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.

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- 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 | 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

4000 character(s) remaining

| Yes Votes | | No Votes | | Abstain Votes | | Institution | Medical College of Wisconsin Edit |

Details (0) | 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	▼			09/08/2021	fake consent v1 9-08-21		☐	☐	Save Cancel

No records found

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To Meeting Agenda | Create Follow-Up Review | Submit | Submit and Close | Clear | 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

RC Total Accrual Goal (Upper): N/A   IRB Expiration: 09/14/2021

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

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Yes Votes | No Votes | Abstain Votes | 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			09/08/2021	fake consent v1 9-08-21		☐	N/A	☐

Attach a File or URL

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