Participant ID: _____ Participant Initials: _____

Clinical Center: _____ Site: _____ Visit Number: _____ Reset Patient / RC

CRF Date: ____ / ____ / ____ RC ID: _____ Reset All

PROCEDURAL OR UNANTICIPATED PROBLEMS

1. Has the participant had any reportable procedural or unanticipated problem(s) **[see codes below]**? ❑1 Yes ❑0 No

   a. If ***YES***, how many events? ___ ___

2. Problem report [**if more than 2 problems, continue on additional page(s)**]:

Problem #	PUP Code See codes below	Date of Onset MM/DD/YYYY	Treatment for PUP No = 0 Yes = 1
	__ __ __ - __ __	__ __/ __ __/ __ __ __ __	
Comments: [Codes for ABI, BIA, EBT, ECG, ECO and MIS require brief narrative explaining type of occurrence (limit to 25 words)]			

Problem #	PUP Code See codes below	Date of Onset MM/DD/YYYY	Treatment for PUP No = 0 Yes = 1
	__ __ __ - __ __	__ __/ __ __/ __ __ __ __	
Comments: [Codes for ABI, BIA, EBT, ECG, ECO and MIS require brief narrative explaining type of occurrence (limit to 25 words)]			

PUP Codes:

ABI-01	Ankle Brachial Index (ABI)
	Blood Testing-related
BLD-01	Presyncopal episode or fainting episode
BLD-02	Severe hematoma
BLD-03	Prolonged bleeding
BLD-04	Infection at the needle insertion site
BIA-01	Bioelectrical Impedance Analysis (BIA)
EBT-01	A pregnant or breast feeding woman, excluded from this procedure per the study protocol, is inadvertently exposed to this test
ECG-01	Electrocardiogram (ECG)
ECO-01	Echocardiogram

	GFR Testing-related
GFR-01	An inadvertent administration of a dose of Iothalamate, greater than the prescribed dose, occurs
GFR-02	Allergic reaction to Iothalamate
GFR-03	A pregnant or breast feeding woman, excluded from this test per the study protocol, is inadvertently exposed to this test
GFR-04	Fluid overload in association with GFR, per clinical assessment
GFR-05	Symptomatic hypoglycemic event in diabetic participants undergoing GFR test
MIS-01	For example, "the phlebotomist was stuck with the needle used to draw the participant's blood" or any other problem not coded elsewhere on this grid

Important:

- This CRF must be completed and entered into the database within 72 hours of 'first knowledge' of the "unanticipated problem."
- In accordance with 45 CFR 46, all "unanticipated problems involving risks to subjects or others" must be promptly reported to:
  1. Appropriate institutional officials (e.g., PI and others, prn).
  2. Your IRB (in accordance with their reporting timelines/guidelines).
  3. The Sponsor (for this study, Sponsor notification will occur via regular reports from the SDCC rather than from direct site reporting).