1. **Date of occurrence** \_\_ \_\_ / \_\_ \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

Day Month Year

Time interval

Baseline

Procedure

Discharge

28 DFU

90 DFU

6 MFU

1 YFU

1. **Protocol Deviation Code**

* 1 Inclusion Criteria (specify which criteria the patient did not meet) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* 2 Exclusion Criteria (specify which criteria the patient met) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* 3 Informed Consent not signed by subject
* 4 Informed Consent signed after procedure
* 5 Informed Consent not signed by the PI
* 6 Protocol Mandated Clinical Follow up Visit
* 7 Physical Exam
* 8 Laboratory values not collected (specify which were not done) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* 9 Invasive Hemodynamics Assessment
* 10 Invasive Hemodynamics parameters not collected (specify which ones were not done) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* 11 Protocol mandated medications not given
* 12 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Reason for Deviation**

* Not done
* Out of time window
* Out of range
* Physician preference
* Does not apply
* Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Description:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. **Comment:**

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