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| INSTRUCTIONS |
| * **Do not submit this form if you are currently filing for continuing IBC approval.**
* **THIS FORM MUST BE TYPED.**
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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:  |
| SECTION 2: STUDY STATUS |
| 1. **Indicate the status of this study at your site**:
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| **[ ]**  | **Activities requiring IBC approval have been completed at this site**.* Note: Selecting this option will terminate your IBC approval. The PI is responsible to maintain other required approvals (e.g., IRB approval) if needed.
 |
| **[ ]**  | **Study is closed to enrollment at this site** (subjects are active in the study and/or remain in follow-up) but activities requiring IBC approval continued (e.g., study agent continues to be used and/or administered to subjects; blood draws to detect levels of study agent continue). * Note: You will still be required to file for continuing approval if you don’t report completion of activities requiring IBC review prior to expiration of IBC approval.
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| 1. **Date status changed:**
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| 1. **Provide a summary of study agent administration at your site:** **[ ]  🡨 Check here if not applicable.**
 |
|  | **Subject ID** | **# Doses** |  | **Subject ID** | **# Doses** |  | **Subject ID** | **# Doses** |  | **Subject ID** | **# Doses** |  |
|  |       |       |  |       |       |  |       |       |  |       |       |  |
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| 1. Have there been any emergencies, potential biohazard problems, spills, significant safety issues, contamination, sero-conversion, etc. ***not previously reported to BRANY IBC***? [ ] YES [ ]  NO
 |
| * 1. If **YES**, describe the event circumstances and the response:
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| 1. Have there been any Serious Adverse Events related to the source of DNA or the host vector system at your site that have ***not previously been reported to BRANYIBC***? [ ] YES [ ]  NO
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| * 1. If **YES**, **describe ALL SAEs.** Include description, relationship to study agent, relationship to source of DNA and/or the host vector system, and expectedness. ***Use an additional page if necessary.***

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