



**Office for Clinical Research  
Clinical Trial Automated System (CTAS)  
Standard Operating Procedure (SOP)**

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**SOP Title:** Completing Tasks in the CTAS  
**SOP Number:** OCR-CRSS-SOP-3.00  
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**APPROVED BY SIGNATURES:**

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| <b>Date</b>         | <b>Version</b> | <b>Description of Change</b>            | <b>Author</b>      |
|---------------------|----------------|---|--------------------|
| 3 May 2018          | 1.0            | Initial Version (1 <sup>st</sup> draft) | Chade Granderson   |
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1.0 Terminology and Acronyms

| Term                               | Definition   |
|------------------------------------|--|
| BPMS                               | Business Process Management System   |
| CRSS                               | Clinical Research Support Services   |
| CTAS                               | Clinical Trial Automated System – an application developed to assist the OCR-CRSS with improving the pre-award approval process for new, industry sponsored clinical trials (per the NIH definition) and intersects between OCR, OTT, IRB and Winship.   |
| Clinical Trials Active Study Query | Query generated weekly from the OCR log; includes all new industry sponsored clinical trials within assigned date range.   |
| Duplicate Record                   | Study with multiple records in the OCR log   |
| EPEX                               | Emory Proposal Express – an application developed to assist in budget development, electronic routing, and institution approval related to extramural funding at Emory and is a necessary accompaniment to any Grant or Contract requiring Institutional endorsement.  |
| IRB                                | Institutional Review Board   |
| Clinical Research Navigator        | Responsible for collection, upload, and management of clinical trial research data in the Clinical Trial Automated System (CTAS). Tracks and reports monthly pre-award key performance indicators, including sponsor response times, escalation reports, and exception reports. Identifies and escalates any data driven gaps, trends, system or staff problems noted in the pre-award approval process as they become evident, and coordinates and documents the management of the issues resolution process and ongoing enhancement efforts. Facilitates the generation of monthly, quarterly, and annual metrics through the CRSS Scorecard to measure the impact of services and programs. |
| OCR                                | Office for Clinical Research   |
| OSP/OTT                            | Office of Sponsored Programs/Office of Technology Transfer   |
| RAS                                | Research Administration Services   |
| SOP                                | Standard Operating Procedure   |

|         |  |
|---------|--|
| Winship | Winship Cancer Institute - a cancer research center that provides cancer diagnosis, treatment and support for cancer patients. |
|---------|--|

## 2.0 Document Purpose

The purpose of this SOP is to define the steps when completing tasks in CTAS.

## 3.0 Scope

This SOP applies to all new, industry sponsored clinical trials (per the NIH definition <https://grants.nih.gov/policy/clinical-trials/definition.htm>) submitted to the OCR via EPEX. These studies require tasks to be completed in the CTAS for real-time tracking and reporting performance metrics for all responsible departments that intersect in the pre-award process.

## 4.0 Responsibilities

The Clinical Research Navigator is responsible for completing all tasks in CTAS for facilitation and follow-up throughout the pre-award process once a week.

## 5.0 Procedures

### Step 1: Track the RAS tasks within the Work Console

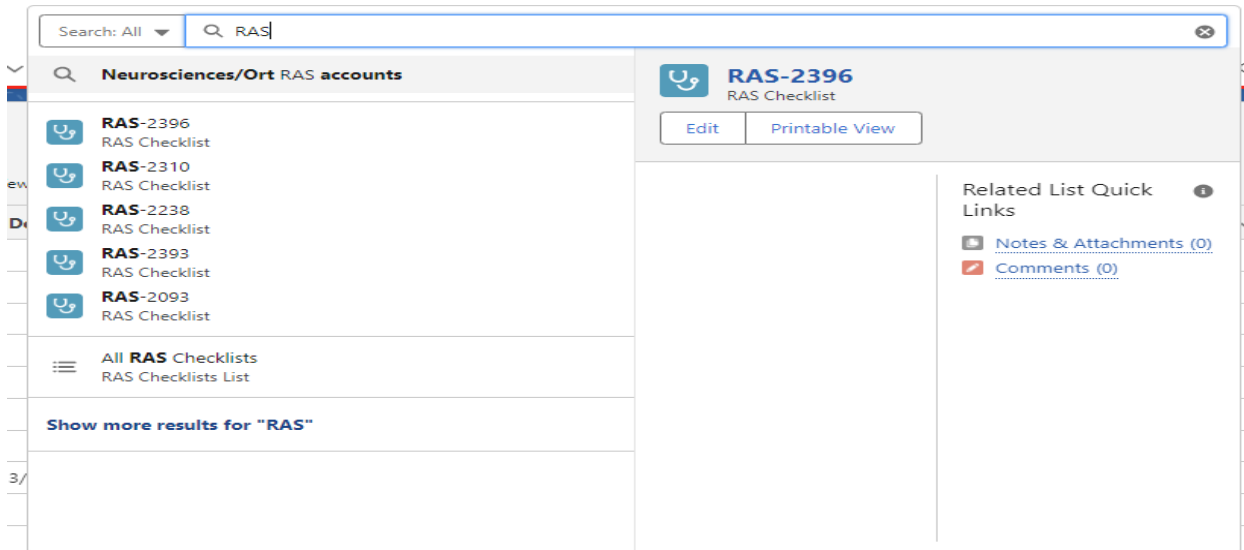
1. Access the CTAS by logging into <https://emory.lightning.force.com/> using Emory University credentials.
  - 1.1 Once logged in, Salesforce displays **all** tasks that requiring completion for each pre-award department whether in Progress or Staging

| IRB No        | Full Study Title  | Department                | Division                    | O...    | R...        | O...        | OSP...      | OTT...      | IR...     | W...        | Sc... | Fe...                               |
|---------------|---|---------------------------|-----------------------------|---------|-------------|-------------|-------------|-------------|-----------|-------------|-------|-------------------------------------|
| STUDY00005360 | Non-invasive Vagal Nerve Stimulation in Opioid Use Disorders UH3  |                           | Doss Administrative Account | Pending | Completed   | Completed   | Not Started | No Match    | Completed | Not Started | 3     | <input checked="" type="checkbox"/> |
| STUDY00005526 | The Role of Inflammation in CNS Mechanisms of Anhedonia and Psychomotor Slowing in Depressed Peo...             |                           | Doss Administrative Account | Pending | Completed   | Completed   | Not Started | No Match    | Completed | Not Started | 3     | <input checked="" type="checkbox"/> |
| STUDY00005929 | Early substitution of subcutaneous abatacept for belatacept as costimulation blockade to minimize CNI e...      | Surgery                   |                             | Pending | Completed   | Completed   | Not Started | No Match    | Completed | Not Started | 3     | <input checked="" type="checkbox"/> |
| STUDY00005301 | A Phase I/IIa Randomized, Placebo-Controlled Trial of Conserved-Mosaic T-cell Vaccine in a Regimen wit...       | Medicine                  |                             | Pending | Completed   | Completed   | Not Started | No Match    | Completed | Not Started | 3     | <input checked="" type="checkbox"/> |
| STUDY00004691 | Oral microbiome and periodontal diseases in oral HPV infection among people living with HIV                     | Gynecology and Obstetrics | Doss Administrative Account | Pending | Completed   | Completed   | Not Started | No Match    | Completed | Not Started | 3     | <input checked="" type="checkbox"/> |
| STUDY00006267 | A phase 1 clinical trial to evaluate the safety and immunogenicity of ferritin nanoparticles expressing natl... | Medicine                  |                             | Pending | Completed   | Completed   | Not Started | No Match    | Completed | Not Started | 3     | <input checked="" type="checkbox"/> |
| STUDY00001734 | The LATITUDE Study: Long-Acting Therapy to Improve Treatment Success in Daily Life - A Phase III Study...       | Medicine                  |                             | Pending | Completed   | Completed   | No Match    | Completed   | Completed | Not Started | 3     | <input checked="" type="checkbox"/> |
| STUDY00006199 | Wearable wireless vital signs monitor for high blood pressure subjects  | Medicine                  |                             | Pending | Not Started | Completed   | Not Started | No Match    | Overdue   | Not Started | 1     | <input type="checkbox"/>            |
| STUDY00005563 | Effect of Dietary Approaches to Stop Hypertension (DASH) Diet on Heart Failure Status in Older Adults           | Medicine                  |                             | Pending | Completed   | Completed   | Not Started | No Match    | Completed | Not Started | 3     | <input checked="" type="checkbox"/> |
| STUDY00005938 | The North American Therapeutics in Epidermal Necrolysis Syndrome (NATIENS) Study: A Phase III Rando...          | Surgery                   |                             | Pending | Completed   | Completed   | Not Started | No Match    | Overdue   | Not Started | 2     | <input checked="" type="checkbox"/> |
| STUDY00006303 | Checking Vitamin C After Colectomy  | Surgery                   |                             | Pending | Not Started | Completed   | Not Started | No Match    | Completed | Not Started | 2     | <input type="checkbox"/>            |
| STUDY00005873 | A Phase II Study of Ribociclib And Endocrine Treatment of Physician's Choice for Locoregional Recurrent...      |                           | Doss Administrative Account | Pending | Not Started | Completed   | No Match    | Not Started | Overdue   | Not Started | 1     | <input type="checkbox"/>            |
| STUDY00006033 | Embedding and Evaluating Multidisciplinary Diabetes Management and Continuous Glucose Monitoring...             | Medicine                  |                             | Pending | Not Started | Completed   | No Match    | Not Started | Completed | Not Started | 2     | <input type="checkbox"/>            |
| STUDY00006592 | EMBOLIC PROTECTION IN PATIENTS UNDERGOING HIGH-RISK VALVE SURGERY   | Surgery                   |                             | Pending | Completed   | Completed   | Not Started | No Match    | Overdue   | Not Started | 2     | <input checked="" type="checkbox"/> |
| STUDY00004354 | Anticoagulation in Intracerebral Hemorrhage (ICH) Survivors for Stroke Prevention and Recovery                  | Neurology                 | Doss Administrative Account | Pending | Completed   | Completed   | Not Started | No Match    | Completed | Not Started | 3     | <input checked="" type="checkbox"/> |
| STUDY00005341 | Comparison of Anti-coagulation and anti-Platelet Therapies for Intracranial Vascular Atherosclerosis            | Neurology                 | Doss Administrative Account | Pending | Completed   | Completed   | Not Started | No Match    | Completed | Not Started | 3     | <input checked="" type="checkbox"/> |
| STUDY00005725 | Prophylactic Intra-Operative Ventricular Arrhythmia Ablation in High-Risk LVAD Candidates (PIVOTAL)             | Medicine                  |                             | Pending | Completed   | Completed   | Not Started | No Match    | Completed | Not Started | 3     | <input checked="" type="checkbox"/> |
| STUDY00001988 | WE-TRUST (Workflow Optimization to Reduce Time to Endovascular Reperfusion for Ultra-fast Stroke Tre...         | Neurology                 | Doss Administrative Account | Pending | Not Started | Completed   | No Match    | Not Started | Overdue   | Not Started | 1     | <input type="checkbox"/>            |
| STUDY00006679 | A Phase I Multicenter Dose Escalation and Dose Expansion Study of Antibody-Drug Conjugate MYTX-01...            |                           | Doss Administrative Account | Pending | Not Started | Not Started | No Match    | Not Started | Overdue   | Not Started | 0     | <input type="checkbox"/>            |
| STUDY00006305 | De-Escalation of Therapy in Early-Stage TNBC Patients Who Achieve pCR After Neoadjuvant Chemothera...           |                           | Doss Administrative Account | Pending | Completed   | Completed   | Not Started | No Match    | Completed | Not Started | 3     | <input checked="" type="checkbox"/> |
| STUDY00005794 | Giving Standardized Estradiol Therapy in Transgender Women to Research Interactions with HIV Therapy...         | Medicine                  | Medicine: Infectious Dis    | Pending | Not Started | Completed   | Not Started | No Match    | Overdue   | Not Started | 1     | <input checked="" type="checkbox"/> |

- 1.2 Tasks can be tracked in the order by which a study typically follows through the Emory pre-award process: RAS, OCR, OTT, IRB, Office of Quality, and First Patient First Visit (FPFV).

2. Track RAS tasks by typing “RAS” in the search box within in CTAS.

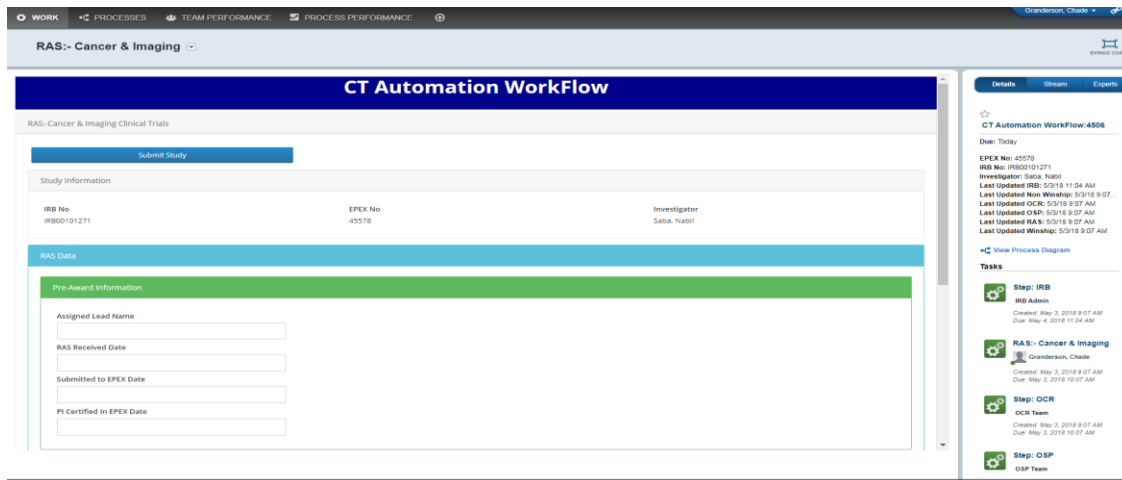
2.1 Studies that require tracking will appear as “Overdue”.



3. Click on the blue hyperlink to open a study specific RAS task page.

| <input type="checkbox"/>            | RAS Checklist Name ↑ | Status      | Department Approval Date | PI Certified in Expec Date | Overall Status | Clinical Trial | ExpecNo    | Last Modified Date  |  |
|-------------------------------------|----------------------|-------------|--------------------------|----------------------------|----------------|----------------|------------|---------------------|--|
| <input type="checkbox"/>            | RAS-1638             | Not Started |                          |                            |                |                |            | 2/22/2022, 10:53 AM |  |
| <input checked="" type="checkbox"/> | RAS-1639             | Not Started |                          |                            |                |                |            | 2/22/2022, 10:38 AM |  |
| <input type="checkbox"/>            | RAS-1650             | Not Started |                          |                            |                |                |            | 3/1/2022, 11:22 AM  |  |
| <input type="checkbox"/>            | RAS-1651             | Not Started |                          |                            |                |                |            | 3/1/2022, 11:20 AM  |  |
| <input type="checkbox"/>            | RAS-1652             | Not Started |                          |                            |                |                |            | 3/1/2022, 11:23 AM  |  |
| <input type="checkbox"/>            | RAS-1656             | Not Started |                          |                            |                |                |            | 3/1/2022, 11:24 AM  |  |
| <input type="checkbox"/>            | RAS-1711             | Not Started |                          |                            |                |                |            | 3/30/2022, 10:30 AM |  |
| <input type="checkbox"/>            | RAS-1725             | Pending     | 3/30/2022                | 3/28/2022                  | Completed      | CT-00001734    | 0000068068 | 2/8/2023, 6:13 PM   |  |
| <input type="checkbox"/>            | RAS-1726             | Not Started |                          |                            |                |                |            | 4/25/2022, 12:29 PM |  |
| <input type="checkbox"/>            | RAS-1729             | Not Started |                          |                            | Completed      | CT-00001738    |            | 4/5/2022, 6:11 PM   |  |
| <input type="checkbox"/>            | RAS-1730             | Pending     | 9/17/2020                | 9/17/2020                  | Completed      | CT-00001739    | 0000059868 | 2/8/2023, 5:54 PM   |  |
| <input type="checkbox"/>            | RAS-1731             | Not Started |                          |                            | Completed      | CT-00001740    |            | 4/6/2022, 5:27 PM   |  |
| <input type="checkbox"/>            | RAS-1732             | Not Started |                          |                            |                |                |            | 4/25/2022, 12:48 PM |  |
| <input type="checkbox"/>            | RAS-1733             | Pending     | 4/7/2022                 | 4/6/2022                   | Completed      | CT-00001742    | 0000068118 | 2/8/2023, 6:14 PM   |  |
| <input type="checkbox"/>            | RAS-1734             | Not Started |                          |                            |                |                |            | 4/25/2022, 12:23 PM |  |
| <input type="checkbox"/>            | RAS-1735             | Pending     | 4/13/2022                | 3/31/2022                  | Completed      | CT-00001744    | 0000068439 | 2/8/2023, 6:20 PM   |  |
| <input type="checkbox"/>            | RAS-1736             | Pending     | 3/29/2022                | 3/28/2022                  | Completed      | CT-00001745    | 0000068483 | 2/8/2023, 6:22 PM   |  |
| <input type="checkbox"/>            | RAS-1737             | Pending     | 4/12/2022                | 4/11/2022                  | Completed      | CT-00001746    | 0000068657 | 2/8/2023, 6:34 PM   |  |
| <input type="checkbox"/>            | RAS-1738             | Pending     | 4/13/2022                | 4/12/2022                  | Completed      | CT-00001747    | 0000068692 | 2/8/2023, 6:35 PM   |  |

3.1 The study specific task page will open, displaying fields requiring data entry.



3.2 The following fields will be entered in the RAS task:

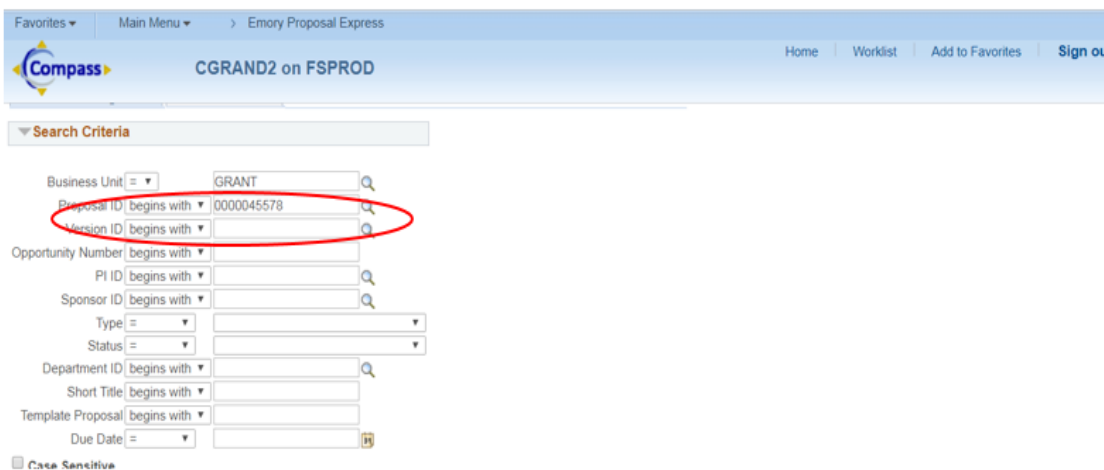
- Date Submitted to EPEX
- Date PI Certified in EPEX

This information can be found via the Emory Proposal Express (EPEX) system.

[https://compass-login.emory.edu/psc/fsprod/EMPLOYEE/ERP/c/NUI\\_FRAMEWORK.PT\\_LANDINGPAGE.GBL?httpredirect=true](https://compass-login.emory.edu/psc/fsprod/EMPLOYEE/ERP/c/NUI_FRAMEWORK.PT_LANDINGPAGE.GBL?httpredirect=true) → Emory Self Service → Emory Grants → Emory Proposal Express

4. Enter the EPEX number in the *Proposal ID* field with five preceding zeros.

4.1 Click “Search” at the bottom of the page.



4.2 The EPEX record for the specific study will open. Click “pending approval”.

**Emory Proposal Express**

Proposal ID: 0000045578      Version: V101

\*Title(82): CA2099TM:Phase 3 Study of Nivolumab(+Cisplatin) in SCCHN

Description: **Limited to 254 Characters. Use attachments if more information is needed.**  
 CA2099TM:Phase 3 Study of Nivolumab or Nivolumab plus Cisplatin, in Combination with Radiotherapy in Participants with Cisplatin Ineligible and Cisplatin Eligible Locally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN)  
 21 characters remaining

Principal Investigator: 0363971      Saba,Nabil Fawzi      \*Department: 732500      SOM: HMO: Med Onc

\*Sponsor ID: 00000648      BRISTOL MYERS SQUIBB

Sponsor Program:      Link to RFP:     

Purpose: TRIAL

\*Proposal Type: New      \*Proposal Status: **Pending Approval**

4.3 The proposal status will be displayed. This is the information that will be provided in the CTAS RAS task page.

- Date Submitted to EPEX = Most recent date of approval in the *GM Department Approval* box
- Date PI Certified in EPEX = Date the PI certified the study in the *GM Certification* box

4.3.1 Once these fields are populated with data, the *Overall Status* will be designated as “Complete” for the RAS task.

**GM Certification**

BUSINESS\_UNIT=GRANT, PROPOSAL\_ID=0000045578, VERSION\_ID=V101: **Awaiting Further Approvals**

Attributes Approval

**Certified**  
 Nabil F Saba MD/FACP  
 GM Certification  
 01/30/18 - 6:03 PM

**GM Department Approval**

BUSINESS\_UNIT=GRANT, PROPOSAL\_ID=0000045578, VERSION\_ID=V101, SUB\_PROP\_NBR=00074019, DEPTID=732500: **Awaitin**

Attributes Approval

**Approved** → **Approved** → **Approved**

Cheryl Bowie  
GM Department Approval  
01/31/18 - 7:27 AM

Jim McKay  
Inserted Approver  
01/31/18 - 11:08 PM

Sagar Lonial MD  
Inserted Approver  
02/01/18 - 2:24 AM

Comments

The screenshot shows the top section of the RAS interface. At the top left, it says "RAS:- Cancer & Imaging" with a dropdown arrow. Below this, there are two input fields: "Submitted to EPEX Date" with the value "02/02/2018" and "PI Certified In EPEX Date" with the value "01/30/2018". Below these is a green bar labeled "OverAll Status". Underneath that is a "Status" dropdown menu currently set to "Completed". On the right side, there are tabs for "Details", "Stream", and "Experts". Below the tabs, there is a list of update times: "Last Updated Non Winship: 5/3/18 9:07...", "Last Updated OCR: 5/3/18 9:07 AM", "Last Updated OSP: 5/3/18 9:07 AM", "Last Updated RA S: 5/3/18 9:07 AM", and "Last Updated Winship: 5/3/18 9:07 AM". Below this is a "View Process Diagram" link. Under the "Tasks" section, there is a task titled "Step: IRB" by "IRB Admin", with creation and due dates: "Created: May 3, 2018 9:07 AM" and "Due: May 4, 2018 11:04 AM".

4.3.2 If there is no information to populate both of these fields, the *Overall Status* will be designated as “Active” and the task “saved for later”.

This screenshot shows the middle section of the RAS interface. It features a "Comments History" table with columns for "Comments", "User", and "Send As Email". Below the table is a green "Add New Comments" button with a left-pointing arrow. At the bottom of this section are two blue buttons: "Submit Study" and "Save For Later". The "Save For Later" button is circled in red.

4.4 Click “Submit”. The task will now be removed from the RAS task queue. The task will remain in the queue until the “Overall Status” is complete and the record is submitted.

This screenshot shows the same middle section of the RAS interface as the previous one. The "Comments History" table and "Add New Comments" button are present. At the bottom, the "Submit Study" button is circled in red, while the "Save For Later" button is no longer circled.

5. Continue steps 2-4 until all RAS tasks have been updated and none are listed as “Overdue” in the tasks queue.

### Step 2: Track the OCR tasks within the Work Console

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1. Access the OCR log by using the following pathway:  
: Database- M:\Budget & Negotiations\OCR Study Log\OCR Study Log.mdb
2. Track OCR tasks by clicking “OCR Checklist” at the top of the CTAS Home Page.
  - 2.1 Studies that require tracking will appear as “Overdue”.
3. Click on the blue hyperlink to open a study specific OCR task page.
  - 3.1 The study specific task page will open, displaying fields requiring data entry.
  - 3.2 The following fields will be entered in the OCR task:
    - Assigned Lead Name
    - Date OCR Received
    - Date PRA sent to PI
    - Date Budget Sent to Sponsor
    - Date Completed
4. Search the IRB number in the OCR log.
5. Populate the fields in the OCR task page with the following information from the OCR log.
  - Assigned Lead Name = Project Manager
  - Date OCR Received = Submission Complete
  - Date PRA sent to PI
  - Date Budget Sent to Sponsor
  - Date Completed
  - 5.1 Once these fields are populated with data, the *Overall Status* will be designated as “Complete” for the OCR task.
  - 5.2 If there is no information to populate both of these fields, the *Overall Status* will be designated as “Active” and the task “saved for later”.
6. Click “Submit”. The task will now be removed from the OCR task queue. The task will remain in the queue until the “Overall Status” is complete and the record is submitted.
7. Continue steps 3-6 until all OCR tasks have been updated and none are listed as “Overdue” in the tasks queue.

### Step 3: Track the OSP/OTT tasks within the Work Console

1. Log into the OTT/OSP electronic tracking system (eCTS) or electronic grants tracking system (eGTS) using Emory University credentials  
<https://osp.emory.edu/resources/systems/ects.html>  
[https://orawebprod.emory.edu/shared\\_web/secured\\_apps/ora\\_electronic\\_award\\_tracking/app\\_ora\\_electronic\\_award\\_tracking\\_show.php](https://orawebprod.emory.edu/shared_web/secured_apps/ora_electronic_award_tracking/app_ora_electronic_award_tracking_show.php)

The screenshot shows the CTAS Home Page interface. At the top, there is a search bar and a navigation menu with tabs for 'Comments', 'CRSS', 'IRB Checklists', 'OCR Checklists', 'OSP- Federal Contracting Group', and 'OSP- Industry Contracting Group'. The last two tabs are circled in red. Below the navigation is a table with columns for 'Department', 'Division', and several status columns. The table lists various studies with their respective statuses.

| Study Title   | Department                | Division                    | O...    | R...        | O...      | OSP...  |
|---|---------------------------|-----------------------------|---------|-------------|-----------|---------|
| Opioid Use Disorders UH3  |                           | Doss Administrative Account | Pending | Completed   | Completed | Not Sta |
| isms of Anhedonia and Psychomotor Slowing in Depressed Peo...       |                           | Doss Administrative Account | Pending | Completed   | Completed | Not Sta |
| ept for belatacept as costimulation blockade to minimize CNI e...   | Surgery                   |                             | Pending | Completed   | Completed | Not Sta |
| olled Trial of Conserved-Mosaic T-cell Vaccine in a Regimen wit...  | Medicine                  |                             | Pending | Completed   | Completed | Not Sta |
| s in oral HPV infection among people living with HIV                | Gynecology and Obstetrics | Doss Administrative Account | Pending | Completed   | Completed | Not Sta |
| ty and immunogenicity of ferritin nanoparticles expressing nati...  | Medicine                  |                             | Pending | Completed   | Completed | Not Sta |
| y to Improve Treatment SUccess in Daily Life - A Phase III Study... | Medicine                  |                             | Pending | Completed   | Completed | No Me   |
| igh blood pressure subjects   | Medicine                  |                             | Pending | Not Started | Completed | Not Sta |
| ertension (DASH) Diet on Heart Failure Status in Older Adults       | Medicine                  |                             | Pending | Completed   | Completed | Not Sta |
| ormal Necrosis Syndrome (NATIENS) Study: A Phase III Rando...       | Surgery                   |                             | Pending | Completed   | Completed | Not Sta |
|   | Surgery                   |                             | Pending | Not Started | Completed | Not Sta |
| ine Treatment of Physician's Choice for Locoregional Recurrent ...  |                           | Doss Administrative Account | Pending | Not Started | Completed | No Me   |

2. Track OSP/OTT tasks by clicking “OSP- Federal or OSP- Industry” at the top of the CTAS Home Page.
  - 2.1 Studies that require tracking will appear as “Overdue”.
3. Click on the blue hyperlink to open a study specific OSP/OTT task page.

6 items • Updated a few seconds ago

| OSP Checklist Name |                          |
|--------------------|--------------------------|
| 1                  | <a href="#">OSP-3292</a> |
| 2                  | <a href="#">OSP-2533</a> |
| 3                  | <a href="#">OSP-3107</a> |
| 4                  | <a href="#">OSP-2781</a> |
| 5                  | <a href="#">OSP-2705</a> |
| 6                  | <a href="#">OSP-2979</a> |

| OTT Checklist Name |                          |
|--------------------|--------------------------|
| 1                  | <a href="#">OTT-2508</a> |
| 2                  | <a href="#">OTT-2220</a> |
| 3                  | <a href="#">OTT-2270</a> |
| 4                  | <a href="#">OTT-2333</a> |
| 5                  | <a href="#">OTT-2420</a> |
| 6                  | <a href="#">OTT-2211</a> |
| 7                  | <a href="#">OTT-2446</a> |
| 8                  | <a href="#">OTT-2416</a> |
| 9                  | <a href="#">OTT-2326</a> |
| 10                 | <a href="#">OTT-2299</a> |
| 11                 | <a href="#">OTT-2271</a> |
| 12                 | <a href="#">OTT-2215</a> |

3.1 The study specific task page will open, displaying fields requiring data entry.

3.2 The following fields will be entered in the OSP task:

- Assigned Lead Name

- Date OTT/OSP Received
- Date First Revision Sent
- Date Negotiations Complete
- Date CTA Sent to Sponsor
- Date Fully Executed Contract Sent to Sponsor
- Date File Sent for eNOA

4. Search the EPEX number within eCTS on the home page.

ORA Web Services - Main Menu Logout

**Contracts Tracking System**

**Welcome to Electronic Contract Tracking System (eCTS)**

Please be advised information shown below represents the status of contracts as of close of business on the previous day.

Search for contract status by typing in the Search Box (just below and to the right) any word or words from any ONE OR SEVERAL of the following search fields: **Investigator, Sponsor, School/Department, Study Title, or Status**. Words from multiple fields can be combined in a single search. Once the search results are presented click on the linked Proposal ID to display additional details.

Search Tips: Please enter any search term in the Search box. Filtering will begin immediately. Separate search terms by a space. For example to search for contracts involving Dr. Smith and Pfizer, you need only type: **smi pfi** to get meaningful results. To show only Pending contracts, type: **smi pfi pen** and the narrower results will show.

Show  entries Search:

| Proposal ID | Investigator | Title                   | Sponsor | School/Department | Status | Analyst |
|-------------|--------------|-------------------------|---------|-------------------|--------|---------|
|             |              | Longitudinal Studies of |         |                   |        |         |

5. Click the hyperlink for the proposal ID to open the record.

Show  entries Search:

| Proposal ID                | Investigator  | Title   | Sponsor                 | School/Department       | Status  | Analyst      |
|----------------------------|---------------|---|-------------------------|-------------------------|---------|--------------|
| <a href="#">0000045850</a> | Dhakar,Monica | 1042-SE-2001: A double-blind randomized, placebo controlled study to evaluate the | MARINUS PHARMACEUTICALS | SOM: Neurology: General | Pending | Jane OConnor |

Showing 1 to 1 of 1 entries (filtered from 13,126 total entries) ◀ Previous Next ▶

RESTRICTED USE NOTICE: ORA Web Services users are prohibited from storing sensitive data, such as ePHI, HIPAA, FISMA, SSN and PCI data within these Services.

6. Populate the fields in the OSP task page with the following information from eCTS.

Secure | [https://oraws2.emory.edu/snared\\_web/secure\\_apps/ct\\_apps/osp\\_electronic\\_contract\\_tracking/ects\\_ContractDetail.cfm?Proposal\\_ID=0000045850](https://oraws2.emory.edu/snared_web/secure_apps/ct_apps/osp_electronic_contract_tracking/ects_ContractDetail.cfm?Proposal_ID=0000045850)

| Proposal ID: | School/Department:         | Sponsor:                   | Title   | Status: |
|--------------|----------------------------|----------------------------|---|---------|
| 0000045850   | SOM: Neurology:<br>General | MARINUS<br>PHARMACEUTICALS | 1042-SE-2001: A double-blind randomized, placebo controlled study to evaluate the | Pending |

**IMPORTANT DATES:**

| Received by Contract Group: | First Revision Sent | Negotiations Completed | Signed Sent to Sponsor | Fully Executed | File Sent for NOA |
|-----------------------------|---------------------|------------------------|------------------------|----------------|-------------------|
| 02-22-2018                  | 03-19-2018          | 03-23-2018             |                        |                |                   |

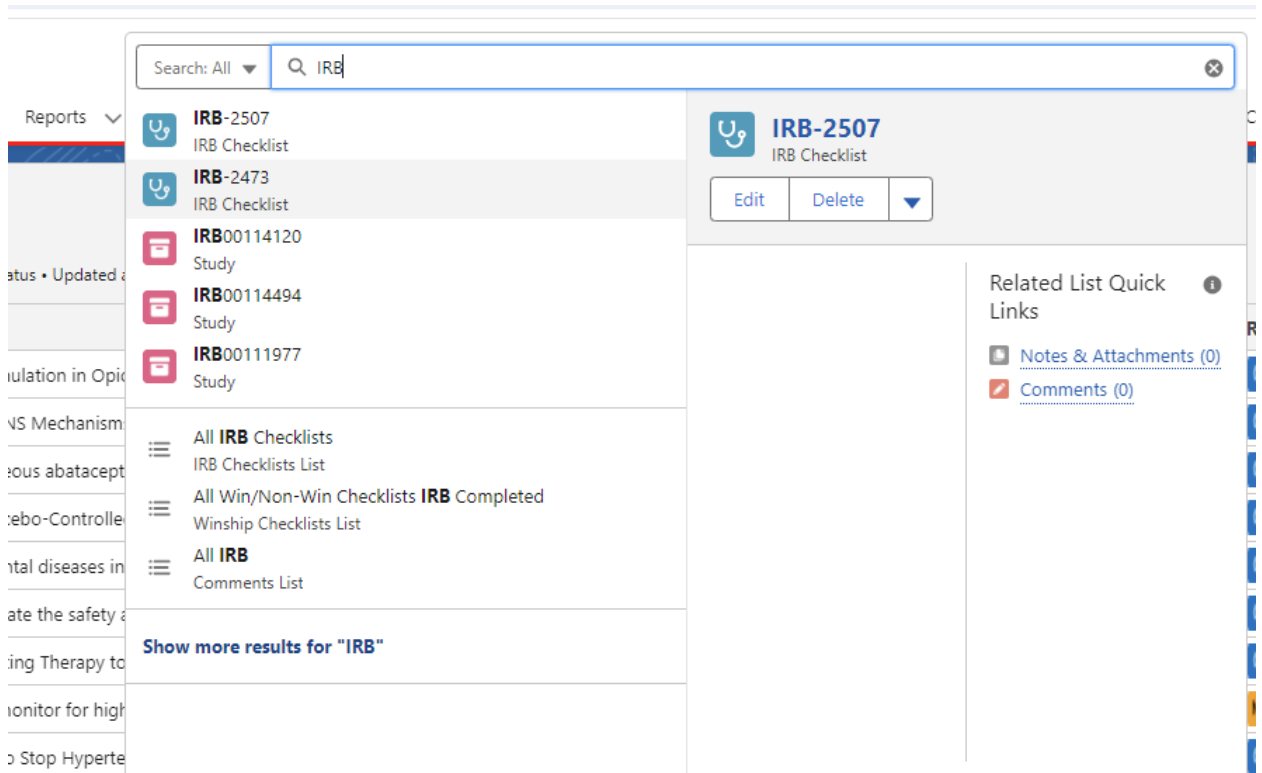
**DETAILS:**

03/01/2018: CTA uploaded in EPEX appears to be an old Emory template. Jane sent email to Tara and Alex to see if they had a copy of the sponsor CTA. Tara replied that sponsor wants to use Emory template. Jane emailed Tammie for copy of current CTA template - she will find and send to me in a day or two.  
 03/06/2018: Jane sent email to Tammie to see if she has located a current template for me to use  
 03/13/2018: Jane sent follow up email to Tammie - CTA Template located?  
 03/16/2018: Talked with Tammie - she will send me template  
 03/18/2018: Tammie provided template  
 03/19/2018: Jane sent agreement to sponsor for review.  
 03/23/2018: Sponsor made a few minor changes that were acceptable, Jane notified sponsor and instructed them to upload budget into CTA once finalized.  
 04/19/2018: Jane sent email to Tara and Alex Hall re: budget finalized, IRB approved? sponsor contact: Bonnie Dettore - bdettore@marinuspharma.com PI contact: Tara Falk Alex Hall (clinical coordinator) Rie Calcaterra - acalc01@EMORY.EDU (budget)

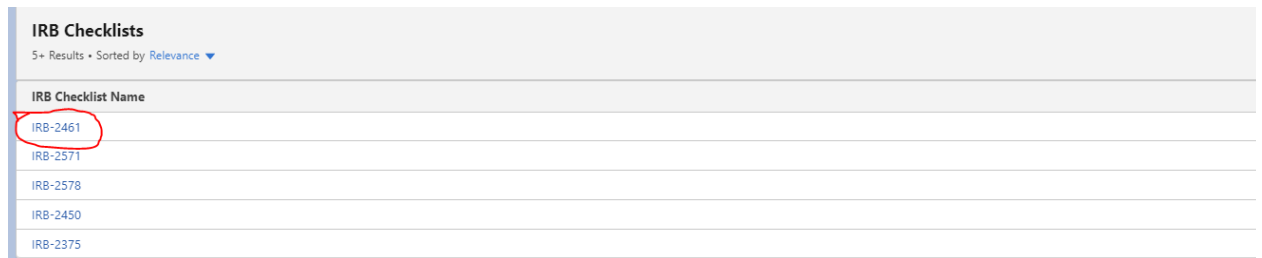
- 6.1 Once these fields are populated with data, the *Overall Status* will be designated as "Complete" for the IRB task.
- 6.2 If there is no information to populate both of these fields, the *Overall Status* will be designated as "Active" and the task "saved for later".
7. Click "Submit". The task will now be removed from the OCR task queue. The task will remain in the queue until the "Overall Status" is complete and the record is submitted.
8. Continue steps 3-7 until all OCR tasks have been updated and none are listed as "Overdue" in the tasks queue.

**Step 4: Track the IRB tasks within the Work Console**

1. Log in to eIRB  
<https://www.irb.emory.edu/index.html>
2. Track IRB tasks by typing "IRB" in the search box within CTAS.



- 2.1 Studies that require tracking will appear as “Overdue”.
3. Click on the blue hyperlink to open a study specific IRB task page.

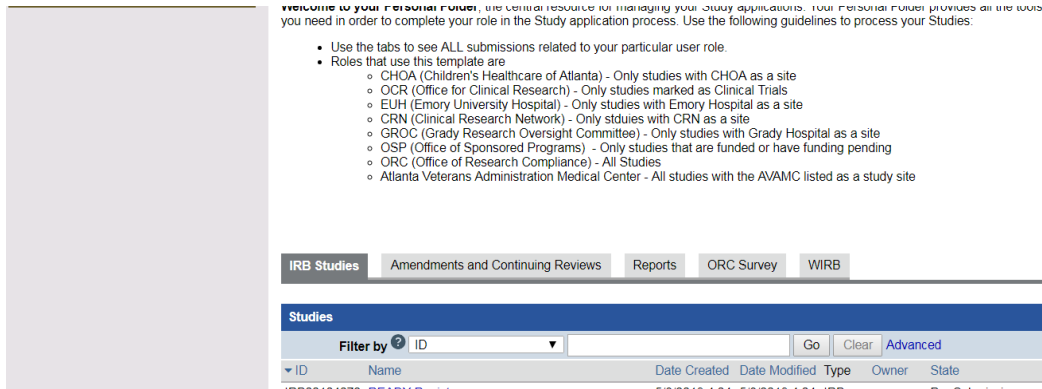


3.1 The study specific task page will open, displaying fields requiring data entry.

3.2 The following fields will be entered in the IRB task:

- Assigned Lead Name
- Internal IRB
  - Date Received in the IRB
  - Date of Full Board Review
  - Date Submitted for Contingency Review
  - Date of Final IRB Approval
- External IRB
  - Date Received in the IRB
  - Date Sent to External IRB
  - Date Final IRB Approval

4. Search the IRB number on the eIRB homepage.
  - 4.1. Click “Go”



- 4.2 Open the IRB record by clicking the study title hyperlink.

5. Populate the fields in the IRB task page with the following information from the OCR log.
  - Assigned Lead Name
  - Internal IRB
    - Date Received in the IRB = Submitted by Department date
    - Date of Full Board Review
    - Date Submitted for Contingency Review
    - Date of Final IRB Approval
  - External IRB
    - Date Received in the IRB = Submitted by Department date
    - Date Sent to External IRB = Assign to owner date
    - Date Final IRB Approval

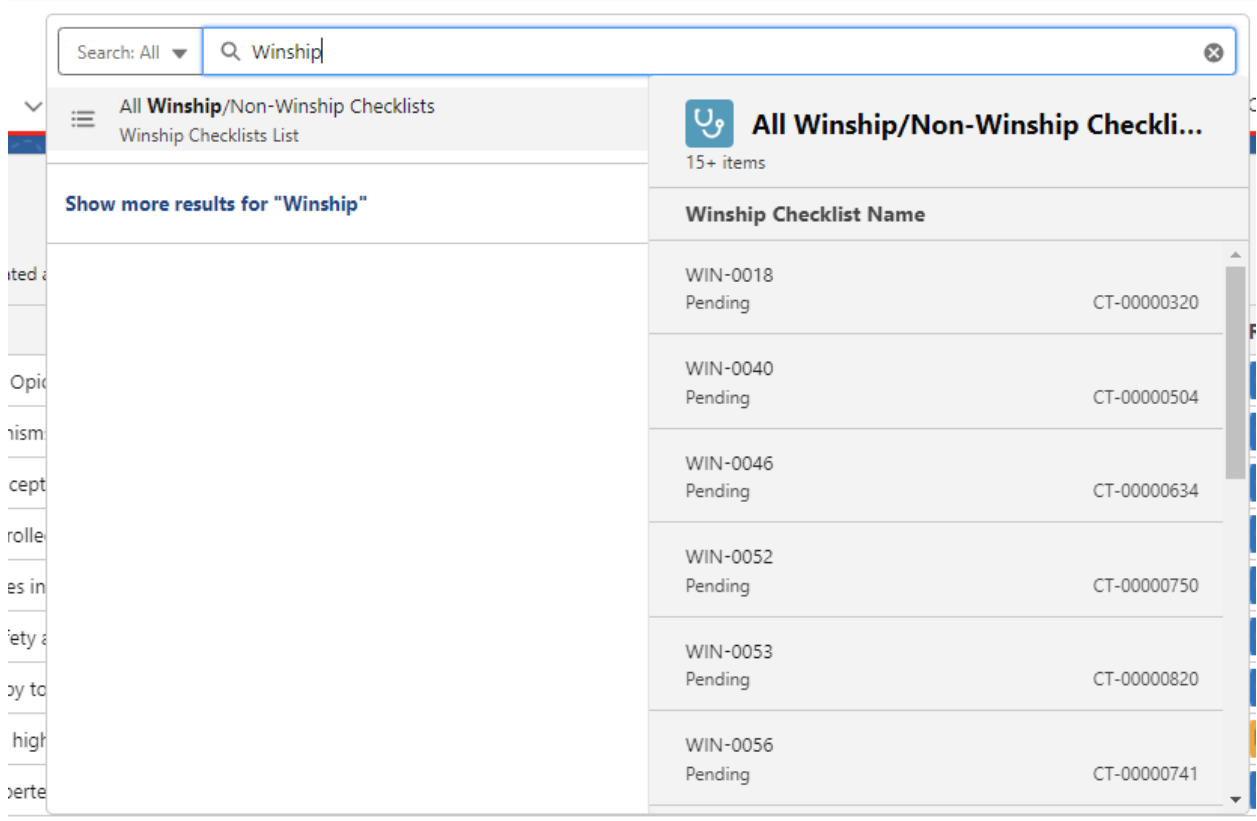
5.1 Once these fields are populated with data, the *Overall Status* will be designated as “Complete” for the IRB task.

5.2 If there is no information to populate both of these fields, the *Overall Status* will be designated as “Active” and the task “saved for later”.

6. Click “Submit”. The task will now be removed from the OCR task queue. The task will remain in the queue until the “Overall Status” is complete and the record is submitted.
7. Continue steps 3-6 until all OCR tasks have been updated and none are listed as “Overdue” in the tasks queue.

#### **Step 5: Track the Winship/Non-Winship tasks within the Work Console**

1. Track Winship/Non-Winship tasks by typing “Winship” in the search box within CTAS.



1.2 Studies that require tracking will appear as "Overdue".

\*Note both Winship and Non-Winship studies will appear in this tasks. Office of Quality milestones, Winship milestones, and First Patient First Visit (FPFV) will be tracked within the Winship tasks.

2. Click on the blue hyperlink to open a study specific Winship/Non-Winship task page.

| Winship Checklist | First Patient First | Status  | Clinical Trial | Last Modified Date | OCRStatus | RASStatus | IRBStatus | FederalStatus | IndustryStatus |
|-------------------|---------------------|---------|----------------|--------------------|-----------|-----------|-----------|---------------|----------------|
| 1 WIN-0018        |                     | Pending | CT-00000320    | 2/23/2023, 8:19 PM | Completed | Completed | Completed | NA            | Completed      |
| 2 WIN-0040        |                     | Pending | CT-00000504    | 2/23/2023, 8:24 PM | Completed | Completed | Completed | NA            | Completed      |
| 3 WIN-0046        |                     | Pending | CT-00000634    | 2/23/2023, 8:29 PM | Completed | Completed | Completed | NA            | Completed      |
| 4 WIN-0052        |                     | Pending | CT-00000750    | 2/23/2023, 8:46 PM | Completed | Completed | Completed | NA            | Completed      |
| 5 WIN-0053        |                     | Pending | CT-00000820    | 2/23/2023, 8:37 PM | Completed | Completed | Completed | NA            | Completed      |
| 6 WIN-0056        |                     | Pending | CT-00000741    | 2/23/2023, 9:49 PM | Completed | Completed | Completed | Completed     | Not Started    |
| 7 WIN-0064        |                     | Pending | CT-00000961    | 2/23/2023, 9:54 PM | Completed | Completed | Completed | Completed     | Not Started    |
| 8 WIN-0069        |                     | Pending | CT-00000940    | 2/23/2023, 8:48 PM | Completed | Completed | Completed | NA            | Completed      |
| 9 WIN-0073        |                     | Pending | CT-00000932    | 2/23/2023, 9:03 PM | Completed | Completed | Completed | NA            | Completed      |
| 10 WIN-0075       |                     | Pending | CT-00000959    | 2/23/2023, 9:52 PM | Completed | Completed | Completed | Completed     | Not Started    |
| 11 WIN-0078       |                     | Pending | CT-00001005    | 2/23/2023, 9:05 PM | Completed | Completed | Completed | NA            | Completed      |
| 12 WIN-0080       |                     | Pending | CT-00000794    | 2/23/2023, 9:50 PM | Completed | Completed | Completed | Completed     | Not Started    |
| 13 WIN-0095       |                     | Pending | CT-00000763    | 2/23/2023, 8:39 PM | Completed | Completed | Completed | NA            | Completed      |
| 14 WIN-0096       |                     | Pending | CT-00000917    | 2/23/2023, 8:57 PM | Completed | Completed | Completed | NA            | Completed      |
| 15 WIN-0123       |                     | Pending | CT-00000880    | 2/23/2023, 9:51 PM | Completed | Completed | Completed | Completed     | Not Started    |
| 16 WIN-0131       |                     | Pending | CT-00000899    | 2/23/2023, 8:51 PM | Completed | Completed | Completed | NA            | Completed      |
| 17 WIN-0140       |                     | Pending | CT-00000729    | 2/23/2023, 9:48 PM | Completed | Completed | Completed | Completed     | Not Started    |
| 18 WIN-0147       |                     | Pending | CT-00000620    | 2/23/2023, 8:30 PM | Completed | Completed | Completed | NA            | Completed      |
| 19 WIN-0157       |                     | Pending | CT-00000960    | 2/23/2023, 9:53 PM | Completed | Completed | Completed | Completed     | Not Started    |
| 20 WIN-0159       |                     | Pending | CT-00000926    | 2/23/2023, 8:56 PM | Completed | Completed | Completed | NA            | Completed      |
| 21 WIN-0161       |                     | Pending | CT-00000886    | 2/23/2023, 9:01 PM | Completed | Completed | Completed | NA            | Completed      |
| 22 WIN-0162       |                     | Pending | CT-00000971    | 2/23/2023, 8:55 PM | Completed | Completed | Completed | NA            | Completed      |

2.1 The study specific task page will open, displaying fields requiring data entry.

3. Enter the dates the studies were entered and completed in the Office of Quality database. This can be accessed via the Emory Healthcare intranet using healthcare login credentials.

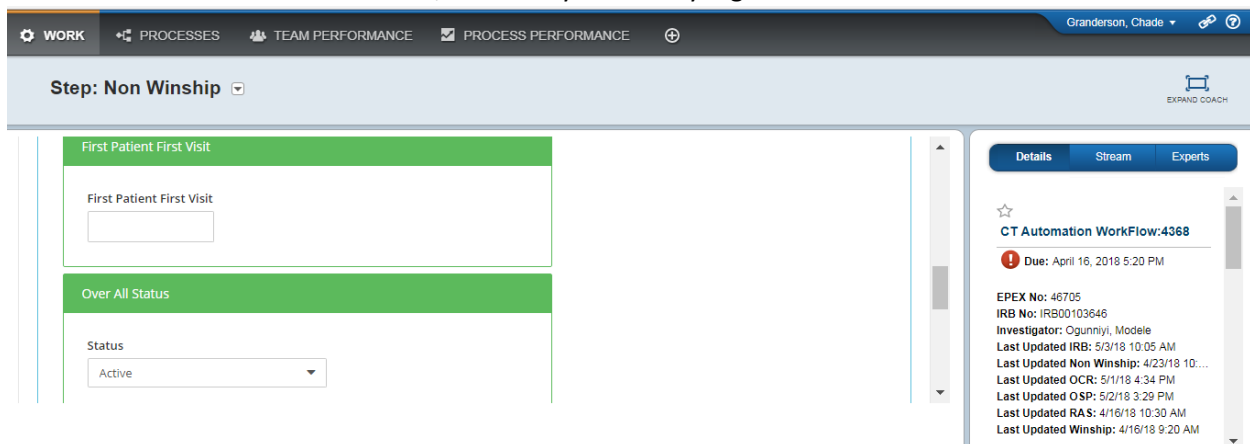
<http://ehnotes3.eushc.org/enterprise/clinicaltrialtracking.nsf/LoginForm?OpenForm>



4. Enter the date the First Patient First Visit date by information provided in the Emory Research Management System (ERMS).

<https://erms.emory.edu/>

4.1 To access ERMS, use Emory University login credentials.



4.2 Once these fields are populated with data, the *Overall Status* will be designated as “Complete” for IRB task.

4.2 If there is no information to populate both of these fields, the *Overall Status* will be designated as “Active” and the task “saved for later”.

5. Click “Submit”. The task will now be removed from the OCR task queue. The task will remain in the queue until the “Overall Status” is complete and the record is submitted.
6. Continue steps 2-5 until all OCR tasks have been updated and none are listed as “Overdue” in the tasks queue.

### **Step 6: Track the ‘Over-all’ Tasks with the CT Admin Console**

1. Click on CT Admin Console



2. Open the 'Over all' Task by clicking CT Admin

| EPEX # | IRB #       | Investigator | Department          | Study Title  | Study Type | Ras Type         | RAS       | OCR    | OSP     | IRB              | Over All | Winship NonWinship | Application no | Score |
|--------|-------------|--------------|---------------------|--|------------|------------------|-----------|--------|---------|------------------|----------|--------------------|----------------|-------|
| 43538  | IRB00098340 | Saba, Nabil  | Hematology/Oncology | A Randomized, Phase II Study Evaluating Concurrent or Sequential Fixed-Dose Pembrolizumab in Combination with Cisplatin and Intensity Modulated Radiotherapy (IMRT) in Intermediate or High Risk, Previously Untreated, Locally Advanced Head and Neck | WCI        | Cancer & Imaging | Completed | Active | Pending | IRB Staff Review | CT Admin | Active             | 183            | 1     |

3. Enter eNOA Issued Date

Note: Project details and demographics fields are pre-populated

3.1 Once these fields are populated with data, the *Overall Status* will be designated as "Complete" for the Over-all task.

### CT Admin Console

**Project Details**

EPEX Number:     IRB Number:     Type Of Study:     RAS Type:

**Demographics**

Department:     Division:     Affiliate:     Study Proposal Number:

CRO:     Sponsor:     Investigator:

Title of Study:

**Pre-Award Information**

Sponsor

CTA Sent By Sponsor:     eNOA Issued Date:

3.2 Click submit study.

|   |                      |
|---|----------------------|
| CTA Sent By Sponsor                       | eNOA Issued Date     |
| <input type="text"/>                      | <input type="text"/> |
| <b>Emory CSSR</b>                         |                      |
| PI Sent Final Protocol to Regulatory Team |                      |
| <input type="text"/>                      |                      |

**6.0 Training Log**

| By signing below, I hereby acknowledge that I have read, comprehend and agree to comply with the attached SOP/IOP. |                  |                |             |
|--|------------------|----------------|-------------|
| <u>Name</u>  | <u>Signature</u> | <u>Version</u> | <u>Date</u> |
|  |                  |                |             |
|  |                  |                |             |
|  |                  |                |             |

