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): <u>https://erp.app.emory.edu/submissions</u>

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.

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					No Sub	nissions Found									

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

Create New Submission		
he purpose of this submission is to begin an entry or update of a study in OnCo <u>nportant</u> : If a study needs review to confirm the need for a coverage analysis, p	ore. Jease email <u>OCR@emory.edu</u> directly to request review.	
lease answer the preliminary questions below to determine the correct forms to elect forms.	o submit OR click on <u>Bypass Preliminary Questions</u> to man	ually
Preliminary Questions	Bypass Preliminary Questions	
es your study require development of a Coverage Analysis (CA)?* 0		▼
es your study require budget/development negotiation by OCR?* 0		
es your study require management by OCR Invoicing?* 0		
his study being conducted or does it have a procedure/test done in an Emory elect	Healthcare (EHC) facility?*	
bes this study require special labs or labs that require special processing to be Select	performed by the Emory Medical Laboratory (EML)?*	
es this study require services to be performed in the Emory Radiology Depart	ment?*	· ·
Cancel Submit]	Clicking Submit will set OCR Submission form and CRKP_EML and RAD selections
ate Submission – Bypass the Question	nnaire and Manually Select	Forms Select OCR Submission form.
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OCR Clinical Research eForms

- 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	e – Opened/Editable	Form		Click on	Submissions	tab	
EMORY UN	IIVERSITY Research Portal						
Home Pro	ofile Submissions		Sharon Gray •	Home	Profile	Submissions	
Office for Clinical Research (OCR) PreAward	Home / Submissions / OCR PreAward Submiss	sion		or Subm	vissions broad	crumb	
Submission Form	Office for Clinical R	esearch (OCR) Pre	Award Submission Form	01 30011	IISSIOIIS DI Eau	crumb	
Required Documents Other Documents (if available/applicable)	The Office for Clinical Research (OCR) must rec Coverage Analysis (CA) and/or budget develop For any questions about this form or submission	eive the OCR PreAward Submission Form with all ment or negotiation. All Externally Funded studies as to OCR_email OCR@emory.edu.	fields completed and all required documents to begin the will need to have documents routed to OCR via EPEX as well.	Home / 🤇	Submissions / O	CR PreAward Submission	
Principal Investigator & Department Information	Initial or Amendment*	NIH Clinical Trial* 10 Ves No		to returr	n to the Subm	issions list.	
Clinical Research Coordinator Information	Sensitive Study* Yes No N/A Unknown	Enterprise or Oncology Study*	Will this study be routed through the Winship regulatory team?*				
Department/Research Administrator (DA/RA), RAS Information or	OCR Submission Type*		⊖ Yes ⊖ No		Office for Clinical		
Regulatory Specialist	Coverage Analysis and Budget		x ~		Research (OCR) Pre Submission Form	Award	
				Vertical	Required Docume	nts	
				menu	Other Documents available/applicabl	(if le)	
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Bottom of I	Form			Click Save form to sa form for p	or Submit act ve form upda rocessing.	ion buttons on the tes or submit the	
Submitter's Name By checking this box, you are	signing Save			Save	Submit		

OCR Clinical Research eForms General Overview

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.

	ET E	MORY UNIVERS MORY Rese Home Profile	BITY earch Po Submissions	ortal									Sharon Gray	y*
	Hor S	me / Submissions Submiss ctive Sub	sions	ns							Creat	e Submission		
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Ŀ	~		Prozonic, Jennifer L.	PSR-00242	OCR Submission	OCR Submission	Initial	Saved	06/14/2023 05:17 PM		Edit Convert	Delete		_
			Prozonic, Jennifer L.	CRKP-0000034	CRKP Form			Saved	06/14/2023 05:18 PM		Edit			Form sats are displayed
			Prozonic, Jennifer L.	EML-00029	EML Form			Saved	06/14/2023 07:04 PM		Edit			with status for each form.
			Prozonic, Jennifer L.	RAD-0000018	RAD Form			Saved	06/14/2023 07:05 PM		Edit			
	~			PSR-00236	OCR Submission	OCR Submission		Saved	06/07/2023 02:00 PM		Edit Convert	t Delete		
				CRKP-0000033	CRKP Form			Saved	06/07/2023 04:01 PM		Edit			
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										Intera	active acti	on hutt	ons ch	now when

tion buttons show v 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	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	OCR CRKP RAD EML
		ensure all required fields are complete. A submission will not complete unless validation is successful, displaying errors on screen to the Submitter.	

Action Buttons and Form States (continued)

Action	Available when Status =	Description	Form(s)
View	Submitted	Submitted forms continue to be available in the Submissions list but are not editable.	OCR CRKP RAD
View		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.	EML
Create New	Submitted	Submitted CRKP, RAD, and EML forms continue to be available in	CRKP
Version		the Submissions list but are not editable. If a new version needs to be created and routed, the Create New Version button copies the	RAD EML
Create New Version		previously submitted information into a new form that can be edited, saved, and submitted.	
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	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	Determines the Reference Lists, Forms, Protocol Annotations, Notifications,
Oncology	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	The Winship Regulatory team also enters studies in OnCore. Therefore, auto-
routed through the	creation of an OnCore record via the Prestudy Forms application is not
Winship Regulatory	allowed when this question is answered "Yes".
CCD Submission Turns	OCD Due Assend offere A trunce of Due Assend completes. Coverage Analysis
OCK Submission Type	- OCR Preaward offers 4 types of Preaward services: Coverage Analysis
	Only, Coverage Analysis and Budget (Creation and/or Negotiations), Budget Only for Dro Award convices, and Budget Only for Invoicing
	Submitter can also select "Indetermined – 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	Removed PI Effort Sheet (in Required Documents)
Attachments	- Additional document types (in Other Documents):
	 IDS Data Sheet
	 CRC/Data Manager Effort
	 Miscellaneous Documents
Emory IRB Approval	Initial IRB approval date of the study.
Date	
Target Enrollment	IRB subject approval number for enrollment. This field already existed in the
per IRB	CT Activation Only Submission form and was added to all other OCR
	Submission forms.
Use of Emory	Use of Emory Investigational Drug Services. This field already existed in the
Investigational	CT Activation Only Submission form and was added to all other OCR
Service	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	Principal Investigator	Principal Investigator	Principal Investigator
Name	Name	Name	Name
Principal Investigator	Principal Investigator	Principal Investigator	Principal Investigator
Email	Email	Email	Email
Principal Investigator	Principal Investigator		
Office Phone #	Office Phone #		
Principal Investigator	Principal Investigator		
Cell Phone #	Cell Phone #		
Principal Investigator			Principal Investigator
Dept.			Department
CRC Contact 1	CRC Contact	Study Coordinator	
Name	Name	Name	
CRC Contact 1		Study Coordinator	
Email		Email	
CRC Contact 1	CRC Contact		
Office Phone #	Office Phone #		
CRC Contact 1 Cell	CRC Contact		
Phone #	Cell Phone #		
CRC Contact 2	Additional CRC Contact		
Name	Name		
CRC Contact 2			
Email			
CRC Contact 2	Additional CRC Contact		
Office Phone #	Office Phone #		
CRC Contact 2	Additional CRC Contact		
Cell Phone #	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	OCR CT Compliance	A New OCR Clinical Trials Activation Only Form has been submitted					
Form	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	OCR CT Compliance	A New OCR Subject Tracking Only Form has been submitted					
Submission Form	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					
	Pl and Submitter	OCR Expanded Access Submission has been returned					
	Pl 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.