Create Study Start-Up Binder

1. The coordinator is made aware of the study
2. UC IRB Pre-Submission
   1. This should result in an IRB number being assigned.
3. Click the admin key and add the UC IRB Number to the data source list as well as any other data source items for that study.
4. Create a binder using the Study Start-up Binder Template
5. Fill Out binder details page
   1. Only the Title and Description are required fields. We recommend only filling out these two fields start-up binders to minimize duplication of work.
   2. Please include the words “Start-Up” in your binder title.
6. Fill Out Binder Setup Page
   1. Fill out UC IRB Number and PI name
   2. For any other fields such as Person Name or IRB, if you do not know these items yet, you can put the N/A option.
      1. Once you find out those pieces of information you can come back and update those fields if you need to pull in the centrally managed documents associated with those or need to add these to certain study-specific documents such as Financial Disclosure Forms.
7. Add appropriate people if needed to the start-up binder.
8. Add documents and requests for signature as needed.

Archive Start-Up Binder and Create Full Study Binder

1. Initial IRB Approval is received (Or some other document that normally comes after approval)
2. Make sure any documents that have been uploaded to unfiled documents but not filed yet have been filed appropriately. If not, these documents will not transfer over to the full study binder and you will need to re-upload them.
3. Go to the Binder Details page of your Start-Up Binder and click edit.
   1. Change status to archived and hit save
   2. This will remove the Start-up binder from your active binder list.
4. Create the full study binder as you normally would have before.
   1. On the Binder Setup page, make sure you use the same UC IRB Number and PI name as you did on the start-up binder to ensure all study-specific documents flow over appropriately.
5. Use the Study binder as you normally would.