University Hospitals
Clinical Research Center

Transfer Study to New UH PI Study: _____

General Requirements

☐ Notify any Sub-I's or other study staff (COI's, SC's, Biostatisticians, pharmacists, Etc.) of the impending change in Investigators.

☐ Reach out to UHResearchCompliance@UHhospitals.org for assistance with ClinicalTrials.gov registration, PI Transfer, and results reporting.

- Case comprehensive Cancer Center studies should reach out to Kevin Hoy (kch38@case.edu) for assistance.

☐ Ensure that the study sponsor approves the replacement PI.

☐ Ensure any community/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

☐ 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.

☐ If the open study will remain at UHCMC under a new PI, the departing physician must provide the name of the new PI to the Grants and Contracts team (UHCRCGrantsContracts@UHhospitals.org).

Research Finance Requirements

☐ Ensure Research Finance (ResearchBiller@UHhospitals.org) is notified to assess outstanding receivables and re-assess the award balance.

☐ If your study utilizes a patient billing calendar, reach out to your Research Finance Specialist to update the PI information on both the Velos eResearch Study Summary and on the study billing calendar. This will impact proper allocation of PI fees

Grants Accounting Requirements

☐ Ensure Grants Accounting (UHCRCGrantsAccounting@UHhospitals.org) is notified to assess outstanding receivables and re-assess the award balance.

IRB Requirements

☐ Submit a modification to the UH IRB to change the PI.

☐ Consult the UH IRB Investigator Manual to determine requirements about communicating the PI change to study participants. Once IRB approved, reach out to any patients actively enrolled in the study and notify them of the New Principal Investigator.

If your study has an IND / IDE

☐ Reach out to FDASupport@UHhospitals.org for assistance from the CRC Support Core in transferring or terminating that agreement (Oncology studies can reach out to the SCC CTU for assistance).

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If your study is an oncology or cancer study
☐ Ensure Oncore is brought up to date prior to study transfer. 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 Transfer.
☐ Have the new PI review order sets and/or prescriptions.
☐ Create a new Delegation of Authority Log with the new PI for IDS staff.
☐ Transfer revised exception request documentation to new PI per protocol, when applicable.
☐ Update any and all pharmacy files (DARF, etc.).
☐ Transfer your Pharmacy Terminal Distributor License and list new PI DEA Registrant (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 and ensure that the data download is transferred to the new investigator (DahmsCRU@UHhospitals.org)
☐ Alert the DCRU of the New PI and provide them with a copy of the IRB approval of the Investigator Change.