OnCore Calendar Requests in iLab: Study Team

Effective July 2023, the OnCore calendar ordering process has been revised with the implementation of OnCore Financials. Initial calendar requests will not generate a charge, but the cost will be incorporated into a one-time OnCore CTMS fee applied to all industry-sponsored studies invoiced upon IRB approval. There is no calendar or CTMS fees applied for Non-Industry Sponsored or Investigator-Initiated studies. A calendar amendment fee *may* apply if significant changes are necessary that require a new calendar purchase. The Study Team personnel will enter calendar requests in iLab and the OnCore Admin/Office of Research will coordinate Test Builds and billing.

Roles: Study Team Member Submitting Request (Study Team)
OnCore Admin (OC Admin)
Grants & Contracts Office CDA Reviewer (GCO Admin)
Office of Research Billing Contact (OoR Admin)

A. Initial Requests

NOTE: *Personnel must be a member of the lab for which the request is for. A list of pre-identified labs may be developed as needed. For instance, Cancer Center personnel can submit requests through the "Cancer Center CTO (MCW) Lab."*

1. Under the OnCore Calendar Requests Core, Study Team initiates a new OnCore Calendar build request in iLab using the **Request Service** button.

2. Study Team completes the OnCore Calendar Request Form:

a. Indicate if this is an **Initial** or **Amendment** build (see Amendment Instructions on page 5)

b. All initial requests must include **OnCore Protocol Number**

c. If available, include NCT Number

d. Attach a PDF-copy of the current protocol document and include the version date

e. Indicate whether the Funder is Industry-Sponsored. If the funder is Industry-Sponsored, the GCO Admin needs to review a copy of the Confidentiality Agreement:

    i. If you have a copy of the CDA, upload it at this point.

    ii. If you do not have a copy of the CDA, you must explain the lack of CDA (this may delay your calendar build).

f. If the funder is NOT Industry Sponsored, select the correct Sponsor Type.

g. If you would like to have any study coordinators notified when the test build has been completed, list their email addresses separated by semicolons:

Study coordinators to be notified that test build is complete (optional) *List email addresses separated by semicolons*	email@mcw.edu; address@mcw.edu

h. **Save the completed form**. Please note that there is <u>no cost</u> for an initial calendar build fee ($0.00). Skip over the blue rows for "Protocol Share Allowed" and "Calendar Testing."

Please save your form! ➡ ✓ save completed form 💾 save draft of form ❔

⚠ After saving your form, please submit your request to the core.

📄	Reviewing for Protocol Share	**description:** If the sponsor is for-profit, Grants & Contracts must review the CDA and approve the protocol share.	**note:** click to edit	Not Started ❔
📄	Calendar Testing	**description:** Started: Forte has completed the build of the TEST calendar. Finished: Study Team has approved final version of calendar.	**note:** click to edit	Not Started ❔

➕ add service
⚠ Please fill out any forms that are highlighted in red.

Cost

The core will review and update this projected cost. You will only be billed for completed work.

Total Projected Cost: $ [0.00]

i. Under the Payment Information section, <u>no account selection is required</u>. Under the drop down, select Please Select. Then **Submit Request to Core.**

Payment Information

You may supply the Project or General Ledger Account (optional)
Please select the payment method: ❔

%		
1	100.0 %	[Please select ▾]

100.0% Total Allocated ❔

➕ Split Charge

enter additional payment information

✓ submit request to core 💾 save draft request ✖ Cancel

j. After submitting a new request, it will appear on the "View My Requests" tab in a status of "Waiting for Core to Begin" until the OC Admin begins reviewing it.

OnCore Calendar Requests

MEDICAL COLLEGE OF WISCONSIN

ℹ **Alert!**
You're browsing this page in "Customer Test Mode"... Ready to turn it off

About Our Core | Request Services | View My Requests | Contact Us

Reload Active Requests

▼ **active requests**

Searching within **active requests**: Results in this tab are restricted by *Status* (show details)
Please use the filter panels in the left-hand menu to drill down to requests of interest. You can also save filters to custom tabs! Click here for more details.

◄ Hide Filters

▼ Keywords					
[ ] Go	Displaying 1 out of 1 result. (Page 1 of 1)				
▶ Status	**date**	**for**	**service id**	**status**	**cost**
▶ Category	▶ Sep 16 (Sep 16 2020)	AshLeigh Sanchez Admin (MCW) Lab	OCCR-AS-34 OnCore Calendar R...	Waiting for Core to Begin	$0.00 ($0.00)
▶ Labels			OnCore Protocol ID#: 888888	▶ Begin	
▶ Assigned To					
▶ Lab					

3. Study Team can monitor the progress of a request(s) anytime on the "View My Requests" tab. Once the request has been started by the OC Admin, you will notice the request go into a status of "Processing." Underneath, you will also see the status of the current milestone (for tracking work).

    a. If you have submitted a request for a non-Industry funder, skip to step 4.

    b. If you have submitted a request for an Industry-Sponsored study, you will receive an email notification sent from iLab that the milestone status has been updated to "Reviewing for Protocol Share – started"
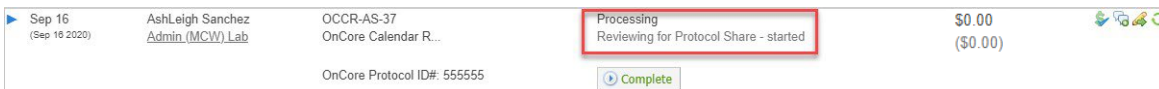
    c. The GCO Admin reviews the CDA to confirm it is acceptable to share the protocol with Advarra/BOS.

    d. If it is not acceptable, the GCO Admin will communicate necessary changes via the comment feature. Open the request using the drop-down arrows on the left and scroll down to the "Comments" section. Comments are logged on the request and sent via email notifications from iLab:
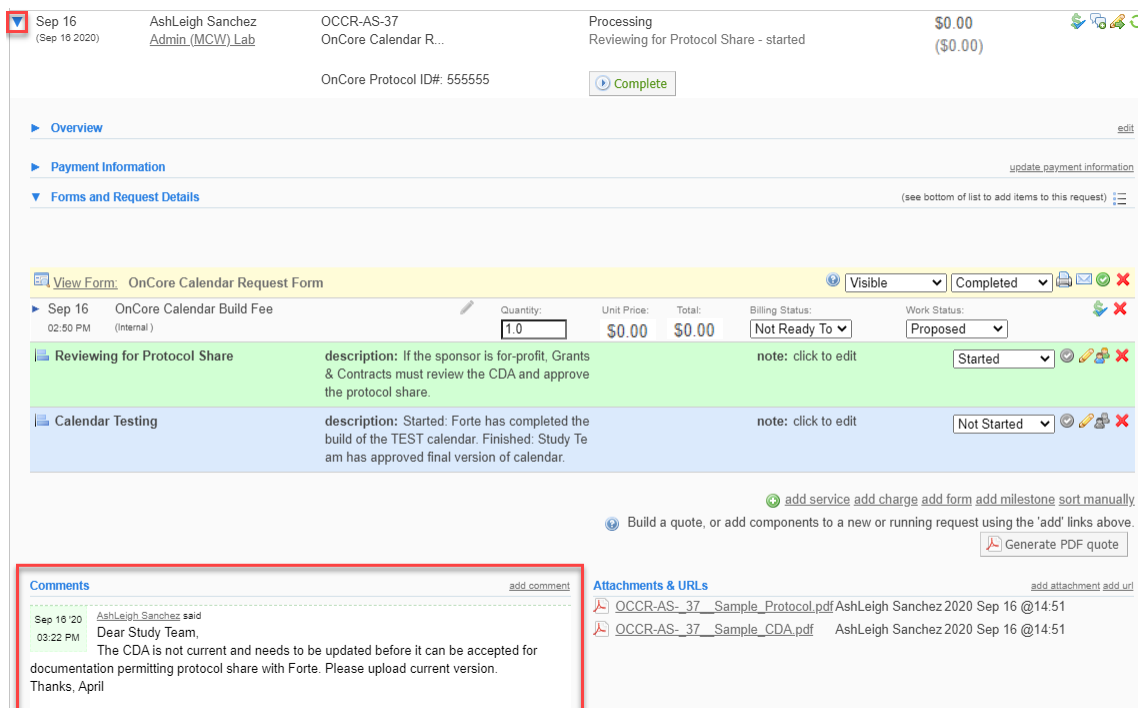
e. You can communicate updates back to GCO Admin via the Comment Feature. To upload an additional document or provide a link, use the "Attachments & URLs" section.
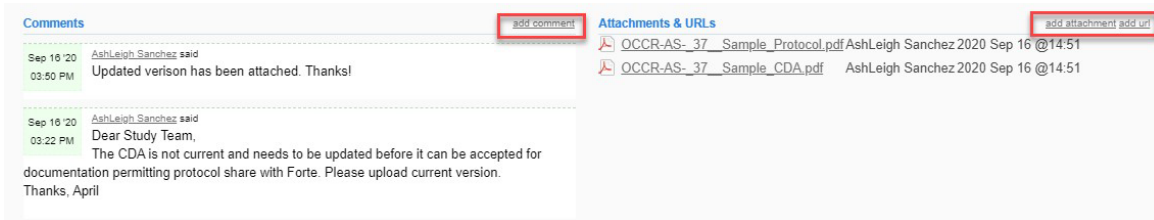

f. If/when the GCO approves the documentation in the CDA permitting the sharing of the protocol with Advarra/BOS, it will be noted in the comments section.

4. Study team will be notified via email notification from iLab that the overall request is in a status of "Processing > Reviewing for Protocol Share – finished" if the request is for a non-industry sponsor OR once the GCO admin has confirmed protocol share is approved for an Industry sponsor.
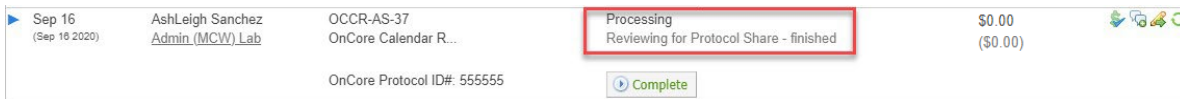
5. The OC Admin will submit the calendar build request to Advarra/BOS.

6. Once the Test Calendar has been uploaded to OnCore by the vendor, the OC Admin will initiate the testing milestone. The overall request will be updated to a status of "Calendar Testing – started" and an email notification will be sent to the study team from iLab.
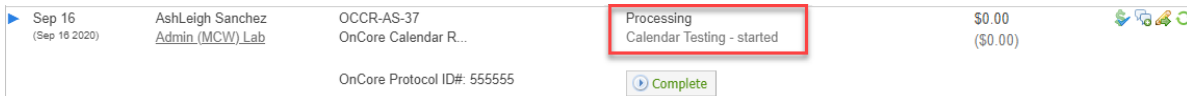
7. **The Study Team must thoroughly review the Test Calendar in OnCore within 30 days** and submit any changes to the OC Admin (this can be done via email).

8. Once the Study Team has completed testing and confirmed the final calendar, the OC Admin will mark the request complete, which will auto-finish the "Calendar Testing" milestone and close the request.
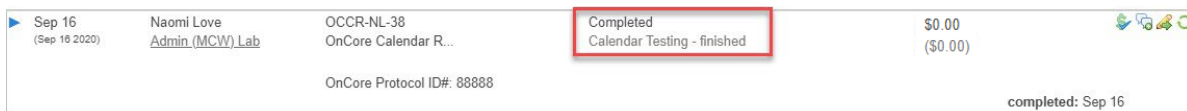
B. Calendar Amendment Requests

1. **Study Team completes the OnCore Calendar Request Form:**

   a. Indicate **Amendment** build

   b. Include **OnCore Protocol Number**

   c. If applicable, include NCT Number

   d. Upload a PDF-copy of the protocol amendment document and include the new version date

   e. Indicate if this is an Industry-Sponsored amendment

   f. For Amendments, no need to include CDA again

   g. If you would like to have any study coordinators notified when the amendment build has been completed, list their email addresses separated by semicolons

   h. Follow remaining submission process as outlined above.

★ OnCore Protocol ID# TEST-STUDY-1234

Forms and Request Details

📧 View Form: OnCore Calendar Request Form - Updated

Note: If applicable, attach a signed copy of the Confidentiality Agreement (CDA) and a copy of the protocol in order to submit your request. The Grants & Contracts Office will review your application and CDA. If approved, the Protocol will be disclosed to Forte.

★ Is this a Initial build or an Amendment build?
  ○ Initial
  ◉ Amendment

NCT Number
If applicable
[   ]

★ **Attach Protocol as a PDF**
  🔗 please upload

★ **Protocol Version Date**
Please ensure there are no pending amendments - If so, use most recent protocol version
[July 24, 2023 16:03] 📅

Is this an industry sponsored amendment?
  ◉ Yes
  ○ No
For Amendments, no need to include CDA again

Other comments?
[   ]

Study coordinators to be notified that Amendment build is complete (optional)
List email addresses separated by semicolons
[   ]

For any calendar-related questions, contact OnCore@mcw.edu.
For iLab-related questions/assistance, please contact iLab@mcw.edu.