|  |
| --- |
| INSTRUCTIONS |
| * **Notify the IBC of all changes to the previously approved research.**
* **THIS FORM MUST BE TYPED. Incomplete submissions will result in delayed processing.**
 |

|  |
| --- |
| SECTION 1: ABOUT THE STUDY & SUBMITTER |
| Sponsor Name and Protocol ID:  | BRANY File #:  | Principal Investigator:  |
| Person completing this form:  |   | E-mail:  | Phone:  |
| Study Title:  |

|  |
| --- |
| SECTION 2: SPECIFY SUBMITTED ITEM(S) |
| [ ]  **PROTOCOL AMENDMENT(S)** and/or **INVESTIGATOR BROCHURE UPDATE(S)**List submitted item(s) here 🡪 Version/Date:* Attach a summary of changes
* [ ] Does the **Amendment(s) to protocol require changes to the consent?** [ ] **Yes** [ ] **No**
* If **Yes,** attacha detailed summary of changes is & the revised, IRB-approved consent.
 |
| 1. **[ ]** **[ ]  CONSENT FORM REVISION** (**without amendment to protocol/investigator brochure**)
* Attach a detailed summary of consent changes is & the revised, IRB-approved consent.
* What is the reason for this revision?
 |
| 1. [ ] [ ]  **PERSONNEL CHANGE:** Indicate which personnel are to be added or removed from the study
	* For all added personnel, attach **CV (Curriculum Vitae)** and for those who will **handle the study agent**, attach evidence of **appropriate infection control training**.

|  |  |  |
| --- | --- | --- |
| **Action** | **Name** | **Handling study agent?** |
| [ ]  Remove | [ ]  Add |       | [ ]  Yes | [ ]  No |
| [ ]  Remove | [ ]  Add |       | [ ]  Yes | [ ]  No |
| [ ]  Remove | [ ]  Add |       | [ ]  Yes | [ ]  No |
| [ ]  Remove | [ ]  Add |       | [ ]  Yes | [ ]  No |
| [ ]  Remove | [ ]  Add |       | [ ]  Yes | [ ]  No |

 |
| 1. [ ]  **SERIOUS ADVERSE EVENT –** Report events that are related to the source of DNA or the host vector system. **Please attach additional sheets with supporting data!**

|  |  |
| --- | --- |
| **1. Date of Event:**  | **2. Report Date:**  |
| **3. Serious Adverse Event Description:**  |
| **4. Seriousness****:** |
| [ ]  Fatal [ ]  Immediately Life Threatening [ ]  Required/Prolonged Hospitalization | [ ]  Congenital Anomaly[ ]  Permanent Disability[ ]  Important medical event requiring intervention to prevent the outcomes above. |
| **5. Outcome:**  | **6. Relationship to Study Agent:** |
| [ ]  Fatal [ ]  Resolved [ ]  Resolved with Sequelae[ ]  Not Resolved [ ]  Unknown | [ ]  Definitely Related**\***[ ]  Probably Related**\***[ ]  Possibly Related**\***[ ]  Unrelated  | **\***If **related**, explain relationship: |

 |
|

|  |
| --- |
| 1. **[ ]  OTHER** – *please provide a description of the item(s) and attach additional sheets as necessary* :

 |

 |
| SECTION 3: PI SIGNATURE |
|  |
| Principal Investigator Signature | Date |