

CCI Clinical Trial Implementation Cheat Sheet

Below are the steps from application to opening of the study in our scheduling system:

- Application to CCI (applications can be submitted to CCI/Catalyst and the IRB simultaneously – there is no need for one to wait for the other to be approved).*
- How is this study funded? *
 - If industry/sponsored study:
 - ↳ confirm budget and contract are complete
- Study information request email is sent to study to confirm resources and provide any additional/missing information. *
- Study team staff can reach out to pharmacy as early as when the application and IRB approval comes through. Kevin Zinchuk and team offer one on one consults with study staff to discuss the medication (IV or other, needles needed, supplies needed, etc) and study flow even before the implementation meeting. This can be arranged by reaching out to the whole IDS pharmacy. They can email them at BWHRXIDS@partners.org. *
- Check all other non-CCI services that need to be coordinated *
 - ↳ Ultrasound
 - ↳ PFT lab
 - ↳ Radiology
 - ↳ Partners Research Core services (researchcores.partners.org/cores)
 - ↳ Any other departments that will be performing testing that will be paid by Research
- Review of study by CCI Operations team (this stage takes at least 1 week or 3 weeks depending type of review it undergoes).
- Conditional approval/approval of the study (this depends on review) is granted.
- Study team then prepares study orders. Non-Nursing Study templates will be provided by the responsible Operations Coordinator. Nursing Study order templates will be initially drafted by study team coordinators and then sent to Outpatient Nursing team. Study team coordinators to contact pharmacy when preparing study orders if this has not been done already. For any CCI clinical trial that has inpatient overnight visits, the PI and study team initiate draft set of study orders and CCI Inpatient nursing, lab coordinator and Nutrition teams review for final approval. The CCI coordinates development of epic admission research templates from the approved CCI protocol orders.
- Implementation meeting- to discuss briefly about study, study visits, resources, scheduling system, billing process, etc. The operations coordinator initiates scheduling the date and booking the room. The study PI and essential staff (study coordinators, pharmacy, nurses and operations coordinator) should be available for this meeting to clarify any additional questions pharmacy or nursing may have.
- Study team needs to be familiar with CCI scheduling system, if not staff should reach out to Joyce Clark for training. (jclark14@bwh.harvard.edu). *
- Confirm the PI has eCommons ID (For new user registration go to: ecommons.med.harvard.edu). *

- Study Open in the system to schedule visits if all requirements/documents requested are provided.
- For new patients, when sending the first orders, study team/coordinator to remember to email the signed consent to the nurses with the orders (cciadvancedoutptservices@partners.org).

*These steps can be addressed/carried out simultaneously and have no need to wait for the previous step to be addressed/completed.