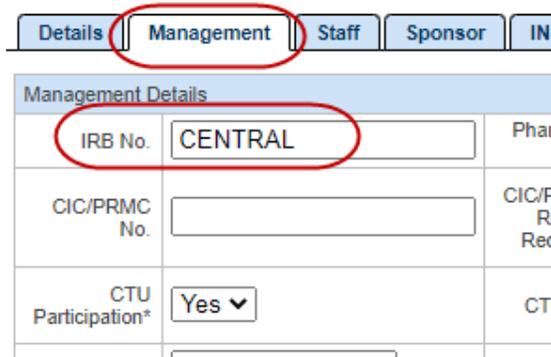


Central IRB Review Process

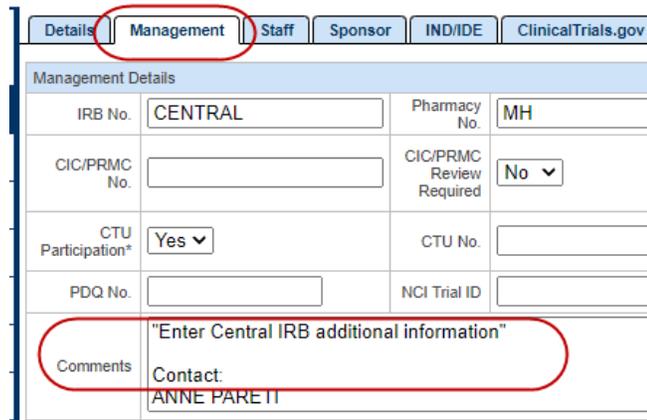
- At the time of study submission, study team will enter “CENTRAL” or “LOCAL” in OnCore, under PC Console -> Management tab -> “IRB No”.



The screenshot shows the OnCore Management tab interface. The 'Management' tab is selected and circled in red. Below it, the 'Management Details' section contains a table with the following data:

IRB No.	CENTRAL	Phar
CIC/PRMC No.		CIC/P R Req
CTU Participation*	Yes	CTI

- The study team will add any information in their possession regarding patient reimbursement, stipends, hotel stays or other patient information that would be relevant to finalizing the ICF when submitting new study request in OnCore, under PC Console -> Management tab -> “Comments”.



The screenshot shows the OnCore Management tab interface with more details. The 'Management' tab is selected and circled in red. The 'Management Details' section contains a table with the following data:

IRB No.	CENTRAL	Pharmacy No.	MH
CIC/PRMC No.		CIC/PRMC Review Required	No
CTU Participation*	Yes	CTU No.	
PDQ No.		NCI Trial ID	

Below the table, the 'Comments' section is circled in red and contains the text: "Enter Central IRB additional information" and "Contact: ANNE PARETI".

- The study team will at the same time of submission to CTO also request Ceded Review from Local IRB.
- The CTO Project Specialist will notify the contract officer and budget specialist that central IRB is being utilized.

Contract Officer will negotiate subject injury and patient reimbursement language in the contract. Budget specialist will be engaged by contract officer to finalize the patient reimbursement/stipend with the sponsor if terms are unique or contested. Otherwise, contract officer will also finalize these terms within the contract.

- Once terms are finalized, the study team will be notified. Contract Officer will complete the consistency checklist before the contract is executed and mark “CONTRACT NOT COMPLETE.” This allows the study team to take the language from the checklist, incorporate it into the ICF and send to sponsor for approval before it is submitted to Central IRB.
- Study team will upload a final ICF into iStar and will submit to Central IRB.

Central IRB Review Process

7. Study team will enter the USC IRB number in OnCore: under Management tab -> IRB No - “CENTRAL-HS-##-#####” or “LOCAL-HS-##-#####”.

The screenshot shows the OnCore interface with the 'Management' tab selected. The 'Management Details' section contains the following fields:

IRB No.	CENTRAL-HS-21-00001
CIC/PRMC No.	
CTU Participation*	Yes
PDQ No.	

8. Upon contract/budget finalization, Contract Officer will complete the ICF consistency check in iStar. Once the contract is executed, contract officer will go back into iStar to reconfirm the language and mark “CONTRACT IS FULLY EXECUTED”.
9. Internal IRB will approve ceded review.
10. Evidence of Central IRB approval will be uploaded to OnCore and is a required document before CTO will open to accrual in OnCore and release ROF upon execution of final contract (i.e. IRB approval letters). Upload document under PC Console -> Documents/Info -> Attachments/Links, select document type “Central IRB Approval Letter”

The screenshot shows the OnCore interface with the 'Attachments/Links' tab selected. The 'Add Attachment' section contains the following fields:

Select Protocol	9L-21-6
Main	»
Treatment	»
Institution	
Accrual	
Status	»
Reviews	»
Documents/Info	»

The 'Add Attachment' section also includes:

- Link to External EDC: External EDC URL
- Document Type: Central IRB Approval Letter (selected)
- Description: Amendment Request Form, Calendar Build Notes, Central IRB Approval Letter, CIC Checklist, CISO-Budget
- Version Date: 10/05/2021

11. When CTO is activating the study, contract office will:
- remove “CENTRAL” or “LOCAL” from PC Console -> Management tab -> IRB No

The screenshot shows the OnCore interface with the 'Management' tab selected. The 'Management Details' section contains the following fields:

IRB No.	HS-21-00001
CIC/PRMC No.	
CTU Participation*	Yes
PDQ No.	

Central IRB Review Process

- b. link iStar and OnCore
- c. select IRB company under PC Console -> Reviews -> IRB tab -> “Committee” (per iStar).

Study: 5C-21-1: Ph 3 Balstilimab vs Investigator Choice Chemo in R

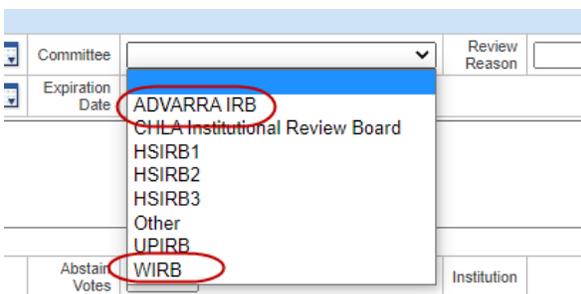
Full Title of Application:	5C-21-1: A Phase 3 Trial of Balstilimab versus Investigato	
Principal Investigator:	Koji Matsuo	Contact
Faculty Advisor:		Review
IRB Administrator:	Maria Brown	IRB Re
Effective Approval Date:	9/29/2021	Letter c
Expiration Date:		Approv
Enrollment Status:	a. Enrolling New Subjects/Data/Specimens	
Reviewing IRB:	Advarra IRB	

D1. Ceded Review

Ceded Review should only be used if you are relying on a ceded review, please consult the IRB before continuing w

D1.1. Indicate which IRB has approved or will approve this study:

- NCI CIRB
- CHLA Institutional Review Board (CHLA)
- WCG IRB
- UCLA
- University of Cincinnati
- Advarra IRB
- Other



12. All other study activation processes remain unchanged.