**VA COOPERATIVE STUDY #578**

**Participant ID:__ __ __ - __ __ __ __**

## SOURCE DOCUMENT WORKSHEET FOR FORM 14: 12 HOURS POST PROCEDURE

To be completed by study personnel via medical record review on all participants after the 12 hour period following their initial angiography. Once completed, this data should be entered into eDC and this form should be filed in the Participant's Study Binder.

1. What was the study drug capsule bottle number(s) dispensed to the participant?

   ___**BottleNo**_____ _____

2. Were study drug capsules administered prior to the angiography procedure? **NacBefore**

   (*The study protocol recommends a dose of study drug capsules be administered at least one hour prior to the procedure.)*

   ☐ Yes **1**

   ☐ No (If no, complete a Protocol Deviation Form if needed.) **2**

   **Blank: -1**

3. On the day of the participant's angiography procedure, were study drug capsules administered after the angiography procedure? **NacAfter** **Blank: -1**

   (*The study protocol recommends a dose of study drug capsules be administered at least one hour after the procedure.)*

   ☐ Yes **1**

   ☐ No (If no, complete a Protocol Deviation Form if needed) **2**

4. Was the participant given any **non-study IV fluid** within the 12 hours following their angiography procedure? **NSIVPost** **Blank: -1**

   ☐ Yes (If yes, specify the type of fluid below) **1**

   ☐ No **2**

   What type of non-study IV fluid was the participant given? (*Check all that apply*.)

   ☐ 5. Saline **SalinePostProc** **Yes: 1** **No: 2** **Blank: -1**

   ☐ 6. Sodium bicarbonate **BicarbPostProc** **Yes: 1** **No: 2** **Blank: -1**

   ☐ 7. Other **OtherIVPostProc** **Yes: 1** **No: 2** **Blank: -1**

   (8. Specify other non-study IV fluid type: ____**OtherIVPostProcSpecify**_____)

9. Did the participant require the use of any IV inotropes within the 12 hours following their angiography procedure? *(For example, inamrinone (Inocor), milrinone (Primacor), dobutamine)* **Inotrope12Post**

   ☐ Yes **1**

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☐ No **2**

**Blank: -1**

10. Did the participant require the use of any IV vasodilators within the 12 hours following their angiography procedure? (For example, nesiritide (Natrecor) or nitrates/GTN) **Vasodilator12Post** **Blank: -1**

☐ Yes **1**

☐ No **2**

11. Did the participant require the use of any IV vasopressors within the 12 hours following their angiography procedure? *(For example, dopamine (Intropin), phenylephrine (Neosynephrine), norepinephrine/noradrenalin (Levophed), epinephrine/adrenalin, ephredrine, vasopressin, metarminol bitartrate (Aramine))* **Vasopressor12Post** **Blank: -1**

☐ Yes **1**

☐ No **2**

12. Did the participant experience any episodes of hypotension [*defined as systolic blood pressure <90 mmHg and/or MAP < 55 mmHg*] within the 12 hours following their angiography? **Hypo12Post** **Blank: -1**

☐ Yes **1**

☐ No **2**

13. Did the participant require any additional radiological procedures involving contrast administration including coronary or non-coronary angiography or computed tomography within the 12 hours following their angiography? **AddDye12Post** **Blank: -1**

☐ Yes **If yes, answer Q14.1-Q14.6** **1**

☐ No **2**

14.1 Was the additional procedure planned? **AddDyePost12Planned** **Blank: -1**

☐ Yes **1**

☐ No **2**

14.2. What contrast dye was administered during the additional procedure? **AddDyeType12Post**

**Blank: -1**

☐ Iodixanol (Visipaque) **1**

☐ Iopamidol (Isovue) 2

☐ Iopromide (Ultravist) **3**

☐ Ioversol (Optiray) **4**

☐ Ioxilan (Oxilan) **5**

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☐ Ioxaglate (Hexabrix) **If checked, answer Q14.4** **6**

☐ Iohexol (Omnipaque) **If checked, answer Q14.4** **7**

☐ Other contrast dye **8** (14.3 Specify: ____**AddDye12PostOth**___)

14.4 The contrast dye you noted as administered during the procedure (ioxaglate (Hexabrix) or iohexol (Omnipaque)) has been associated with a higher risk of contrast nephropathy. What was the reason for choosing this contrast dye type? **AddDye12PostExplain** **Blank: -1**

☐ It is the only contrast dye available at my facility. **1**

☐ It is the least expensive with comparable safety. **2**

☐ No specific reason **3**

☐ Other reason **4** (14.5 Specify: ___**AddDye12PostExplainOth**____)

14.6 What was the total volume of contrast administered during the additional procedure? _____ mls **AddDye12PostVol**

**REMINDER**: All participants are required to have a blood sample collected 96 hours post-angiography to be sent to the Central Laboratory. If a participant is discharged from the hospital before 96 hours, determine whether he/she will be able to return to the site for this blood draw or, if unable, if the mobile specimen collection service will be required (US participants only).

15. Date Form Completed: ___**F14Complete**__

Signature of person completing the form: _____