1. Fill out and submit the electronic intake form via the following link: [YCCI Intake Form](https://ycci.co1.qualtrics.com/jfe/form/SV_1C9Xqb30laYT8Ox)
   1. NOTE: All studies rendering billable services must request OnCore support for subject management via this Intake Form. This is also the recommended mechanism for participant compensation. Once built in OnCore, the study team will receive an email requesting review/approval of the protocol calendar.
2. YCCI leadership will review the protocol/applicable documents for feasibility.
3. Once deemed feasible to conduct the study utilizing YCCI clinical research resources, the study team will be emailed a YCCI conditional approval letter to include in your IRB submission.
   1. NOTE: This letter is for the purposes of obtaining IRB approval. Further action is required before your study can be activated.
4. After receiving conditional approval, a YCCI registered nurse will be assigned to work on the study (study lead), and that person will help to guide the study team through this process and assist with Epic orders, arrange for an in-service, etc.
5. Concurrent with IRB submission: Please reference the Epic orders template (see Appendix) and utilize the OnCore calendar build export as a starting point to create MD orders. The assigned study lead will help to finalize these orders and will submit the orders in IRMA along with the eRx that IDS creates (if applicable). Once the orders are built, the study’s PI will receive an email from the Epic Team requesting that the orders be verified by the PI or designee (must be MD/PA/APRN). Once verified, the orders will be put in place and ready for use.
   1. NOTE: The study team cannot begin seeing patients in YCCI clinic space until the Epic orders are built/verified. There is an approximate 3-week turnaround time from receipt of orders to when they are available for use in Epic.
6. Once IRB approval is obtained, the study team must:
   1. Send the IRB approval letter to [clinicalresearchresources@yale.edu](mailto:clinicalresearchresources@yale.edu)
   2. Request an in-service with your assigned lead RN for clinical and lab staff
7. Once the above action items have been completed and the study has a fully executed contract with COA assignment, your study can be activated for use of the approved YCCI resources.

APPENDIX:

**Epic Orders Template**

ORDERS - HIC #: xxxxxxxxxx

Visit #:

Study Title:

Name of PI:

Name of Responsible MD (if different from PI):

* Subject to arrive at HRU at designated time
* RN to Verify Informed Consent
* RN to insert peripheral IV (for blood collection or infusion)
* Infuse 0.9NS @ 30mL/hr. (or whatever is applicable)
* Obtain vital signs (specify what you need and timepoints)
* Specify blood draw time points as well as what tubes are needed and volume
* All medications need to be written to include
  + Name of drug
  + Route of drug
  + Dose of drug
  + Frequency of administration
  + For example: RN to administer DRUG X, 123mg, inhaled x one (and any special instructions)
* Any other tasks/timepoints or important info must be included.
* We need a word document for each visit in the study that will take place at HRU.

1. **To Request an Appointment at a YCCI clinic**

Please create a referral in Epic (refer to tip sheets). For questions, please contact Lynda Knaggs by phone at 203-688-5067 or email [Lynda.Knaggs@ynnh.org](mailto:Lynda.Knaggs@ynnh.org)



1. **Clinical Trials Process Flowchart**

