

**Description:** As of June 1, 2019, the Office of Clinical Research (OCR) Coverage Analysis and Budget (CAB) team attaches OCR **reviewed/approved** research billing compliance documents directly to the OnCore record for that study. These documents include, as applicable:

- OCR Billing Grid
- OCR COS
- OCR Coverage Analysis
- OCR Device Table
- OCR Drug Table
- OCR FLA
- OCR Pricing Final Professional
- OCR Pricing Final Technical
- OCR Pricing Request

There are three ways to find OCR documents that have been associated with a protocol. Each method has pros and cons:

- Document Search
- Documents/Info > Attachments/Links Tab
- Institution Documents

## DOCUMENT SEARCH

**Document Search** allows you to find documents that are associated with **active** protocols (i.e. protocols with a status of Open to Accrual, Closed to Accrual, or Suspended). It displays documents that were attached in the following locations:

- PC Console > Documents/Info > Attachments/Links (*this is where OCR attaches billing compliance documents*)
- IRB Reviews
- PRMC Reviews created via ePRMS



**Note:** Documents attached to a PRMC or IRB Review must be **Released** in order to be found by Document Search.

When searching for the latest version of a document attached to a review, Document Search returns the latest document based on the **version date**, not the document associated with the latest review in OnCore.

1. Navigate to **Menu > Protocols > Document Search**.

2. In the **Protocol No.** field, type in one of the study identifiers used at UF (see [Find Your Study](#) for details).
3. If you want to see ALL versions of the documents, select the “**Display All Documents**” checkbox. If you only want to see the **most current version** of the documents, leave this box unchecked.
4. Click [**Submit**].

Example of results with “**Display All Documents**” selected – Note that multiple versions of the Informed Consent and Billing Grid are showing:

Document Search Result							
Institution: University of Florida		Protocol No: OCR19883		Keyword:			
Investigator:		Display All Documents: Yes					
Protocol No.	Alt. Protocol No.	Short Title	Protocol Status	Document	File Name	Version Date	Description
OCR19883	AMGEN-001; EZ-AHC-005; EZ-AHC-005	EZ-AHC-005	OPEN TO ACCRUAL	Informed Consent	<a href="#">IRB_Informed_Consent_Revised_Approved.docx</a>	08/01/2018	Revision to include genetic tests
				Informed Consent	<a href="#">IRB_Informed_Consent_Approved.doc</a>	04/30/2018	Main Consent
				OCR Billing Grid	<a href="#">Billing_Grid_OCR12345_YYYY-MM-DD.xlsx</a>	07/15/2018	Billing Grid - revised
				OCR Billing Grid	<a href="#">Billing_Grid_OCR12345_YYYY-MM-DD.xlsx</a>	06/10/2018	
				OCR COS	<a href="#">COS_OCR12345_Radiology.docx</a>	06/10/2018	COS Radiology
				OCR COS IDS	<a href="#">COS_OCR12345_IDS.docx</a>	06/10/2018	
				OCR Coverage Analysis	<a href="#">MCA_OCR12345_YYY-MM-DD.pdf</a>	06/10/2018	MCAW completed by PI
				OCR Device Table	<a href="#">Device_Table_OCR12345.docx</a>	06/10/2018	
				OCR Drug Table	<a href="#">Drug_Table_OCR12345.doc</a>	06/10/2018	

Example of Document Search Result with “**Display All Documents**” **NOT** selected – Note that only the **most recent** versions of the Informed Consent and Billing Grid are showing:

Document Search Result							
Institution: University of Florida		Protocol No: OCR19883		Keyword:			
Investigator:		Display All Documents:					
Protocol No.	Alt. Protocol No.	Short Title	Protocol Status	Document	File Name	Version Date	Description
OCR19883	AMGEN-001; EZ-AHC-005; EZ-AHC-005	EZ-AHC-005	OPEN TO ACCRUAL	Informed Consent	<a href="#">IRB_Informed_Consent_Revised_Approved.docx</a>	08/01/2018	Revision to include genetic tests
				OCR Billing Grid	<a href="#">Billing_Grid_OCR12345_YYYY-MM-DD.xlsx</a>	07/15/2018	Billing Grid - revised
				OCR COS	<a href="#">COS_OCR12345_Radiology.docx</a>	06/10/2018	COS Radiology
				OCR COS IDS	<a href="#">COS_OCR12345_IDS.docx</a>	06/10/2018	
				OCR Coverage Analysis	<a href="#">MCA_OCR12345_YYY-MM-DD.pdf</a>	06/10/2018	MCAW completed by PI
				OCR Device Table	<a href="#">Device_Table_OCR12345.docx</a>	06/10/2018	
				OCR Drug Table	<a href="#">Drug_Table_OCR12345.doc</a>	06/10/2018	

**Document Search pros:**

- Displays documents that were attached in multiple places, **including consents** that the study team has attached to IRB reviews.
- Allows the user to choose to display either all versions OR just current versions of the documents.

**Document Search cons:**

- Will only display documents for active protocols – This means that you can’t see the documents OCR has attached **until the study has been opened to accrual**.

Also see the [Document Search](#) user guide.

## ATTACHMENTS/LINKS TAB

The **Attachment/Links** tab displays:

- Documents uploaded to **PC Console > Documents/Info > Attachments/Links**
- All released (**non-consent**) documents that were uploaded to an IRB review
- Any protocol documents uploaded to the **Protocol Institution > Documents** tab for the UF institution. Documents uploaded to other institutions do NOT appear on this tab.

1. Navigate to **Menu > PC Console**.
2. In the **Select Protocol** field, type in one of the study identifiers used at UF (see [Find Your Study](#) for details).
3. Click on the **Documents/Info vertical tab** and then select the **Attachments/Links** horizontal tab.

The screenshot shows the PC Console interface for protocol OCR19883. The 'Attachments/Links' tab is selected. Below the navigation tabs, there is a table of protocol attachments. The table has columns for Document Type, File Name / URL, Description, Version Date, Expiration Date, Created Date, and Created User. The 'Document Type' column is sorted by type, and the 'Version Date' column is highlighted.

Document Type	File Name / URL	Description	Version Date	Expiration Date	Created Date	Created User
Informed Consent	<a href="#">IRB_Informed_Consent_Revised_Approved.docx</a>		09/15/2018		06/10/2019	ezettler
OCR Billing Grid	<a href="#">Billing_Grid_OCR12345_YYYY-MM-DD.xlsx</a>	Billing Grid - revised	07/15/2018		06/10/2019	ezettler
OCR Billing Grid	<a href="#">Billing_Grid_OCR12345_YYYY-MM-DD.xlsx</a>		06/10/2018		06/10/2019	ezettler
OCR COS	<a href="#">COS_OCR12345_Radiology.docx</a>	COS Radiology	06/10/2018		06/10/2019	ezettler
OCR COS IDS	<a href="#">COS_OCR12345_IDS.docx</a>		06/10/2018		06/10/2019	ezettler

4. Click on the **Document Type** column header to sort the documents by type. All OCR document types begin with "OCR".
5. Find the version you are interested in by reviewing the **Version Date** then click on the blue hyperlink for the document to display it.

Attachment/Links display pros:

- Displays the documents regardless of protocol status.

Attachment/Links display cons:

- Does not allow the user to just display **current** versions of the documents.
- Display excludes **consents** that are attached to IRB reviews.



**Note:** Some study teams upload additional copies of approved consents here, but we **STRONGLY** discourage this practice, as it can cause confusion regarding consent versioning.

Any documents reviewed/approved by IRB should be uploaded and released in the [appropriate IRB review record](#).

Once the protocol is **Open to Accrual** in OnCore, we recommend that study teams use [Document Search](#) to find OCR and IRB documents.

## INSTITUTION DOCUMENTS PAGE

The **PC Console > Institution > [Institution] > Documents** page allows institution-specific documents to be recorded and uploaded. Documents defined here are available to affiliate users both from this page and through [Document Search](#).

The Institution Documents page also displays any institution-specific documents that have been uploaded in Admin > Organizations > [organization] > Attachments.

1. Navigate to **Menu > PC Console**.
2. In the **Select Protocol** field, type in one of the study identifiers used at UF (see [Find Your Study](#) for details).
3. Click on the **Institution vertical tab**.
4. Select the blue hyperlink for the institution for which you want to review documents.

★ PC Console											
Protocol No.: OCR19883		Library: Academic Health Center			PI: Zettler, Edythe, E			Sponsor: Amgen Inc.			
Protocol Target Accrual:		Accrual To Date: 2			Protocol Status: OPEN TO ACCRUAL						
RC Total Accrual Goal (Upper):		IRB Expiration: 04/30/2021									
Participating Institutions											
Select Protocol Type here to search	Institution										
Main	• Study Sites										
Treatment	University of Florida										
Institution	<ul style="list-style-type: none"> <li>• NO UF Health MRN</li> <li>• UF Jacksonville</li> <li>• UF Gainesville</li> </ul>										
Accrual	Uses Research Center IRB	IRB Initial Approval Date	IRB Last Renewal Date	IRB Next Review Date	Current Status	Status Date	Total Accrual	Pending Amendment	Expired Items	Calendar Version	
		04/30/2018	04/30/2018	04/30/2021	OPEN TO ACCRUAL	05/01/2018	2		<a href="#">Item</a>	0	

5. On the **Protocol Institution** page, select the **Documents** vertical tab.

Protocol Institution: University of Florida						
Protocol No.: OCR19883		Library: Academic Health Center		PI: Zettler, Edythe, E		Sponsor: Amgen Inc.
Protocol Target Accrual:		Accrual To Date: 2		Protocol Status: OPEN TO ACCRUAL		
RC Total Accrual Goal (Upper):		Short Title: EZ-AHC-005				
Protocol Attachments						
Staff	Document Type	File Name / URL	Description	Version Date	Expiration Date	Created Date / Created User
Regulatory Items	Informed Consent	<a href="#">IRB_Informed_Consent_Revised_Approved.docx</a>		09/15/2018		06/10/2019 ezettler
IRB Reviews	OCR Billing Grid	<a href="#">Billing_Grid_OCR12345_YYYY-MM-DD.xlsx</a>	Billing Grid - revised	07/15/2018		06/10/2019 ezettler
	OCR Billing Grid	<a href="#">Billing_Grid_OCR12345_YYYY-MM-DD.xlsx</a>		06/10/2018		06/10/2019 ezettler
Consent Forms	OCR COS	<a href="#">COS_OCR12345_Radiology.docx</a>	COS Radiology	06/10/2018		06/10/2019 ezettler
	OCR COS IDS	<a href="#">COS_OCR12345_IDS.docx</a>		06/10/2018		06/10/2019 ezettler
Documents	OCR Coverage Analysis	<a href="#">MCA_OCR12345_YYY-MM-DD.pdf</a>	MCAW completed by PI	06/10/2018		06/10/2019 ezettler
Task Lists						

6. Click on the **Document Type** column header to sort the documents by type. All OCR document types begin with "OCR".
7. Find the version you are interested in by reviewing the **Version Date** then click on the blue hyperlink for the document to display it.

### Institution Documents pros:

- Allows you to see institution-specific documents.

### Institution Documents display cons:

- Same cons as **Attachment/Links** display.
- Involves extra navigation clicks to a screen most UF OnCore users do not use.