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

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

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| 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 |