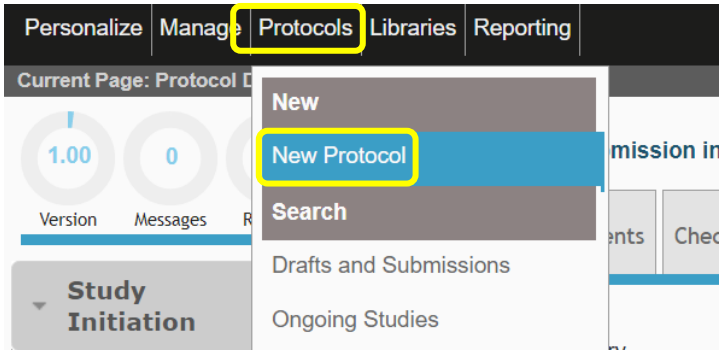
Initiating a New IRB Protocol

Is your study a prospective clinical research study? Has your study been created in Velos eResearch by the Office of Clinical Trials? If yes to 1 and no to 2, do not proceed and email your study documents to clinicaltrials@umc.edu

If yes and your study has already been created in Velos eResearch by the Office of Clinical Trials, **skip to step 4.**

If no to both, proceed to **step 1**.

1. Log into Velos eResearch (www.ummcprod.veloseresearch.com) using your UMMC credentials
2. Click on Protocols – New Protocol



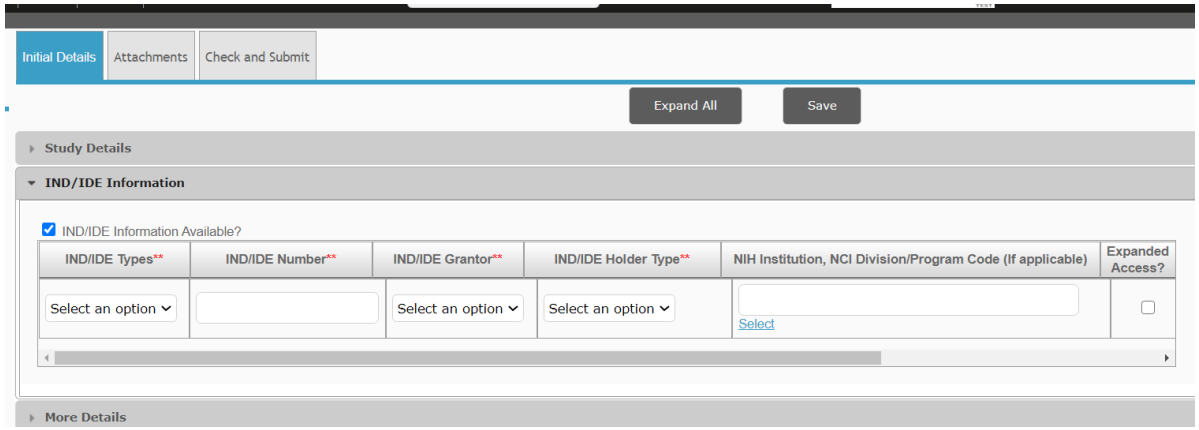
3. **Complete the Initial Details Tab.**
    a. **Study Details**
        - Study Number: [*auto-generated after saving*]
        - Title: Enter title of project
        - Study Entered By: [*auto-generated*]
        - Principal Investigator: Select user

- If Other: Enter Co-PI name *(if applicable)*
- Study Contact: Enter person who should communicate with the IRB and other regulatory/administrative offices
- PI is Major Author/Initiator of Study: Click if PI will be listed as major author on any publications or developed the protocol
- CTRP Reportable: Click if trial is supported by the National Cancer Institute (NCI)
- Primary Objective: Enter major objective of study
- Summary: Enter lay summary *[8th grade reading level]*
- NCT Number: Enter National Clinical Trial Number
- Primary Purpose: Select primary purpose of study
- Agent/Device: Enter agent/device name or number
- Department: Select PI's departments
- Therapeutic Area: Select PI's division/study area
- Disease Site: Select disease site(s) *[Optional]*
- Maximum Accrual: Enter global accrual size for entire study. Once study is saved, the local sample size can be entered.
- Study Duration: Enter duration. Can be in days, weeks, months, or years
- Duration: Select Duration Period
- Estimated Begin Date: Select date study is estimated to begin
- CCSG Data Table 4 Reportable: *[For Cancer studies only]*
- Phase: Select phase
- Study Source: Select study source *[based off sponsor]*
- Study Scope: Select scope
- Clinical Research Category: Select category
- Linked to: *[only for use by OCT]*
- Blinding: Select blinding option
- Randomization: Select randomization option
- Sponsor Type: Select sponsor type
- Sponsor Protocol Number: Enter protocol number as provided by sponsor
- Primary Contact: Enter name and email of sponsor's primary contact

- NIH Grant Information: If study is funded by NIH, provide grant/contract information
- Keywords: Insert all keywords separated by commas. Any keywords listed will be searchable using the top search bar in the Velos system.

b. IND/IDE Information

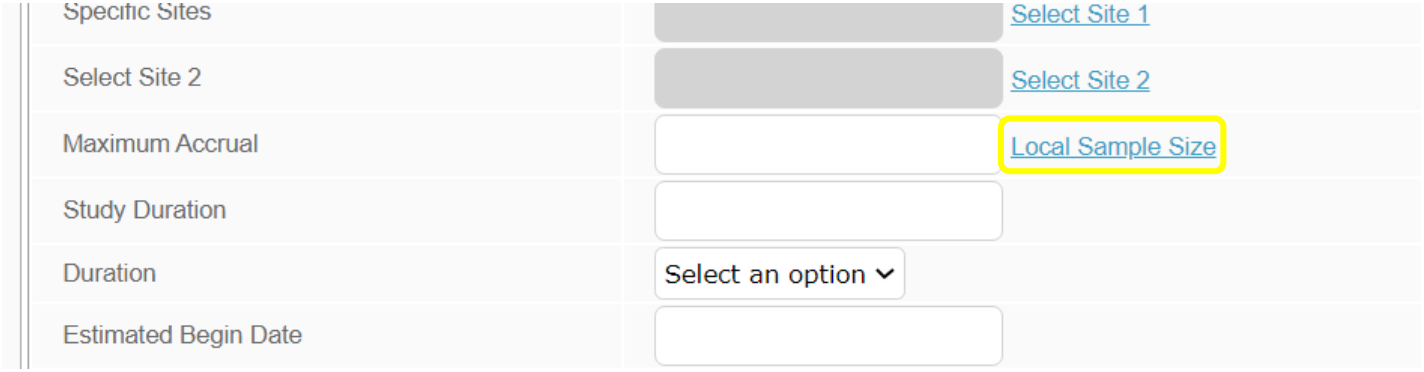
- If study includes the use of an IND/IDE, enter relevant information.

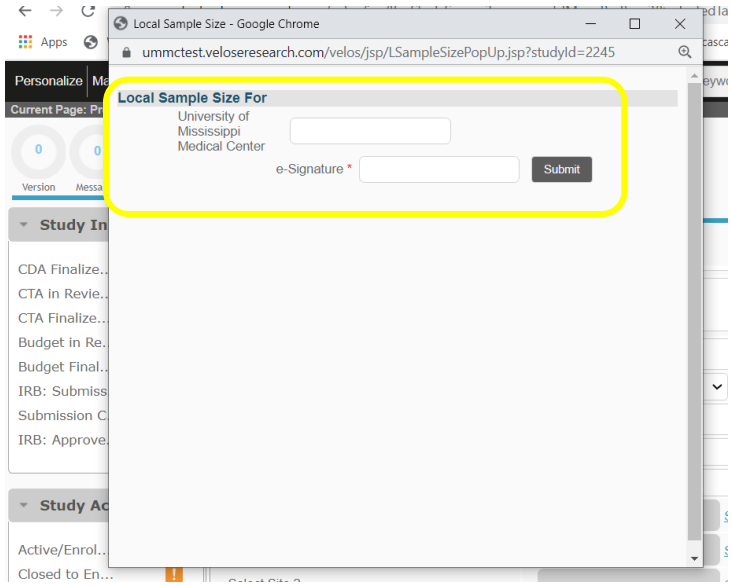


c. More Details

- UMMC IRB Number: *[only for use by the OCT]*
- External IRB Number: If study is reviewed by an external IRB, enter the IRB number
- External IRB Name: Enter external IRB name
- Coordinating Group Number: If study is funded by a cooperative group, enter the group number
- NCI Number: If study is funded by NCI, enter NCI number *[Cancer studies only]*
- SWOG Number: If study is funded by SWOG, enter SWOG number *[Cancer studies only]*
- NRG Number: If study is funded by NRG, enter NRG number *[Cancer studies only]*
- Alliance Number: If study is funded by Alliance, enter NRG number *[Cancer studies only]*
- Short Title: Enter any short titles associated with the study *[e.g., SMART]*
- Prime Sponsor Name: Select Prime Sponsor. *A prime sponsor is defined as the originating source of the project funding.*
- Prime Sponsor Type: Select Prime Sponsor Type

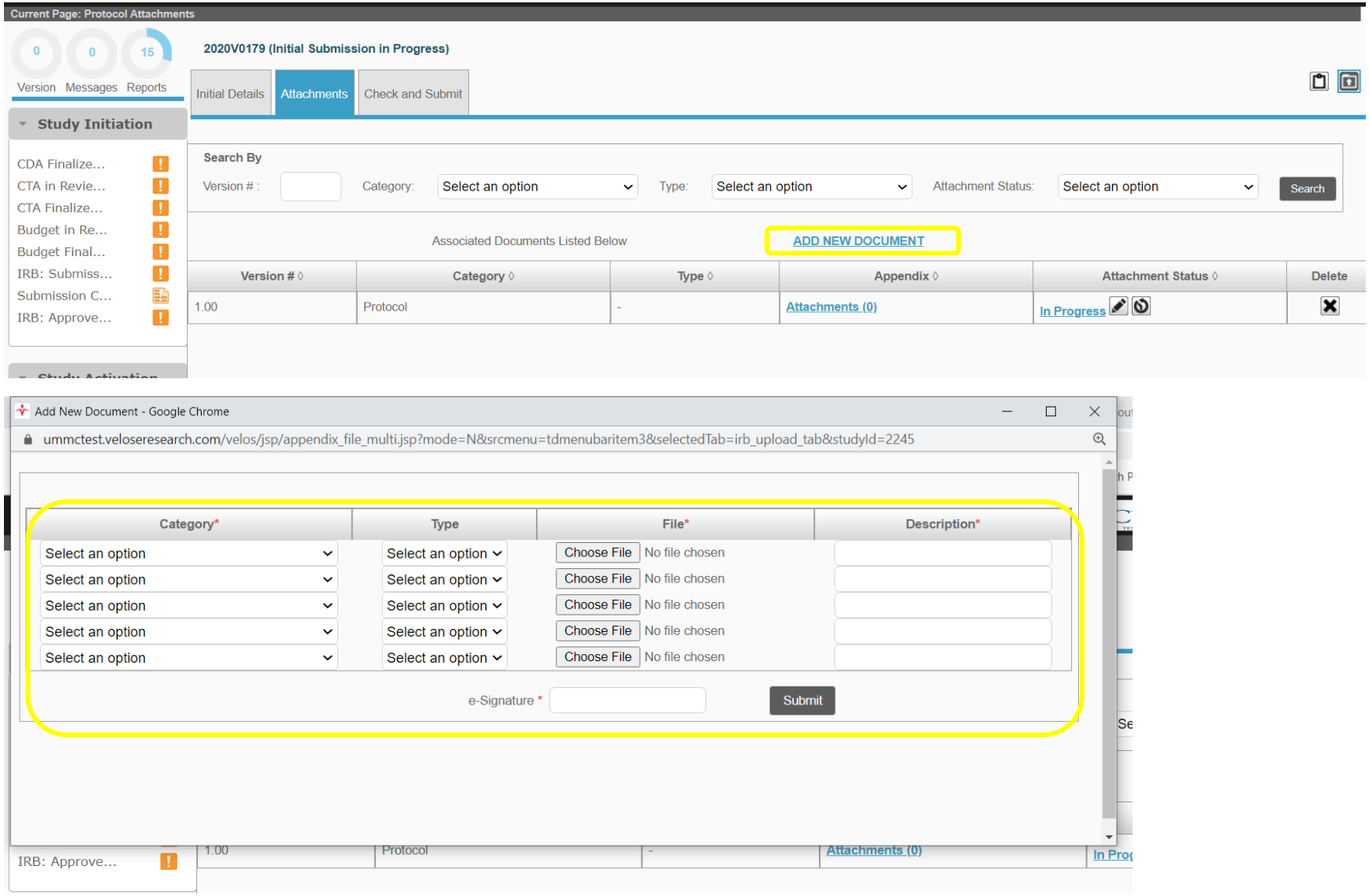
- Sponsor Name: Select Direct Sponsor. *A direct sponsor is defined as the agency or entity from which UMMC directly receives project funding.*
- Inpatient Study: Select if study participants will have inpatient status
- Centers/Institutes: Select Centers/Institutes the trial should be associated with
- OCT Study: *[for OCT use only]*
- Protocol requires informed consent?: Select if protocol requires informed consent
- Send Study to Investigational Drug Service: *[For OCT use only]*
- Click Save.
- Click on Local Sample Size under the Study Details Tab





a) Enter Local Sample Size for UMMC.
b) Enter e-Signature
c) Click Submit

4. **Attachments Tab**
    a. Upload any attachments relevant to your study/IRB review in the applicable category
    b. Click Add New Document
        - For description, please use the following naming convention: Type of Document_Version_Date_Status (e.g., Protocol_V1_12082020_FINAL)
        - Enter e-signature
        - Click submit
        - Repeat for each set of five documents


Current Page: Protocol Attachments
0
0
15
Version
Messages
Reports
2020V0179 (Initial Submission in Progress)
Initial Details
Attachments
Check and Submit
Study Initiation
CDA Finalize...
CTA in Revie...
CTA Finalize...
Budget in Re...
Budget Final...
IRB: Submiss...
Submission C...
IRB: Approve...
Search By
Version # :
Category:
Select an option
Type:
Select an option
Attachment Status:
Select an option
Search
Associated Documents Listed Below
ADD NEW DOCUMENT
Version # ◊
Category ◊
Type ◊
Appendix ◊
Attachment Status ◊
Delete
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Protocol
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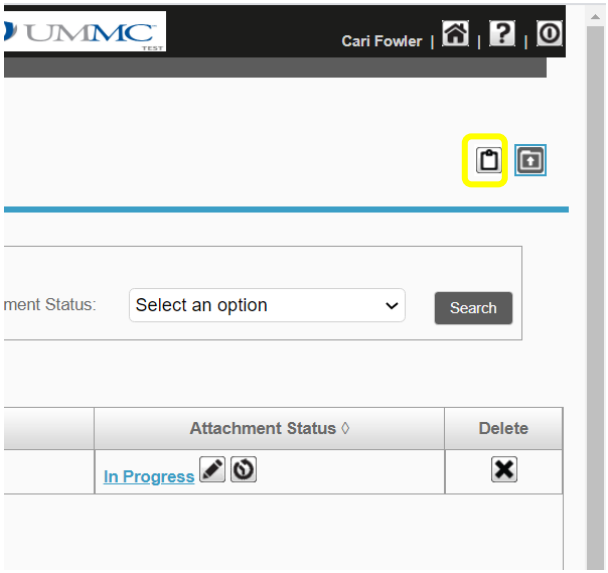
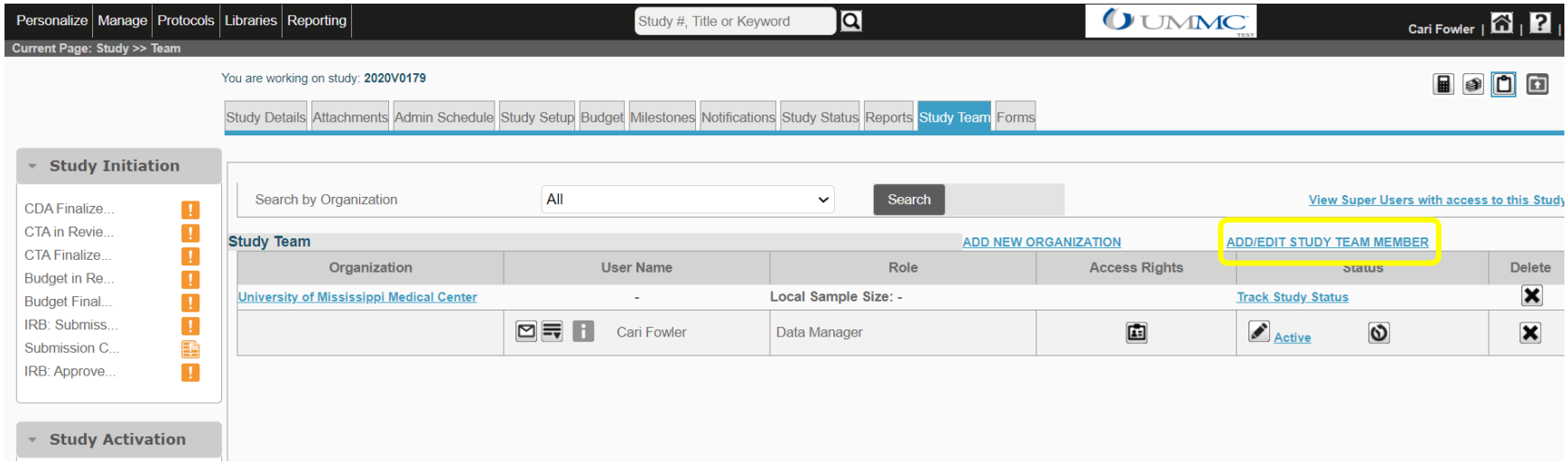
Attachments (0)
In Progress
Add New Document - Google Chrome
ummctest.veloseresearch.com/velos/jsp/appendix_file_multi.jsp?mode=N&srcmenu=tdmenubaritem3&selectedTab=irb_upload_tab&studyId=2245
Category*
Type
File*
Description*
Select an option
Choose File
No file chosen
e-Signature *
Submit

5. Study Team

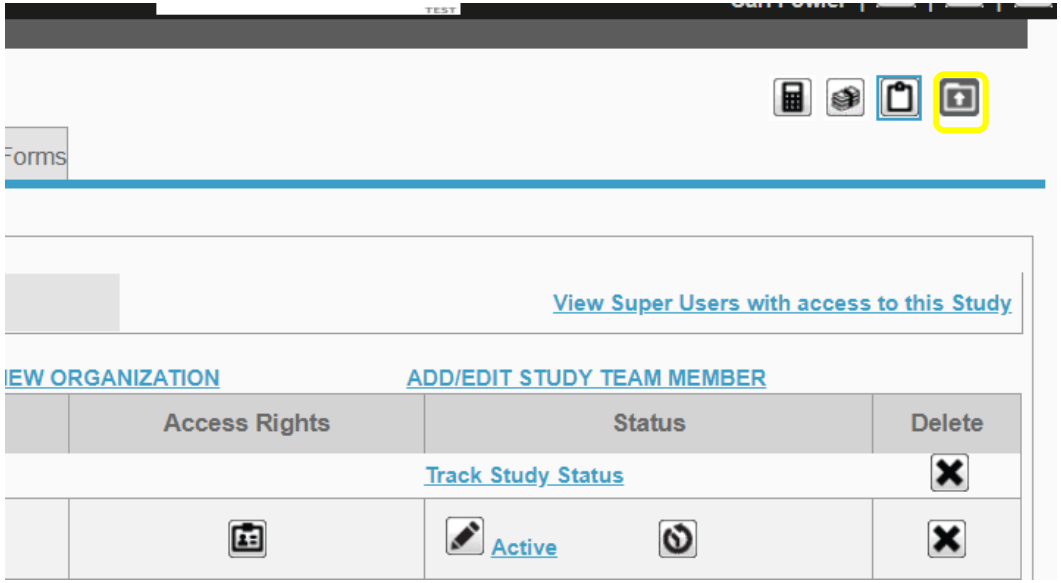
a. Click on the Clipboard icon in the top right corner



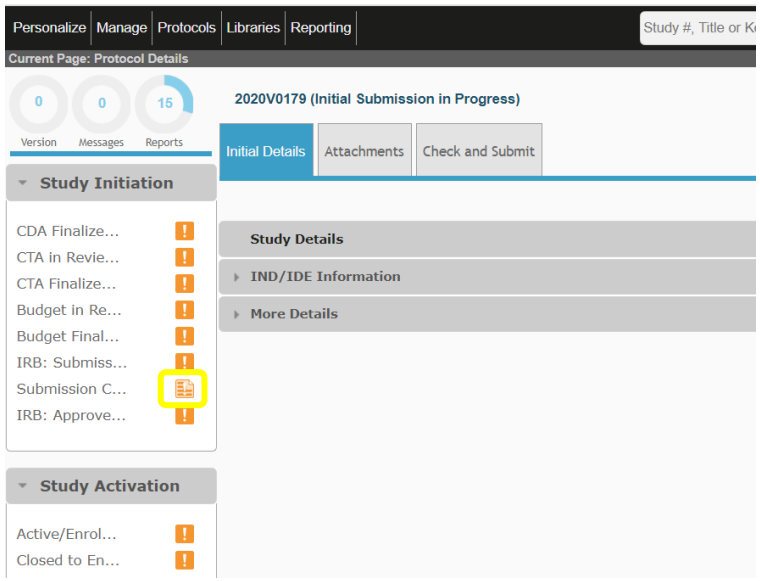
b. Navigate to Study Team Tab
c. Click on Add/Edit Study Team Member



d. Search for study team member and click checkbox to add.
e. Repeat for all study team members
f. Select roles for each member
g. Click Submit
h. Click on the Folder icon in the top right corner



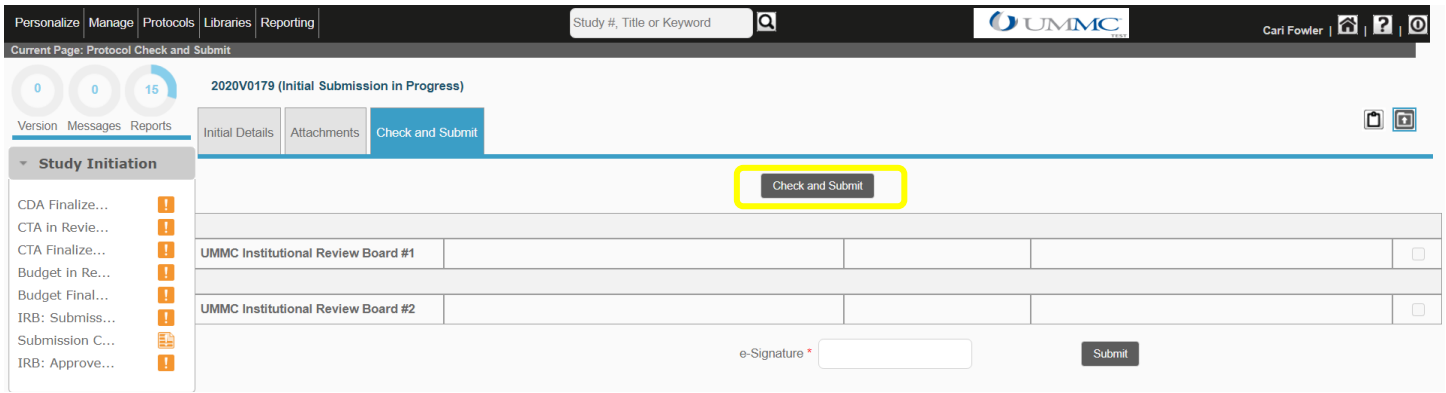
6. Click on Submission Checklist icon in the Workflow Panel



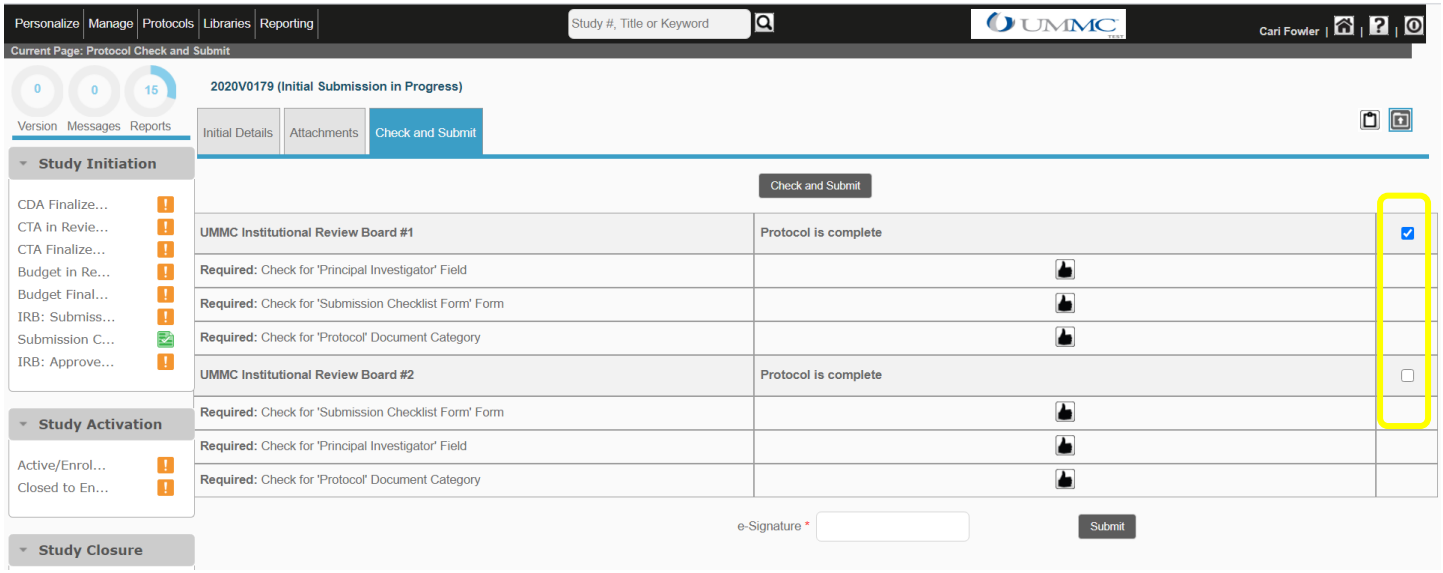
a. Complete the Submission Checklist
b. Select Completed in Form Status
c. Enter e-Signature
d. Click Submit

7. Check and Submit Tab

a. Click on Check and Submit



b. Ensure all three sections have a icon
c. Using the IRB Submission Table below, choose the applicable IRB board for which to send the study by checking the applicable box in the far right column



d. Enter e-signature
e. Click Submit

Congratulations! Your IRB protocol has now been submitted to the Human Research Office for review.

Video: https://youtu.be/CsjrAsdWC54

IRB Meeting Dates		
If your protocol is submitted between:	**It will be reviewed by:**	**On:**
12/24/2020-01/13/2021	IRB1	01/26/2021
01/14/2021-01/27/2021	IRB2	02/09/2021
01/28/2021-02/10/2021	IRB1	02/23/2021
02/11/2021-02/24/2021	IRB2	03/09/2021
02/25/2021-03/10/2021	IRB1	03/23/2021
03/11/2021-03/24/2021	IRB2	04/13/2021
03/25/2021-04/14/2021	IRB1	04/27/2021
04/15/2021-04/28/2021	IRB2	05/11/2021
04/29/2021-05/12/2021	IRB1	05/25/2021
05/13/2021-05/26/2021	IRB2	06/08/2021
05/27/2021-06/09/2021	IRB1	06/22/2021
06/10/2021-06/23/2021	IRB2	07/13/2021
06/24/2021-07/14/2021	IRB1	07/27/2021
07/15/2021-07/28/2021	IRB2	08/10/2021
07/29/2021-08/11/2021	IRB1	08/26/2021
08/12/2021-08/25/2021	IRB2	09/14/2021
08/26/2021-09/15/2021	IRB1	09/28/2021
09/16/2021-09/29/2021	IRB2	10/12/2021
09/30/2021-10/13/2021	IRB1	10/26/2021
10/14/2021-10/27/2021	IRB2	11/09/2021
10/28/2021-11/10/2021	IRB1	11/23/2021
11/11/2021-11/24/2021	IRB2	12/14/2021
11/25/2021-12/15/2021	IRB1	12/28/2021