

OnCore Required Workflow for Subject Consenting when using Florence

- In order for subjects to move to a Consented status in OnCore, and for the Reconsent Required functionality to work, a 'placeholder consent' must be associated with any review where a new/updated consent is introduced
 - The actual consent document should not be added to OnCore
- Cancer studies ONLY: in order for the ACCESS search function to work properly, protocols documents MUST still be added to the IRB Review Tab
- Navigating to the review (PC Console>select the protocol>Reviews>IRB tab
- Find the review (if pushed over from eBridge) and click the Edit hyperlink to attach the placeholder consent(s) to the review. Do NOT click the Add button – this will add a brand new review.

★ PC Console ?

Protocol No.: FLORENCE-TEST-1 Library: Oncology PI: Sponsor:

Protocol Target Accrual: N/A Accrual To Date: 0 Protocol Status: IRB INITIAL APPROVAL

RC Total Accrual Goal (Upper): N/A IRB Expiration: 08/01/2022

Select Protocol: FLORENCE-TEST-1

Summary SRC DSMC IRB LTFU Transfer Other External Committee Actions

IRB Review Reason Counts

	Amendment Review	Continuing Review	Initial Review	Other	Reportable Event
Pending	0	0	0	0	0
Total	0	0	1	0	0

IRB Action History (* denotes a global amendment)

Filter by Review Reason: [v]

Full Name	Review Date	Submit Date	IRB Committee	Review Reason	Review Type	Review No.	Action	Action Date	Expiration Date	Delete?
1.	08/02/2021	07/04/2021	IRB Committee 1	Initial Review	Full	PRO00012345	Approved	08/02/2021	08/01/2022	<input type="checkbox"/>

Don't click Add

Click Edit

- To add a document (Consent, Assent or HIPPA Authorization only from the Florence Deeplink) click the Add button
- Choose the Document Type (Name) chosen for the Deeplink (Consent 1 in this case)
- Enter the Version Date
- Enter the Description (copy/paste the Document Name from Florence)
- Click Save

Update IRB Review ?

Protocol No.: FLORENCE-TEST-1 Library: Oncology PI: Atallah, Ehab Sponsor:

Protocol Target Accrual: N/A Accrual To Date: 0 Protocol Status: OPEN TO ACCRUAL

RC Total Accrual Goal (Upper): N/A IRB Expiration:

Review Information

Review Date	<input type="text" value="09/07/2021"/>	Submit Date	<input type="text" value="09/07/2021"/>	Committee	<input type="text" value="IRB Committee 1"/>	Review Reason	<input type="text" value="Initial Review"/>	Review Type	<input type="text" value="Full"/>
Action	<input type="text" value="Approved"/>	Action Date	<input type="text" value="09/08/2021"/>	Expiration Date	<input type="text" value="09/14/2021"/>	Review No.			<input type="text" value="PRO000012345"/>

Summary

4000 character(s) remaining

Yes Votes: No Votes: Abstain Votes: Institution: Medical College of Wisconsin [Edit](#)

Details (0) Reviewers (0) Communications (0) Notes

Details

Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
<input type="text" value="Consent 1"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="09/08/2021"/>	<input type="text" value="fake consent v1 9-08-21"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text" value="Save"/> <input type="text" value="Cancel"/>

No records found

1/28/2022 [IRB Approval Notice](#) [To Meeting Agenda](#) Create Follow-Up Review Submit Submit and Close Clear ² Close

- **CONSENTS: DO NOT ADD the consent document (either File or URL) to the review tab**
- Placeholder consents must be added for each review where there is an updated consent – so add a new consent placeholder in all CPRs or any AMEs with a new consent. Ensure you use the same Document Type (name) for each consent placeholder to maintain version control. If Consent 1 was used in the Initial Review then you should always use Consent 1 as your document type for all other CPRs and AME reviews with an updated consent.
- Cancer studies ONLY: Add the protocol and upload the protocol document as a File Attachment for the ACCESS search.
- **NOTE:** The source of truth for all documents is now Florence and therefore documents should **NOT** be uploaded in OnCore.

Protocol No.: FLORENCE-TEST-1	Library: Oncology	PI: Atallah, Ehab	Sponsor:
Protocol Target Accrual: N/A	Accrual To Date: 0	Protocol Status: OPEN TO ACCRUAL	IRB Expiration: 09/14/2021
RC Total Accrual Goal (Upper): N/A			

Review Information									
Review Date	09/07/2021	Submit Date	09/07/2021	Committee	IRB Committee 1	Review Reason	Initial Review	Review Type	Full
Action	Approved	Action Date	09/08/2021	Expiration Date	09/14/2021	Review No.	PRO000012345		
Summary	<div style="border: 1px solid gray; height: 100px; width: 100%;"></div> <p>4000 character(s) remaining</p>								
Yes Votes	<input type="text"/>	No Votes	<input type="text"/>	Abstain Votes	<input type="text"/>	Institution	Medical College of Wisconsin Edit		

Details (1)	Reviewers (0)	Communications (0)	Notes
--------------------	---------------	--------------------	-------

Details										Add	Select Previous Details/Docs
Type	Amend-ment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?			
Consent 1	<input type="text"/>	<input type="text"/>	09/08/2021	fake consent v1 9-08-21	<input type="text"/>	<input type="checkbox"/>	N/A	<input type="checkbox"/>			
Attach a File or URL											

IRB Approval Notice To Meeting Agenda	Create Follow-Up Review	Submit	Submit and Close	Clear	Close
--	---	------------------------	----------------------------------	-----------------------	-----------------------