**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** | |