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) _______________________

1
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