An electronic forms capability is available to replace the following paper forms:

- ✓ OCR PreAward Study Submission
- ✓ (OCR) Clinical Trial Activation Only (formerly ERMS Activation)
- ✓ (OCR) Subject Tracking Only (New Form)
- ✓ (OCR) Expanded Access (New Form)
- ✓ CRKP Checklist
- ✓ EML Checklist
- ✓ Radiology Checklist

➢ Study Teams can electronically create and submit the OCR forms to OCR PreAward or CT Compliance teams to begin coverage analysis, budget development, OCR managed invoicing, and/or subject tracking for studies conducted at Emory.

➢ Ancillary CRKP, EML, and Radiology checklist forms that support Emory research can also be created and submitted to directly route to CRKP, EML, or Radiology recipients.

➢ Differences Compared to Paper Forms:

- Additional fields to provide consistency of field sets between OCR Submission form types and gauge OCR scope. Clinical Trial Activation Only, Subject Tracking Only, and Expanded Access forms contain the same field set. The OCR PreAward Study Submissions form contains additional fields that allow supporting documents to be attached, input of CRO information, and selection of protocol required items/services.

- No more emailing of paper forms. Once submitted electronically, the forms are automatically routed to the appropriate team for review and processing.

- Built-in data validation upon form submission. Required fields (each denoted with an asterisk [*]) must be filled to successfully submit. Additional fields on forms may become required as form fields are entered.

- CRKP, EML and Radiology forms are pre-filled with common data entered on the OCR Submission form to relieve Study Team members from duplicating study input across forms.

- Built-in workflow to support OCR acceptance of study submissions that includes internal routing between OCR PreAward and CT Compliance review teams, form return to the Submitter, and auto-creation of study records in OnCore.

➢ Production link - Emory Research Portal (ERP) Submissions page (Emory VPN is required):
https://erp.app.emory.edu/submissions

Please email questions and issues to OCR@emory.edu

ERP Submissions Page

The Emory Research Portal (ERP) Submissions Page is accessible with Emory credentials.
- **Shows a list of active and completed electronic forms for a Study Team member identified on the form as a PI, CRC, or DA/RA/Regulatory Specialist contact.**
    - **The Active Submissions section shows form sets* with OCR forms that have been created and Saved** (and are editable) and forms that are currently Submitted to OCR (and are not editable).**
        - ** A form set is the OCR Submission form plus ancillary CRKP, EML, and Radiology forms.*
        - *** Includes OCR forms that have not been submitted yet and OCR forms that have been submitted and returned by OCR.*
    - **The Completed Submissions to OCR section shows form sets with OCR submissions that have been Accepted or Completed by OCR.**
- **Allows the Study Team member to create, fill out, and submit electronic forms.**
    - **OCR PreAward forms are submitted to OCR PreAward.**
    - **CT Activation Only, Subject Tracking Only, and Expanded Access forms are submitted to CT Compliance.**
    - **CRKP forms are submitted to EHC Nursing.**
    - **RAD forms are submitted to Emory Radiology.**
    - **EML forms are submitted to the Emory Medical Lab.**
- **Once submitted, a PDF version of the form is available to view.**
    - **Study Teams can view the PDF by clicking the View button in the Action column in Active Submissions section on the ERP Submissions page.**
    - **Form Submission Recipients can view the PDF by clicking the attachment link in the the email notification.**
- **Once accepted by OCR, the form set will automatically move to the Completed Submissions to OCR section.**

Click to start a new or amended submission

Create Submission

Create Submission – Take the Questionnaire to Auto-select Forms (optional)

Create New Submission

The purpose of this submission is to begin an entry or update of a study in OnCore.
Important: If a study needs review to confirm the need for a coverage analysis, please email OCR@emory.edu directly to request review.

Please answer the preliminary questions below to determine the correct forms to submit **OR** click on Bypass Preliminary Questions to manually select forms.

| Preliminary Questions | Bypass Preliminary Questions |

Does your study require **development of a Coverage Analysis (CA)**?* ⓘ
Select...

Does your study require **budget/development negotiation by OCR**?* ⓘ
Select...

Does your study require **management by OCR Invoicing**?* ⓘ
Select...

Is this study being conducted or does it have a procedure/test done in an Emory Healthcare (EHC) facility?*
Select...

Does this study require special labs or labs that require special processing to be performed by the Emory Medical Laboratory (EML)?*
Select...

Does this study require services to be performed in the Emory Radiology Department?*
Select...

Cancel | Submit

Clicking Submit will set OCR Submission form and CRKP, EML, and RAD selections

Create Submission – Bypass the Questionnaire and Manually Select Forms

Select OCR Submission form.

- **OCR PreAward Study Submission**
- **CT Activation Only**
- **Subject Tracking Only**
- **Expanded Access**
- **Undetermined (to defer to OCR)**

Based on selected Submission Form, select Submission Type:

PreAward Submission Types:
- **Coverage Analysis (CA) Only**
- **CA and Budget**
- **Budget Only – PreAward**
- **Budget Only – Invoicing**
- **Undetermined (to defer to OCR)**

CT Activation Only Submission Type:
- **CT Activation Only**

Subject Tracking Only Submission Type:
- **Subject Tracking Only**

Expanded Access Submission Type:
- **Expanded Access**

Create New Submission

The purpose of this submission is to begin an entry or update of a study in OnCore.
Important: If a study needs review to confirm the need for a coverage analysis, please email OCR@emory.edu directly to request review.

Please answer the preliminary questions below to determine the correct forms to submit **OR** click on Bypass Preliminary Questions to manually select forms.

| Preliminary Questions | Bypass Preliminary Questions |

Submission Form*
Select...

Enable CRKP Form* ⓘ   Enable EML Form* ⓘ   Enable RAD Form* ⓘ
Select...   Select...   Select...

Cancel | Submit

Click Submit to continue. The selected OCR Submission form will open for editing.
(The OCR PreAward Submission form is presented if Undetermined is selected in Submission Form or Submission Type fields.)

Select ancillary CRKP, EML, and/or RAD forms to create.

- An opened form can be filled-out by selecting or entering text in the fields. Form includes guidance text to indicate required fields and any data formatting requirements.
  (Refer to form guides for more information)
- Use up and down methods on keyboard/touchpad, scroll bar, and/or click links on the vertical menu to navigate to different sections on a form.
- Use the Save button at the bottom of the form to save form updates.
- Use the Submit button when ready to submit the form to OCR.
  - Signature box must be checked to Submit a form.
  - Form will undergo validation to check if all required fields are filled in and if data is entered with the correct format. Any errors found will return on screen and will prevent submission.
- Navigate back to the Submissions List by clicking on the Submissions tab or "Submissions" breadcrumb.

Top of Page – Opened/Editable Form

Click on Submissions tab

or Submissions breadcrumb

to return to the Submissions list.

Vertical menu

Signature box must be checked to Submit a form.

Bottom of Form

Click Save or Submit action buttons on the form to save form updates or submit the form for processing.

Submissions Page – Submissions List

- **The Submissions List will show the form selections chosen for each created submission along with the appropriate action that can be taken with each form.**

Form sets are displayed with status for each form.

Interactive action buttons show when applicable based on form status.

Action Buttons and Form States

Action	Available when Status =	Description	Form(s)
Enable **Enable**	Not Enabled	CRKP, RAD, and EML forms that are not initially selected along with the OCR Submission Form selection on the Create New Submissions pop up can be enabled later from the Submissions list. Once enabled, a CRKP, RAD, or EML form status changes to Saved with an Edit button to open and fill out the form.	CRKP RAD EML
Edit **Edit**	Saved	Forms selected on the Create New Submissions pop up are saved. Study Team Members can click the Edit button to open a form, fill it out, and click the Save or Submit buttons located on the form.	OCR CRKP RAD EML
Convert **Convert**	Saved	Convert a saved OCR Submission form to a different OCR Submission form. There are 4 defined OCR Submission forms: OCR PreAward Submission, CT Activation Only, Subject Tracking Only, and Expanded Access.	OCR
Delete **Delete**	Saved	Delete/Remove an OCR Submission form and ancillary form set (CRKP, EML, RAD) from the Active Submissions section to allow users to remove/clean-up forms that have been created with no further plans to submit to OCR.	OCR
Save (on form) **Save**	Saved	Any form with a status = Saved in the Submissions list is editable. Study Team Members can click the Edit button to open a form, fill it out, and click the Save button to save form updates. The form can be saved repeatedly and will remain in a Saved status until submitted.	OCR CRKP RAD EML
Submit (on form) **Submit**	Saved	Any form with a status = Saved in the Submissions list is editable. Study Team Members can click the Edit button to open a form, fill it out, and click the Save button to save form updates. A Study Team Member can click the Submit button when a form is ready to submit, which will trigger form validation[*] and submit/route the form (and attachments if OCR PreAward submission) for processing. Submission completes when validation is successful, moving the form status to Submitted. [*]Form validation automatically occurs when a form is submitted to ensure all required fields are complete. A submission will not complete unless validation is successful, displaying errors on screen to the Submitter.	OCR CRKP RAD EML
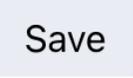
Action Buttons and Form States (continued)

Action	Available when Status =	Description	Form(s)
View **View**	Submitted	Submitted forms continue to be available in the Submissions list but are not editable. If an OCR Submission was submitted but is returned to the Submitter by OCR, the PI and the Submitter will receive an email notification and the form status will appear in a Saved state to allow a Study Team Member to make updates and resubmit to OCR.	OCR CRKP RAD EML
Create New Version Create New Version	Submitted	Submitted CRKP, RAD, and EML forms continue to be available in the Submissions list but are not editable. If a new version needs to be created and routed, the Create New Version button copies the previously submitted information into a new form that can be edited, saved, and submitted.	CRKP RAD EML
View **View**	Accepted	When an OCR Submission has been reviewed and accepted by OCR, the PI and the Submitter will receive email notification and the status of the form will change to Accepted. A status of Accepted indicates that OCR has all information to perform updates in OnCore. The submission will be available in the Completed Submissions to OCR section on a Study Team Member's ERP Submission Page.	OCR
View **View**	Completed	When OnCore updates have completed, OCR will update the submission status to Complete from the application's back end. This status change is also reflected in the Completed Submissions to OCR section on a Study Team Member's ERP Submission Page.	OCR

New/Revised Fields on OCR Forms

Field	Description
Sensitive Study	Classification determined by the IRB upon request from the study team to protect the privacy of individuals participating in clinical research while at the same time facilitating their inclusion in clinical research. A value of "Yes" serves as a flag to exclude study titles from a study participant's EeMR.
Protocol Type	Aligned with the Emory OnCore system and Indicates the type of protocol. Used for reporting purposes.
NIH Clinical Trial	A clinical trial, per the NIH definition, is a research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
Enterprise or Oncology	Determines the Reference Lists, Forms, Protocol Annotations, Notifications, and Signoffs available for the protocol. The Emory OnCore system is divided into 2 study categories: Emory Winship (all Oncology studies connected with the NCI Designated Cancer Center) and Emory Enterprise (all other studies)
Will this study be routed through the Winship Regulatory team	The Winship Regulatory team also enters studies in OnCore. Therefore, auto-creation of an OnCore record via the PreStudy Forms application is not allowed when this question is answered "Yes".
OCR Submission Type	- OCR PreAward offers 4 types of PreAward services: Coverage Analysis Only, Coverage Analysis and Budget (Creation and/or Negotiations), Budget Only for PreAward services, and Budget Only for Invoicing. Submitter can also select "Undetermined – Pending OCR Review" if unsure about the type of PreAward service that is needed. - The CT Compliance team in OCR handles 3 types of submissions: CT Activation Only, Subject Tracking Only, and Expanded Access.
Document Attachments	- Removed PI Effort Sheet (in Required Documents) - Additional document types (in Other Documents): o IDS Data Sheet o CRC/Data Manager Effort o Miscellaneous Documents
Emory IRB Approval Date	Initial IRB approval date of the study.
Target Enrollment per IRB	IRB subject approval number for enrollment. This field already existed in the CT Activation Only Submission form and was added to all other OCR Submission forms.
Use of Emory Investigational Service	Use of Emory Investigational Drug Services. This field already existed in the CT Activation Only Submission form and was added to all other OCR Submission forms.
External IRB	An IRB outside of Emory that has been chosen as the reviewing IRB for a study. This field already existed in the CT Activation Only Submission form and was added to all other OCR Submission forms.
IRB of Record	IRB performing the review on behalf of one or more institutions; also referred to as single IRB and/or central IRB.
Drug Phase	Testing stage of a clinical trial drug. Each stage/phase has a different purpose (i.e., to test safety, determine effectiveness, and identify side effects). This field already existed in the CT Activation Only Submission form and was added to all other OCR Submission forms.

Common Fields Across Forms

Specific field data entered on OCR Submission forms will carry over to ancillary CRKP, EML, and Radiology Checklist forms. If these field values are changed on the ancillary forms, the updated values will reflect on the OCR Submission form if the OCR form is in a Saved (unsubmitted) state.

OCR Form	CRKP	EML	Radiology
Protocol Title	Protocol Title		
Short Title	Brief Title		Study Title/Acronym
IRB #	IRB #	IRB #	IRB #
Principal Investigator Name	Principal Investigator Name	Principal Investigator Name	Principal Investigator Name
Principal Investigator Email	Principal Investigator Email	Principal Investigator Email	Principal Investigator Email
Principal Investigator Office Phone #	Principal Investigator Office Phone #		
Principal Investigator Cell Phone #	Principal Investigator Cell Phone #		
Principal Investigator Dept.			Principal Investigator Department
CRC Contact 1 Name	CRC Contact Name	Study Coordinator Name	
CRC Contact 1 Email		Study Coordinator Email	
CRC Contact 1 Office Phone #	CRC Contact Office Phone #		
CRC Contact 1 Cell Phone #	CRC Contact Cell Phone #		
CRC Contact 2 Name	Additional CRC Contact Name		
CRC Contact 2 Email			
CRC Contact 2 Office Phone #	Additional CRC Contact Office Phone #		
CRC Contact 2 Cell Phone #	Additional CRC Contact Cell Phone #		
Sensitive Study	Sensitive Study		

Email Notifications***

Form	Recipient	Subject Line
OCR PreAward Submission Form	OCR PreAward	A New OCR PreAward Submission Form has been submitted
	PI and Submitter	OCR PreAward Submission has been returned
	PI and Submitter	OCR Acceptance of an OCR PreAward Submission form
OCR CT Activation Only Submission Form	OCR CT Compliance	A New OCR Clinical Trials Activation Only Form has been submitted
	PI and Submitter	CT Activation Only Submission has been returned
	PI and Submitter	OCR Acceptance of an OCR Clinical Activation Only form
OCR Subject Tracking Only Submission Form	OCR CT Compliance	A New OCR Subject Tracking Only Form has been submitted
	PI and Submitter	OCR Subject Tracking Only Submission has been returned
	PI and Submitter	OCR Acceptance of an OCR Subject Tracking Only form
OCR Expanded Access Form	OCR CT Compliance	A New OCR Expanded Access Form has been submitted
	PI and Submitter	OCR Expanded Access Submission has been returned
	PI and Submitter	OCR Acceptance of an OCR Expanded Access form
Radiology Checklist	Radiology	A New RAD Request Form has been submitted
CRKP Checklist	EHC Nursing	A New CRKP Request Form has been submitted
EML Checklist	Emory Medical Lab	A New EML Request Form has been submitted

*** Additional email notifications exist but are internal to OCR.