University Hospitals
Clinical Research Center

Study Closure at UH

Study Name: _____

General Requirements
☐ Notify your department any Sub-I's or other study staff (COI's, SC's, biostatisticians, pharmacists, etc.) of the impending study closure. ☐ Make sure ClinicalTrials.gov is up to date with registration and results reporting, if applicable. If assistance is needed, reach out to UHResearchCompliance@UHhospitals.org for assistance with ClinicalTrials.gov registration and results reporting. • Case comprehensive Cancer Center studies should reach out to Kevin Hoy (kch38@case.edu) for assistance. ☐ Ensure any community or satellite sites are closed appropriately.
Grants & Contracts Requirements
☐ If you are requesting the transfer or sharing of study data (in any format, including de-identified data) or the transfer of biological samples or other materials to another institution you must reach out to the Grants and Contracts team (UHCRCGrantsContracts@UHhospitals.org) to ensure all required approvals are obtained and to ensure the appropriate contract is in place. ☐ Reach out to the Grants & Contracts team (UHCRCGrantsContracts@UHhospitals.org) to ensure that termination is possible based on the terms of the applicable contract, if any exists. ☐ If your research is a result of any invention disclosure please contact the Grants & Contracts team (UHCRCGrantsContracts@UHhospitals.org) if you plan on continuing to work on the subject matter of such disclosure.
Research Finance Requirements
☐ Complete grant close out process: confirm that all patient claims have dropped, been segregated and billed with Research Finance (ResearchBiller@UHhospitals.org). ☐ Resolve any outstanding receivables and identify funding to cover any negative award balance
Grants Accounting Requirements
☐ Ensure all claims have dropped, been segregated, billed, and paid with Grants Accounting (UHCRCGrantsAccounting@UHhospitals.org)
IRB Requirements
☐ Submit a study closure form through Sparta IRB and follow any instructions received to ensure the study is closed properly. If there are study subjects actively involved in study procedures, the study may not be able to be closed immediately. ☐ If required by the Investigator Manual, reach out to any patients actively enrolled in the study and notify them of the impending study closure.
If your study has an IND / IDE
☐ Reach out to FDASupport@UHhospitals.org for assistance from the CRC Support Core in transferring or terminating the agreement (Oncology studies can reach out to the SCC CTU for assistance)

University Hospitals
Clinical Research Center

Study Closure at UH

Study Name: _____

If your study is an oncology or cancer study
☐ Ensure Oncore is brought up to date prior to study closure. Reach out to Kevin Hoy (kch38@case.edu) for assistance if needed.
If your study uses Investigational Drug Services (IDS)
☐ Notify the IDS team of the impending study closure.
☐ Update any and all pharmacy files (DARF, etc.).
☐ Ensure any remaining Test Article is destroyed or returned and ensure that a certificate of destruction or return is filed in your regulatory binder.
☐ Close your Pharmacy Terminal Distributor License and DEA Registration (controlled substances trials only).
If your study uses the Dahms Clinical Research Unit (DCRU)
☐ Ensure you receive the final data download from the DCRU staff (DahmsCRU@UHhospitals.org).
☐ Contact the analytical core to determine the appropriate handling/disposal of any remaining samples in storage (DahmsCRU@UHHospitals.org)