# SINGLE PATIENT TREATMENT FOLLOW-UP of TEST ARTICLE

|  |
| --- |
| **INSTRUCTIONS:**  Submit this form within 5 working days following the use of an investigational test article. This form is only submitted if the single patient IRB Concurrence was granted PRIOR to treatment use as noted on the Request for IRB Concurrence form.  **\*\*DO NOT SUBMIT this form if this is the INITIAL notice to the IRB-HSR\*\*** |

**IRB-HSR#/UVA Study Tracking #**      **Date Request for IRB Concurrence Form Submitted**:

|  |  |  |
| --- | --- | --- |
| **Study Team Information** | | |
| **Physician Name/Email:** | **Study/IRB Coordinator Name/Email:** | |
|  |  | |
| **Test Article Information** | | |
| **Name of Test Article:** | **Manufacturer:** | |
| **Select: IND#**        **IDE#** | **IND/IDE Holder:** | |
| **Emergency Use Information** | | |
| **Date test article administered:** | | |
|  | | |
| **Describe the outcome of the treatment, including any adverse events and/or unanticipated problems. Any subsequent developments must be reported to the IRB in a timely fashion.** [**See UVA Reporting Requirements**](https://research.virginia.edu/irb-hsr/serious-adverse-events) | | |
|  | | |
| **UVA Treating Physician Signature:** | | **Date:** |

**Submit this document to** [**IRBHSR@virginia.edu**](mailto:IRBHSR@virginia.edu)