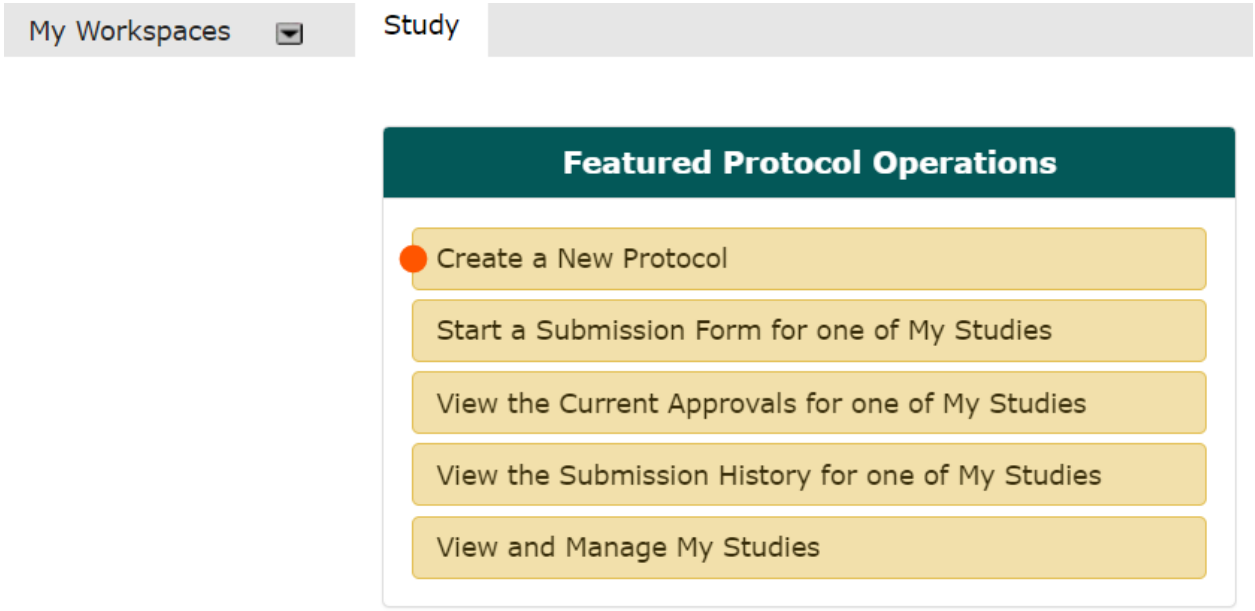
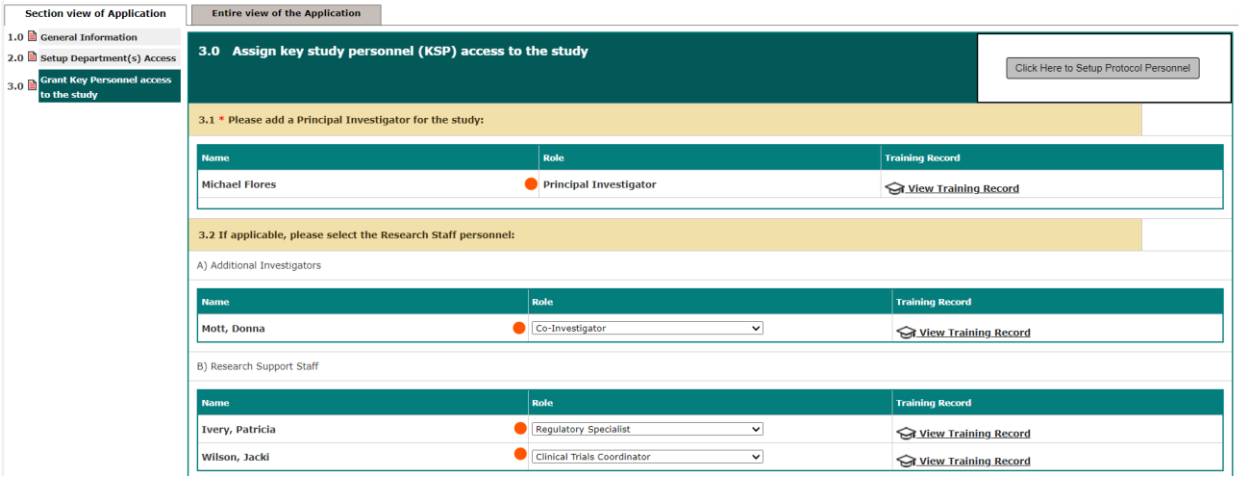
How to Complete a Request to Use External IRB Application in iRIS

1. Select Create a New Protocol in iRIS



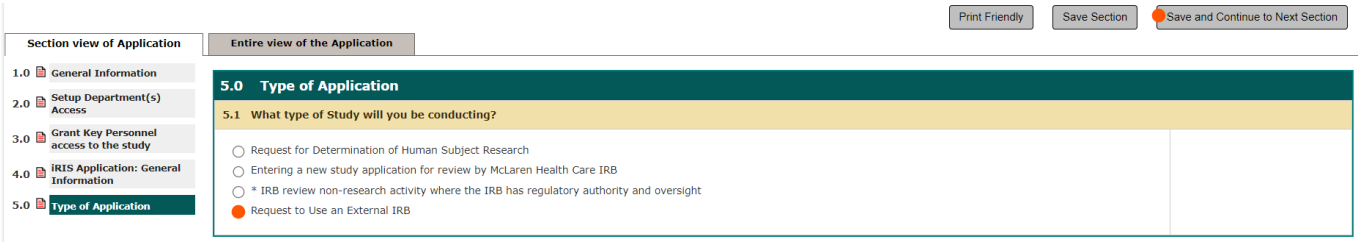
2. In Section 3.0 Setup Key Study Personnel (KSP) List



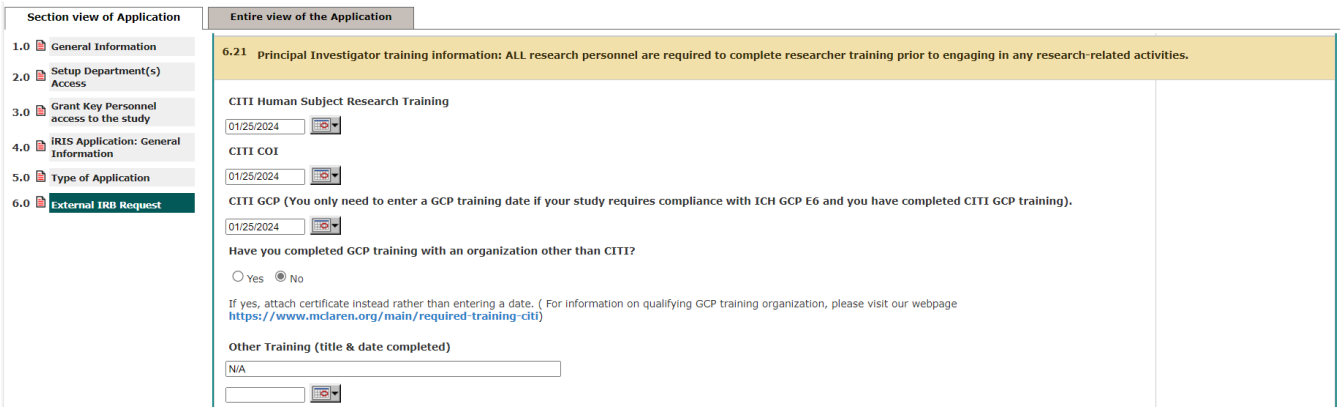
* It is critical to finalize KSP list before moving on with the application and submitting application to the IRB.

How to Complete a Request to Use External IRB Application in iRIS

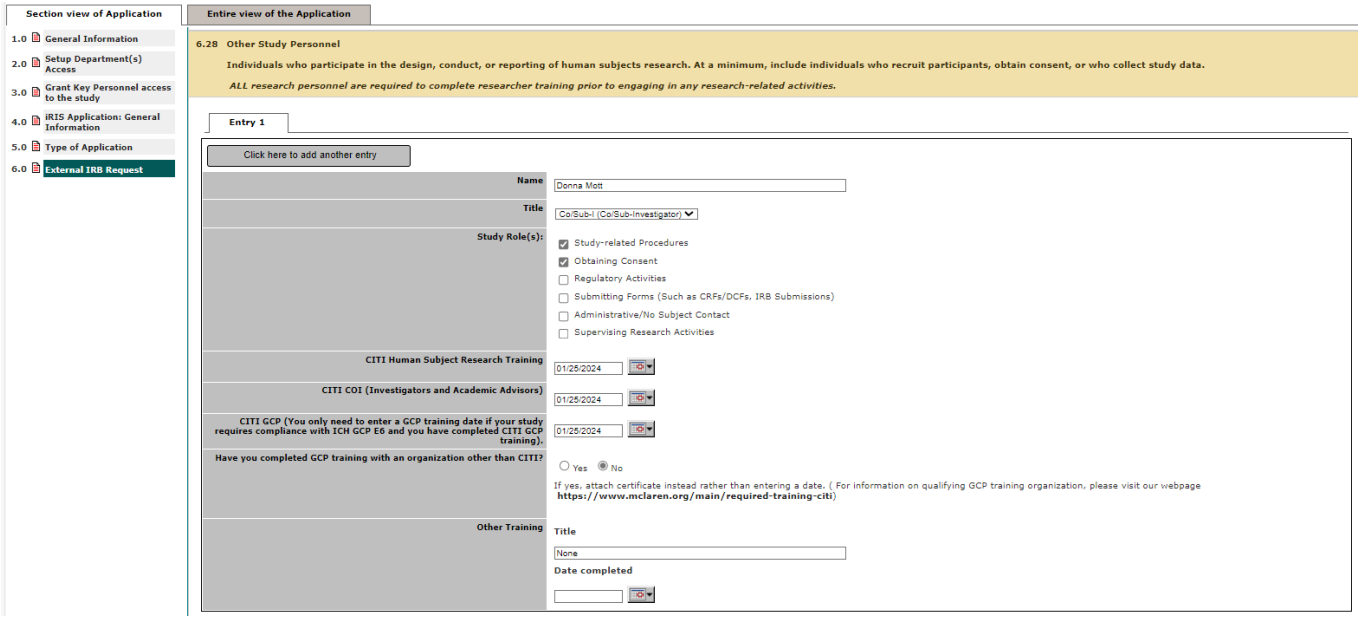
3. In Section 5.0 Select "Request to Use External IRB Application"



4. In Section 6.21 Complete Principal Investigator Information



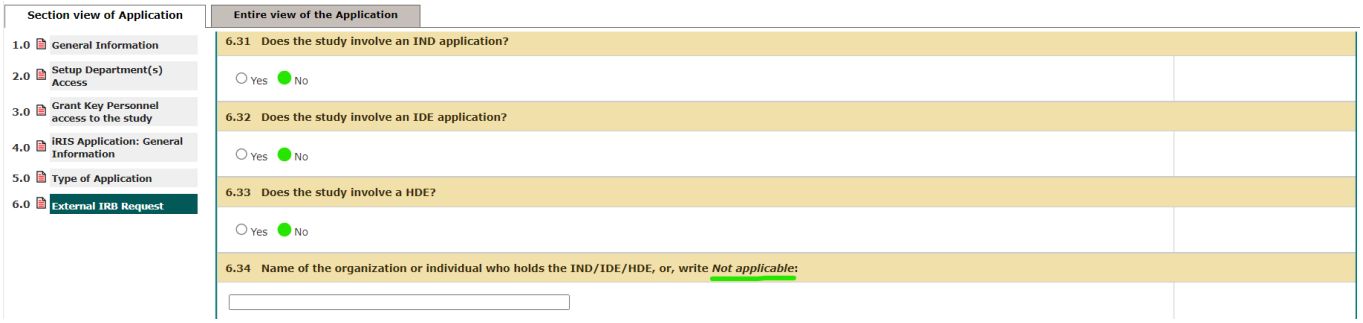
5. In Section 6.28 Fill in Key Study Personnel Information



* Critical that all KSP has verified CURRENT CITI Training

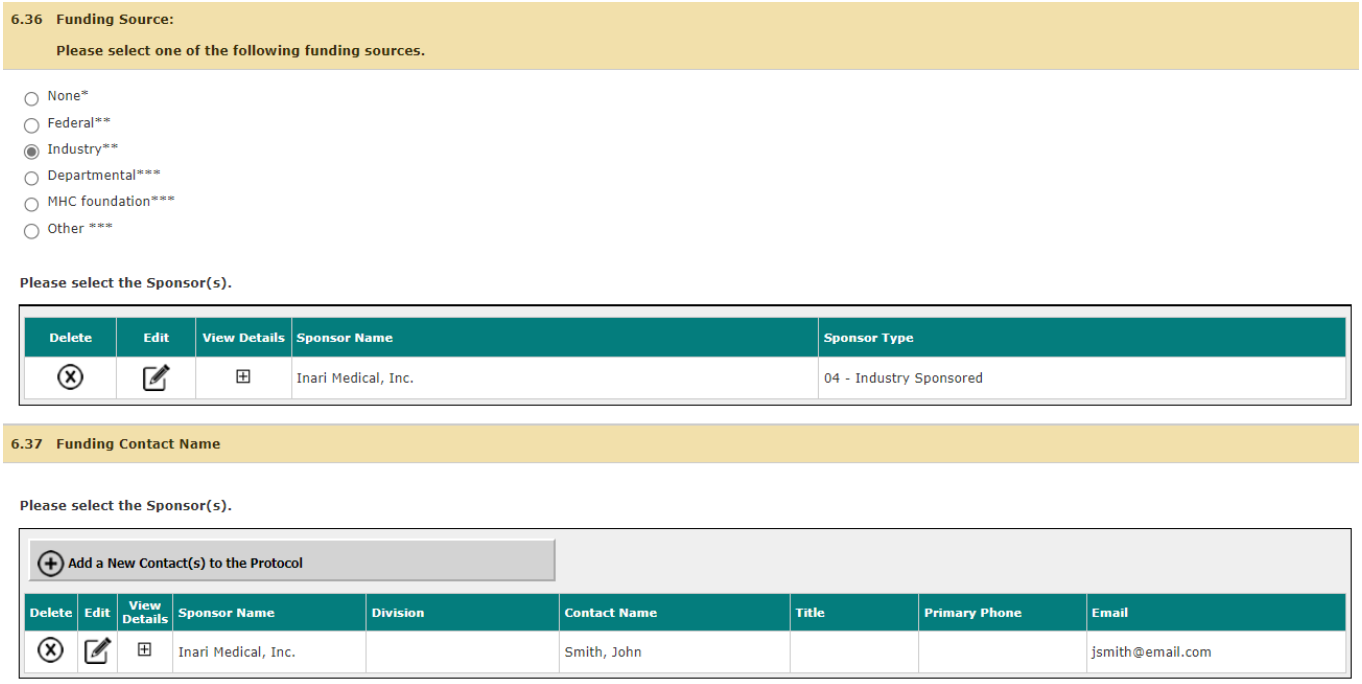
How to Complete a Request to Use External IRB Application in iRIS

6. In Section 6.31 – 6.34 Complete IND/IDE/HDE Information



* Do not put Sponsor (if study has Sponsor)

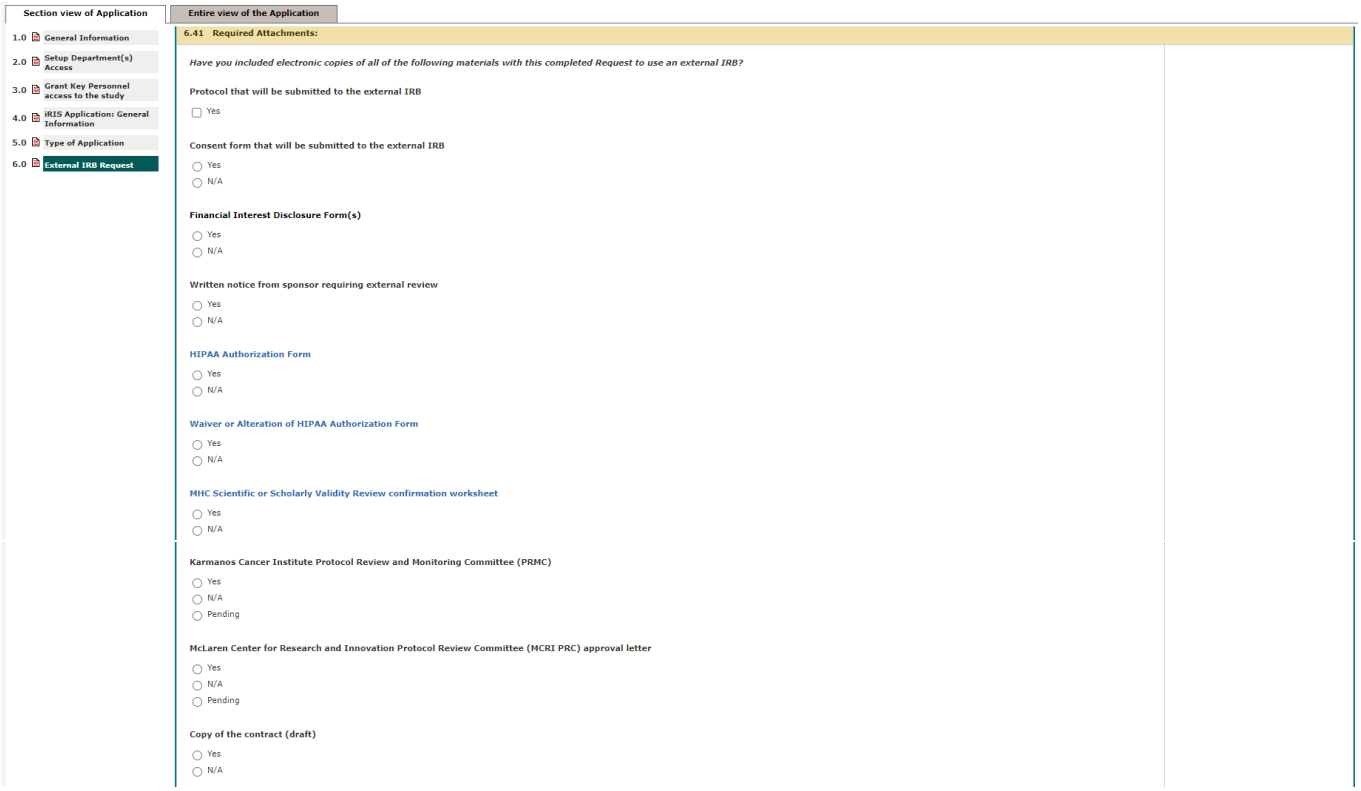
7. In Section 6.36 - Complete Funding/Sponsor Information



How to Complete a Request to Use External IRB Application in iRIS

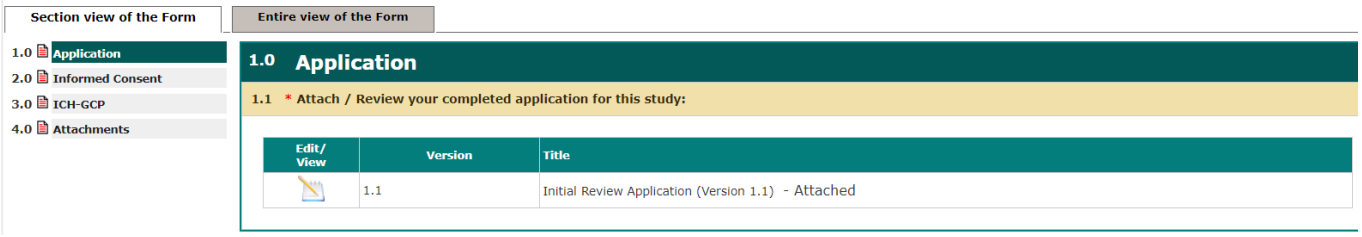
8. In Section 6.41 Attach Required Documents

- PRMC approval letter is only for KCI submissions (current letters only)
- PRC approval letter is only for non-Oncology submissions (current letters only)
- AAHRPP Checklist Contract is only required for Industry Sponsored Studies

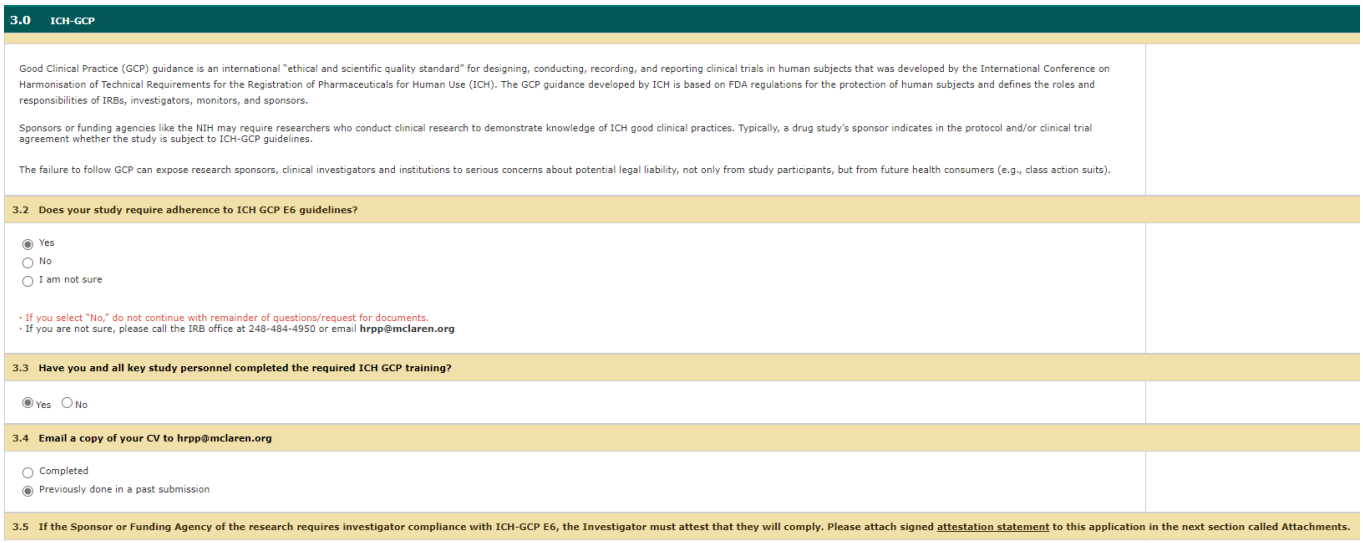


9. Submission Packet

a. Section 1.0 will contain the completed application.
b. Section 2.0 the ICF will already be attached here.
c. Section 3.0 complete the questions as applicable.
d. Section 4.0 the attachments will already be attached here.



How to Complete a Request to Use External IRB Application in iRIS



3.0 ICH-GCP

Good Clinical Practice (GCP) guidance is an international "ethical and scientific quality standard" for designing, conducting, recording, and reporting clinical trials in human subjects that was developed by the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH). The GCP guidance developed by ICH is based on FDA regulations for the protection of human subjects and defines the roles and responsibilities of IRBs, investigators, monitors, and sponsors.

Sponsors or funding agencies like the NIH may require researchers who conduct clinical research to demonstrate knowledge of ICH good clinical practices. Typically, a drug study's sponsor indicates in the protocol and/or clinical trial agreement whether the study is subject to ICH-GCP guidelines.

The failure to follow GCP can expose research sponsors, clinical investigators and institutions to serious concerns about potential legal liability, not only from study participants, but from future health consumers (e.g., class action suits).

3.2 Does your study require adherence to ICH GCP E6 guidelines?

- (•) Yes
- ( ) No
- ( ) I am not sure

· If you select "No," do not continue with remainder of questions/request for documents.
· If you are not sure, please call the IRB office at 248-484-4950 or email **hrpp@mclaren.org**

3.3 Have you and all key study personnel completed the required ICH GCP training?

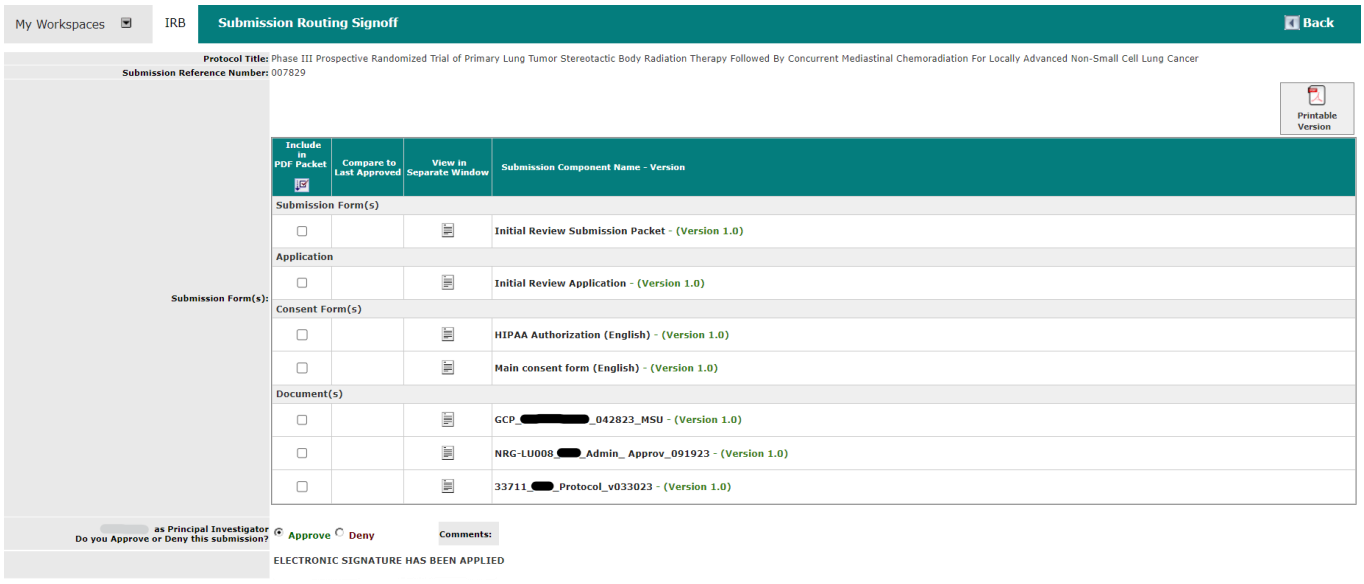
(•) Yes ( ) No

3.4 Email a copy of your CV to hrpp@mclaren.org

- ( ) Completed
- (•) Previously done in a past submission

3.5 If the Sponsor or Funding Agency of the research requires investigator compliance with ICH-GCP E6, the Investigator must attest that they will comply. Please attach signed attestation statement to this application in the next section called Attachments.

10. Signoffs



My Workspaces | IRB | **Submission Routing Signoff** | Back

Protocol Title: Phase III Prospective Randomized Trial of Primary Lung Tumor Stereotactic Body Radiation Therapy Followed By Concurrent Mediastinal Chemoradiation For Locally Advanced Non-Small Cell Lung Cancer
Submission Reference Number: 007829

Printable Version

Submission Form(s):

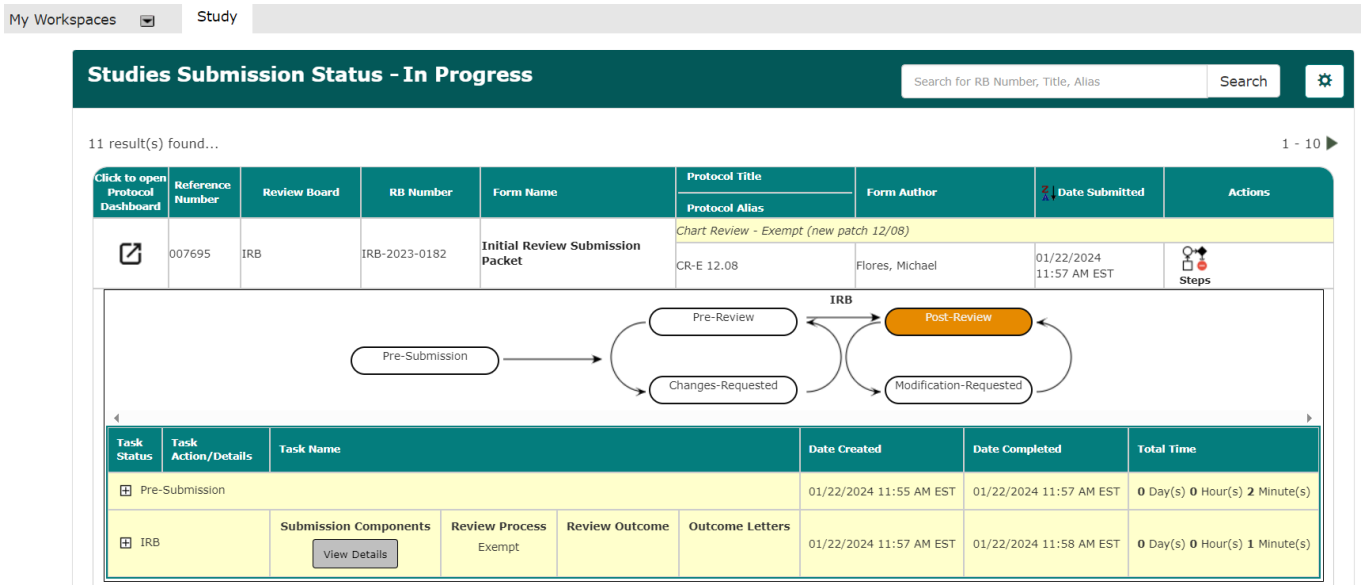
Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name - Version
Submission Form(s)			
☐			**Initial Review Submission Packet** - (Version 1.0)
Application			
☐			**Initial Review Application** - (Version 1.0)
Consent Form(s)			
☐			**HIPAA Authorization (English)** - (Version 1.0)
☐			**Main consent form (English)** - (Version 1.0)
Document(s)			
☐			**GCP_[redacted]_042823_MSU** - (Version 1.0)
☐			**NRG-LU008_[redacted]_Admin_ Approv_091923** - (Version 1.0)
☐			**33711_[redacted]_Protocol_v033023** - (Version 1.0)

[redacted] as Principal Investigator Do you Approve or Deny this submission? (•) Approve ( ) Deny **Comments:**

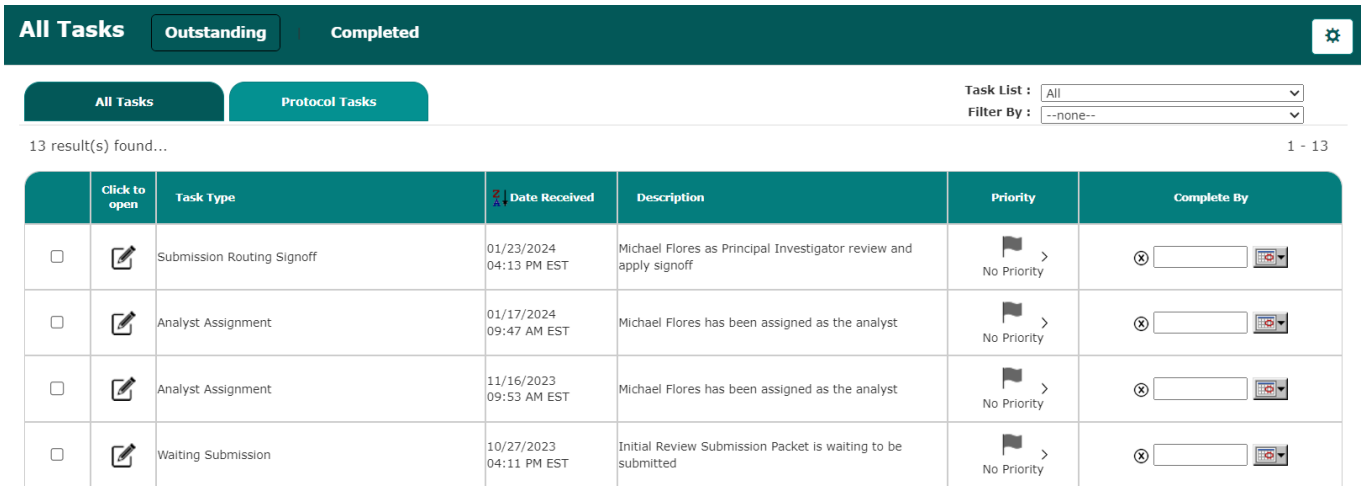
ELECTRONIC SIGNATURE HAS BEEN APPLIED

How to Complete a Request to Use External IRB Application in iRIS

11. Tracking



12. Responding to stipulations



13. Response time

If there are any stipulations from the IRB Analyst or IRB Reviewer and you are not sure how to answer, please contact us. This will cut down on the turnaround time to complete the application.

How to Complete a Request to Use External IRB Application in iRIS

14. Support

The IRB analyst are available for support to get your submission completed. You can reach us via Microsoft Teams, Outlook or call directly. Teams is recommended as we can assist in real time and take you through your issue step by step within your application.