**Study Title:
Sponsor:
IDE #:
Principal Investigator:**

|  |  |  |
| --- | --- | --- |
| **Task- Transfer of ownership of Investigator –Held IDE** | **Date completed and initials** | **Comments, including if an item is not applicable** |
| **Transferring Sponsor-Investigator (S-I) provide the following:**[ ]  Signed Letter (see [template](http://www.or.emory.edu/research-compliance/oric/documents1/IDE%20transfer%20request%20template%20transferrring%20S-I%201%2014%2016.doc)) including the following:* Identification of the new sponsor
* date new ownership will become effective
* statement that all responsible parties will be notified
* assurance that all IDE relevant records will be transferred to new S-I by the date the transfer takes effect
 |  |  |
| **New S-I provide the following:**[ ]  Signed Investigator Agreement[ ]  Signed Letter (see [template)](http://www.or.emory.edu/research-compliance/oric/documents1/IDE%20transfer%20request%20template%20new%20S-I.doc) including the following:* date new ownership will be effective
* statement that new S-I will assume all sponsor responsibilities
* assurance that a complete copy of transferring S-I’s files has been received
* commitment that sponsor will obtain an investigator agreement before allowing participation in the investigation
* commitment to inform all investigators and participating IRBs of the change in sponsorship
 |  |  |
| **Transferring S-I submit to FDA** [ ]  Letter signed by transferring S-I[ ]  Letter signed by new S-I[ ]  If change in protocol requested, copy of the protocol |  |  |
| **New S-I complete IDE Responsibility Form**[ ]  [S-I IDE Responsibility Form](http://www.or.emory.edu/research-compliance/oric/documents1/S-I_IDE_Responsibilities_Form.docx) submitted to ORIC[ ]  New S-I meet with ORIC to review responsibilities |  |  |
| **New S-I update financial agreements, as needed** [ ]  financial supporter (e.g., grant or contract)[ ]  CRO[ ]  materials provider - (e.g., company supplying the device) |  |  |
| **New S-I Update websites, if applicable**[ ]  Trial status updated at clinicaltrials.gov [ ]  Emory Healthcare website updated |  |  |
| **New S-I confirm regulatory documentation is complete** [ ]  Update CVs & financial disclosures for sub-investigators, site monitoring plan |  |  |
| **Study PI submit amendment to IRB**[ ]  update IDE information in eIRB [ ]  update sponsor information in consent & authorization forms[ ]  update protocol as needed |  |  |
| **Non-Emory sites document changes:**[ ]  update sponsor information in consent & authorization forms[ ]  update protocol as needed |  |  |
| **[ ]  Checklist for Transferring Ownership Completed** |  |  |
| **Printed name of person completing this form**  |  |
| **Signature of person completing this form** | **Date** |
| **New Sponsor- Investigator name (printed):** |  |
| **New Sponsor- Investigator signature:**  | **Date** |