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| INSTRUCTIONS | | | | | | | | | | | | | | | | | | |
| * **Do not submit this form if you are currently filing for continuing IBC approval.** * **THIS FORM MUST BE TYPED.** | | | | | | | | | | | | | | | | | | |
| 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**: | | | | | | | | | | | | | | | | | | |
|  | | **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. | | | | | | | | | | | | | | | | |
| 1. **Date status changed:** | | | |  | | | | | | | | | | | | | | |
| 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: | | | | | | | | | | | | | | | | | | |
| 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 | | | | | | | | | | | | | | | | | | |
| * 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.*** | | | | | | | | | | | | | | | | | | |
| SECTION 3: PI SIGNATURE | | | | | | | | | | | | | | | | | | |
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| Principal Investigator Signature | | | | | | | | | Date | | | | | | | | | |