University Hospitals
Clinical Research Center

Study Closure at UH and Open at Another Institution Study Name: _____

General Requirements
☐ Notify your department and any Sub-I's or other study staff (COI's, SC's, biostatisticians, pharmacists, etc.) of the impending study closure.
☐ 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.
☐ Ensure the sponsor approves the transferring of the study to another institution.
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
☐ Please note that it is generally not permissible to transfer PHI to another institution. If the PI wishes to transfer an active study and/or continue patient contact, it should be understood that this would require specific approval on a case-by-case basis from the UHHS Law Department, the UH IRB, and the IRB of the institution receiving the data.
☐ Reach out to the IRB at the other institution and let them know you need to transfer a study. Work with that IRB to open the study at that institution.
☐ If the study is currently enrolling or treating, work with the UH IRB to develop a plan to transfer participants, including a plan to reach out to active patients to notify them of the impending study transfer and any follow up.
☐ Once it is open at the other institution, submit a study closure form through Sparta IRB to close the study at this institution.

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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).
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. ☐ Ensure any remaining Test Article is destroyed or returned and ensure that a certificate of destruction or return is filed in the Pharmacy records for archival binder. ☐ Notify the sponsor of the new UH PI of record taking on responsibility for study document archival records. ☐ Ensure any community/satellite pharmacy have returned study drug and materials to the IDS main campus Control pharmacy or Control Affiliate Pharmacy sites are closed appropriately. ☐ 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 or disposal of any remaining samples in storage (DahmsCRU@UHhospitals.org).