

Study Close-out Checklist

Sponsor:

- Confirm Sponsor is ready to closeout study
- Schedule Close Out Visit (COV)
 - Confirm storage requirements for other study supplies
 - Confirm PI availability to obtain final signatures
- Prepare for COV (study materials, binders, drug, etc)
- Patient Files: file source, medical record, paper CRF, informed consent
 - De-identify if required (see the IRB application)
- Return sponsor equipment and materials (if applicable)
- Ensure pharmacy is ready to destroy IP if not already done so

Systems and Billing - OCR/APEX/CRS:

- Prepare and send final invoice
- Confirm with DA/RFA staff that study is ready to close (ensure final invoice payment has been received)
- Update patient status in OnCore with completed visit dates and ensure all patients are moved to “off study”.
- Confirm all charges expected have hit ledger/ZZ report (30 days after final DOS)
- Email Matthew.Shem@ucsf.edu to close out APEX study build
- Email CRSProtocolServices@ucsf.edu to close study with PCRC/ CRS

Regulatory Documents/Study Supplies:

- Condense and box up study materials (patient and regulatory binders)
 - Save final files and box storage location to shared drive
 - Discard blanks and duplicates
- Scan and save documents that can be kept electronically
 - Consider saving IB, protocol, lab and pharmacy manuals
- Draft and file memo re: storage plan for study documents
- Request drug accountability records and/or file pharmacy binder
- Consider filing any copies of PCRC or CRS documents (temp, lab, calibration logs)
- Confirm all logs are complete (enrollment log with completion dates, delegation logs,...)
 - Review and obtain PI signatures on delegation log (advise doing at COV)
- Discard all lab kits and shipping boxes
 - Donate tubes, etc. to Remedy bin
- File final monitoring report and study results if and when available

IRB:

- Submit close out report to IRB
 - Should be after all study activities are completed and after COV
 - File final closeout acknowledgement and forward to sponsor once we confirm invoice payment
 - Update OnCore status to ‘IRB study closure’

[For more information please refer to ICH E6 \(Section 8\)](#)