University Hospitals

FDA ADMINISTRATIVE ACTION CHECKLIST

GA-106

Date: _____

Sponsor Investigator/PI Name: _____

Department: _____

IND/IDE #: _____

IRB #: _____

Administrative Action to be taken with the Protocol:

- ☐ Transfer to new institution Transfer to new PI at UH Close Study with IRB

Anticipated date of action noted above: _____

Please indicate and sign off that the following items have been reviewed by a current UH employee and verified as complete and in compliance:

Regulatory Review: (Print) _____

(Sign and Date) _____

Monitoring History Review: (Print) _____

(Sign and Date) _____

Data Analysis/Database Review: (Print) _____

(Sign and Date) _____

Data Safety Monitoring Board (DSMB) or Independent Safety Monitoring Review (Print)_____

(Sign and Date) _____

Grants Account/Research Billing Review: (Print) _____

(Sign and Date) _____

Stock/Supply Review and Reconciliation: (Print) _____

(Sign and Date) _____

** *please note that if any of the items are deemed incomplete or out of compliance, it is the responsibility of the sponsor-investigator to reconcile all items prior to any administrative action taking place.*

Have all appropriate parties been notified by the sponsor investigator that are listed in Research SOP GA-106?

☐ **YES** ☐ **NO**

Who will be the responsible party within the department to provide oversight for the copying and packing of study related materials?

Who is the courier service contracted to complete the transfer of documentation to new institution?

As the sponsor-investigator of the above listed protocol, I acknowledge that the information listed above is accurate and the items identified in the checklist above are current and in compliance with all federal and state requirements:

Print:_____

Sign and Date: _____

** Please submit this completed form to the Clinical Research Center, Regulatory/FDA Guidance Core for approval prior to any further administrative action: FDASupport@Uhhospitals.org