**Appendix E: Human Subjects Research Studies**

UH IRB Administration Office 216 844-1529 | uhirb@uhhospitals.org

CWRU IRB Office 216 368-0134 | cwru-irb@case.edu

Background: In order to ensure compliance with applicable laws and Institutional policies faculty departing CWRU with active human subjects research protocols and projects should follow the IRB Guidelines described below.

**Administrative Guidelines for Departing CWRU Faculty with Approved Human Subjects Research Studies that is led by CWRU or UH**

Faculty listed as Principal Investigators (PI) on UH or CWRU IRB approved studies must notify their Department and contact an IRB Specialist in the UH or CWRU IRB Administration Office at least 60 days before departure to facilitate and discuss the status and plan for all open studies and existing data and records.

Faculty have four options for handling active IRB Protocol(s) when they are leaving the university.

* 1. Close the Protocol completely without plans to transfer or continue the study.
  2. Close the Protocol at UH or CWRU and transfer the project to the new institution.
  3. Keep study open at UH or CWRU (naming a CWRU faculty member as the new PI) and open at new site also.
  4. Keep study open solely at UH or CWRU (naming a CWRU faulty member as the new PI).

If the research is a clinical trial, the record at clinicaltrials.gov will need to be updated.

1. If the study will remain at UH/CWRU, a new Record Owner and Responsible Party will be required.
2. If the study will be closed, the PI will need to update the clinicaltrials.gov record indicating the study has closed, provide the results of the study and post the informed consent document.
3. If the study will be transferred to another institution, you will need to work with an administrator to complete the transfer process.

* For federally funded studies or studies approved by the CWRU IRB, contact Kim Volarcik at [kav6@case.ed](mailto:kav6@case.edy)u, 216.368.0134
* For non-federally funded studies approved by the UH IRB, contact Rachael Massey at[rachael.massey@uhhospitals.org](mailto:rachael.massey@uhhospitals.org)**,** 216.844.2005

I acknowledge that I have worked with the UH/CWRU IRB to properly handle IRB protocols.

Faculty Member Signature: Date:

Department Administrator Name: Date:

Department Administrator Signature:

**Appendix E is to be returned as part of the competed Faculty Member Departure packet.**