

**Study Closeout Checklist**

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| **Finalize Study Data** | Once data collection is complete, the research team must verify that all Case Report Forms have been completed and links to identifiers for data to be retained have been destroyed as required by the IRB-approved protocol. Of note, even when other records, source documents, specimens, or data are de-linked per IRB-approved protocol, the signed consent forms and HIPAA forms must be retained, without alteration. Discuss any questions with the IRB or your funding agency/sponsor.  [*https://www.washington.edu/research/hsd/docs/1720*](https://www.washington.edu/research/hsd/docs/1720) |
| NOTES: | |
| **Close Out Research Support Services & Facilities** | Let the departments who supported the study know the study has ended in case they have processes to close out their role. For example, IDS needs to complete a final drug inventory and ensure that any remaining drug is returned to sponsor or disposed of appropriately.   * ITHS CLINICAL RESEARCH CENTER [*https://www.iths.org/investigators/units/crc/*](https://www.iths.org/investigators/units/crc/) * IDS PHARMACY [*https://depts.washington.edu/drugsvcs/home/content/investigational-drug-service-ids*](https://depts.washington.edu/drugsvcs/home/content/investigational-drug-service-ids) * HMC (206) 744-5448 [hmcids@u.washington.edu](mailto:hmcids@u.washington.edu) * UWMC (206) 598-6054, [uwmcids@u.washington.edu](mailto:uwmcids@u.washington.edu) * UW LABORATORY MEDICINE [*http://depts.washington.edu/labweb/*](http://depts.washington.edu/labweb/), (206) 598-6131, [lmofficesupport@uw.edu](mailto:lmofficesupport@uw.edu) * Research Testing Services [*http://depts.washington.edu/labweb/Research/index.htm*](http://depts.washington.edu/labweb/Research/index.htm), (206) 616-8979, [rts@uw.edu](mailto:rts@uw.edu) * UW DEPARTMENT OF PATHOLOGY [*http://www.pathology.washington.edu/research/request/*](http://www.pathology.washington.edu/research/request/) * UW DEPARTMENT OF RADIOLOGY RESEARCH PROGRAM [*http://www.rad.washington.edu/research/research-services*](http://www.rad.washington.edu/research/research-services) |
| NOTES: | |
| **Records Retention** | Generally, UW-held research records must be retained for six years. Records retention must also comply with all other applicable regulations governing the study, including UW Records Retention Schedules. There may be additional requirements associated with the funding agency/sponsor or other agencies, like the FDA, involved in the research.  UW RECORDS MANAGEMENT [*http://f2.washington.edu/fm/recmgt/*](http://f2.washington.edu/fm/recmgt/)  If you are in the UW School of Medicine more specific information about storing UW Medicine patient research records can be found at UW Medicine Records Management Services [*http://www.uwmedicine.org/about/records-management*](http://www.uwmedicine.org/about/records-management) |
| NOTES: | |
| **Final Reports** | Submit final reports to the IRB, FDA, and/or your funding agency/sponsor. Check with your funding source or industry sponsor for more information on their report requirements. [*https://www.washington.edu/research/hsd/docs/1720*](https://www.washington.edu/research/hsd/docs/1720)  FDA regulations require investigator-sponsors who hold an IND to submit a final report to FDA:  [*http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.64*](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.64)  FDA also provides a suggested format for investigator-initiated IDE Final Reports:[*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046717.htm*](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046717.htm) |
| NOTES: | |
| **Billing Closeout Request** | Within 45 days following the delivery of the final study service, use this survey to submit a billing closeout request to CRBB to deactivate your Epic “RRR” study account: [*https://redcap.iths.org/redcap/surveys/?s=8IBRzJ*](https://redcap.iths.org/redcap/surveys/?s=8IBRzJ)  [*http://depts.washington.edu/comply/docs/COM-101Attachment\_C\_Research\_Billing\_Compliance\_Procedures.pdf*](http://depts.washington.edu/comply/docs/COM-101Attachment_C_Research_Billing_Compliance_Procedures.pdf) |
| NOTES: | |
| **Final Accounting of Research Funds** | Contact your department fiscal specialist and CRBB to ensure that all allocable costs have been charged to the study. Both your departmental fiscal specialist and the CRBB representative will work with you to ensure that all funds due to the UW have been received, as well as confirming that all funds received have been earned.  You and your department fiscal specialist can contact OSP and GCA to determine the appropriateness of remaining funds to stay with UW, as well as resolution of overdrafts, balance transfers to income accounts, and final closure of the research budget.  UW CLINICAL RESEARCH BUDGET AND BILLING (206) 543-7774, [crbb@u.washington.edu](mailto:crbb@u.washington.edu)  UW OFFICE OF SPONSORED PROGRAMS (206) 543-4043, [osp@uw.edu](mailto:osp@uw.edu)  UW GRANT & CONTRACT ACCOUNTING (206) 616-9995, [gcahelp@uw.edu](mailto:gcahelp@uw.edu) |
| NOTES: | |
| **Posting Data to Clinicaltrials.gov** | Upload study data and post your study results on [www.clinicaltrials.gov](http://www.clinicaltrials.gov).  [*https://www.clinicaltrials.gov/ct2/manage-recs/faq*](https://www.clinicaltrials.gov/ct2/manage-recs/faq) |
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| **NIH-funded Research Publication Resources** | For NIH-funded research, or research supported in-part by NIH grant resources, the National Institutes of Health Public Access website provides instructions on NIH requirements for preparing manuscripts, what to do once your publication is accepted, and citations/reporting about upcoming publications.  [*http://publicaccess.nih.gov/*](http://publicaccess.nih.gov/) |
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