulation)
☐ HHS (Department of Health and Human Services)
☐ ICH GCP (International Center for Harmonization of Good Clinical Practice)
☐ NSF (National Science Foundation)
☒ **OCR (Office of Civil Rights)/HIPAA**
☐ VA (Department of Veterans Affairs)
☐ Other federal agency
☐ Tribal law
☐ None of the above

2. **Special determinations and waivers:** (check all that apply)

| Determination                                                                        | Related Checklist                                                        |
|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| <input type="checkbox"/> Broad consent                                               |                                                                          |
| <input type="checkbox"/> Children                                                    | HRP-416 - Checklist - Research Involving Children                        |
| <input type="checkbox"/> Children who are wards of the state                         | HRP-416 - Checklist - Research Involving Children                        |
| <input checked="" type="checkbox"/> <b>Individuals with impaired decision making</b> | HRP-417 - Checklist - Adults with Impaired Decision-Making Capacity      |
| <input type="checkbox"/> Neonates of uncertain viability                             | HRP-414 - Checklist - Research Involving Neonates of Uncertain Viability |
| <input type="checkbox"/> Nonsignificant risk device                                  | HRP-418 - Checklist - Non-Significant Risk Device                        |
| <input type="checkbox"/> Non-viable neonates                                         | HRP-413 - Checklist - Research Involving Non-Viable Neonates             |
| <input type="checkbox"/> Pregnant women                                              | HRP-412 - Checklist - Research Involving Pregnant Women                  |

### Guidance updates

The IRB Staff Admin/Reviewer-Owner guides were updated to include information about the Central Actions feature.

There is a new section in the Staff Admin/Reviewer-Owner guides which describes the Central Actions (Mass Updates) functionality and directions on how to use it.

## Agreements-DUA Enhancements

| What has changed...                                                                                  | What it means...                                                                                     | How it looks (as applicable) ...                                                                                                                                            |
|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>SmartForms</b>                                                                                    |                                                                                                      |                                                                                                                                                                             |
| Common Type Agreement (CTA) was added as an item in Question 5 of the Agreement Upload SmartForm. In | Common Type Agreement is a new agreement currently being piloted by OSP for (FAS only at this time). | <div> <div>5.</div> <div> <div> <div>✓ Common Type Agreement (FAS Only)</div> <div>Data Use Agreement</div> </div> <div>Harvard's Common Type Agreement</div> </div> </div> |

addition, two new SmartForms were created for CTA specific information.

Editing: AGR26-0023

Agreement Information

1. \* Are there any sponsored funding sources for this project? ☒ Yes ☐ No [Clear](#)

\* List any proposal, award, or ISRA, that has been submitted to a sponsored programs office (SPA, ORA, OSP, or OTD), including any federal, foundation, industry or other sponsored funding for this project:

| Project #       | Segment Status | GMAS Link  |
|-----------------|----------------|------------|
| view 8969909-01 | Not funded     | 8969909-01 |

2. If there are any other known agreements applicable to the project or this Common Type Agreement (such as any NDA, MTA, or License Agreement), please describe:

Guidance Updates

The Agreements Reviewer-Owner Guide was updated to include information about the Central Actions feature.

There is a new section in the Reviewer-Owner guide which describes the Central Actions (Mass Updates) functionality and includes directions on how to use it.

The Agreements Submission and Reviewer-Owner Guides were updated to include new language re: Common Type Agreements.

OAIR Enhancements 

| What has changed...                                                                                                                    | What it means...                                                                                  | How it looks (as applicable) ...                                                                                                                                                                                                                                                                                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>SmartForm</b>                                                                                                                       |                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                            |
| Links to the conflict-of-interest policy were fixed on the <b>What to Include</b> and <b>Assurance &amp; Certification</b> SmartForms. |                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Notifications</b>                                                                                                                   |                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                            |
| New contact information language was added to OAIR notification email footer.                                                          | The additional contact information will help prevent misdirected questions, saving everyone time. | <div>For system questions, please contact <a href="mailto:oaifhelp@stanford.edu">oaifhelp@stanford.edu</a>.<br/>For questions about disclosure requirements, reporting expectations, or the review of your certification, please contact your school or unit's OAIR/COI administrator or the <a href="#">School's COI administrator</a>.<br/>Office of the Vice Provost for Research</div> |

Safety Enhancements 

| What has changed...                                                                                                               | What it means...                                                                                                                                                                                                                                                                        | How it looks (as applicable) ...                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>SmartForm</b>                                                                                                                  |                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| In the Safety Changes section of a CR/Amendment, item #2 is now a required field.                                                 |                                                                                                                                                                                                                                                                                         | <div>Editing: AMCR25-0001-01</div> <div>Safety Changes</div> <div>1. * Have there been any changes with respect to the approved data safety and management submission?<br/><input type="radio"/> Yes <input checked="" type="radio"/> No <a href="#">Clear</a></div> <div>2. * Have any incidents occurred involving the data?<br/><input type="radio"/> Yes <input checked="" type="radio"/> No <a href="#">Clear</a></div>                                                                                                 |
| The dropdown menu for Question 2 on the Data Information/Data Source page has two new options and some wording changes.           | <p>The dropdown has two new items:</p> <ul style="list-style-type: none"><li>-Externally provided via DUA</li><li>-Externally provided via library license</li></ul> <p>And the previous “Externally provided” option has been changed to “Externally provided via other contract.”</p> | <div>2. * Data source: ?</div> <div><div>Combination of both internal and external</div><div>Externally provided via DUA</div><div>Externally provided via library license</div><div>Internally generated</div><div>Externally provided via other contract</div></div>                                                                                                                                                                                                                                                       |
| Language and Tool Tip have changed for Data Information/Data Source item 5 to include more detail.                                | Question 5 now includes <b>storage</b> as well as receipt of data and the Tool Tip now includes <b>notebooks</b> and clarifies that “ <b>method of transfer</b> ” is only needed if applicable.                                                                                         | <div>5. Will any of the data be stored or received via physical media such as paper, CD, or external drive?<br/><input type="radio"/> Yes <input checked="" type="radio"/> No <a href="#">Clear</a></div> <div>Will any of the data be received via physical media?<br/>For example, paper, notebook, CD, or external drive.<br/>If yes, describe the format, method of transfer (if relevant), and storage location. Provide information to consider as part of the review, including any security measures in place.</div> |
| Helper Text was added to Question 6 of the Data Information/Data Source page and wording of the conditional text box has changed. | There is new helper text that says " <b>Including contracts and licenses under negotiation.</b> " Then when one clicks “yes” the Data Provider Number dropdown field has been renamed to “ <b>Relevant ID numbers (i.e., GMAS, Provider ID, Buy2Pay, etc.)</b> ”                        | <div>6. * Do you have a contract for use of the data? (includes contracts and licenses under negotiation)<br/><input checked="" type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></div> <div>Relevant ID numbers (i.e., GMAS, Provider ID, Buy2Pay, etc.):<br/><input type="text"/></div>                                                                                                                                                                                                                    |

The DSL level descriptions on question 8 of the Data Information/Data Source SmartForm were updated.

The DSL level descriptions now align with what PrivSec has on the policy website.

8. Harvard data security level:  
For more information about Data Security Levels, [click here](#)

2

Minimal impact on university operations, research, reputation, or finances.

3

Moderate impact on university operations, research, reputation, or finances.

4

Significant impact on university operations, research, reputation, or finances.

5

Severe impact on university-wide operations, research, life safety systems, reputation, or finances.

Clear

New

A Tool Tip has been added to the Add/Edit Study Team Member page to include a definition of Data Manager.

A new Tool Tip appears on the upper left of the Add Study Team Member page, within the Protocol Team Member SmartForm with this definition to help clarify for users.

Add Study Team Member

1. Harvard study team member:  
Individuals with an HUID can be chosen here.

First Name:

Last Name:

Affiliation:

If not listed, external team member:

First Name:

Last Name:

Affiliation:

researchsafetydev.harvard.edu/Data/app/portal/HelpContent?ContentId=Co...

A Data Manager is an individual explicitly designated in writing by the Principal Investigator to act on their behalf in managing data access and compliance responsibilities within the team.

Workspace

Project Title now appears on the AM/CR project team display.

The AM/CR Project Team display table has a new column for Title.

| History Documents Contracts Data Tools & Reviews   |                 |                                    |                  |                            |                                                                                                                                 |                 |               |           |  |
|----------------------------------------------------|-----------------|------------------------------------|------------------|----------------------------|---------------------------------------------------------------------------------------------------------------------------------|-----------------|---------------|-----------|--|
| Principal Investigator - Amendment or Amendment/CR |                 |                                    |                  |                            |                                                                                                                                 |                 |               |           |  |
| PI Name                                            | LI Name         | email                              | Training Name    | Completed                  |                                                                                                                                 |                 |               |           |  |
| Curtis Herrera (dr)                                |                 |                                    |                  |                            |                                                                                                                                 |                 |               |           |  |
| Project Team - Amendment or Amendment/CR           |                 |                                    |                  |                            |                                                                                                                                 |                 |               |           |  |
| Filter by                                          | Harvard PI Name | Enter text to search               | +                | Add Filter                 | 36 Clear All                                                                                                                    |                 |               |           |  |
| Harvard PI Name                                    | Harvard LI Name | External PI Name                   | External LI Name | External Affiliation email | Rules on Study                                                                                                                  | Title           | Training Name | Completed |  |
| Lewis                                              | Hamilton (pi)   | lewis@gmail.com                    |                  |                            | Study support (does not imply data access)<br>Data Custodian<br>Can access data<br>Faculty Advisor (does not imply data access) |                 |               |           |  |
| Philip                                             | Infante         | perfuma@turnconconsultinggroup.com | Can access data  |                            |                                                                                                                                 | Consultant Name |               |           |  |