Central IRB Review Process

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

2. 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”.

3. The study team will at the same time of submission to CTO also request Ceded Review from Local IRB.
4. 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.
5. 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.
6. Study team will upload a final ICF into iStar and will submit to Central IRB.
7. Study team will enter the USC IRB number in OnCore: under Management tab -> IRB No - “CENTRAL-HS-##-#####”.  

---
Central IRB Review Process

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 Local and 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)

11. When CTO is activating the study, contract office will:
   a. remove “CENTRAL” from PC Console -> Management tab -> IRB No
   b. link iStar and OnCore
   c. select IRB company under PC Console -> Reviews -> IRB tab -> “Committee” (per iStar).

12. All other study activation processes remain unchanged.