# INSTRUCTIONS FOR STUDY MEDICATION FORM 63 Form # 63A

Designated personnel will print this form in preparation for each study visit or date of action (whenever a change in medication occurs between study visits). Electronically generated forms will be prepopulated as much as possible, based on information in the database, including existing drug/dose at the visit/date of action. *All prepopulated information must be confirmed or corrected.* Alternatively, the form may be printed blank and completed entirely by hand. The completed paper form is to data entered within 3 business days.

This form consists of 4 sections (washout, ACE+ARB, open label, and all study drugs). Determine if each section should be skipped or completed. In each section, the first question (1, 3, 5) seeks confirmation of existing drugs/doses the participant ***has taken*** up to the time of the visit/date of action. The second question (2, 4, 6) requests drugs/doses the participant ***will take during the next period*** (after the current visit/date of action). The fourth section asks how drugs were dispensed and provides space for comments.

**WASHOUT DRUGS:** This section captures labetalol and/or clonidine only. Note that any *additional* or *pre-existing* blood pressure medications taken during the washout period or beyond must *not* be reported on this form, but are to be reported on
Concomitant Medication Form 6.

If the participant has not taken washout drugs at the visit/date of action, or does not need washout drugs at the current visit/date of action, or a washout period is not required, check the first checkbox and skip to the next section (ACE/ARB). If a washout period is required, but washout drugs are not prescribed, check the second box, enter anticipated start date and skip to next section (ACE/ARB).

#1. Existing Drug/Dose: This question refers to washout drugs the participant *has taken* up to the time of the visit or date of action. When generated, the participant's current/existing washout drug(s), dose(s) and start date(s) will print here. If the participant is taking washout drugs, check the appropriate box and complete question #1 (A&B). Verify each drug the participant is taking, as well as dose and start date for *last period*. Make any necessary corrections. Check the "participant confirmed" box to complete #1A, then document compliance in #1B. If the participant is not currently taking washout drugs, check the appropriate box in #1 and skip to #2.

#2. Next Period: This section refers to washout drug the participant *will take* after the visit or date of action. Indicate if washout drugs will be initiated and/or modified and the reason(s). In 2C, write the drug name(s), dose(s) and start date(s) for the *next period*.

**ACE+ARB THERAPY:** This section captures lisinopril and telmisartan/placebo only.

If the participant is on or will begin taking ACE+ARB, check the first checkbox and complete this section. If the participant has not begun ACE+ARB, will not begin at this visit, or has discontinued ACE+ARB, check the second box and skip to the next section.

#3. Existing Drug/Dose: This question refers to ACE+ARB the participant *has taken* up to the time of the visit or date of action. When generated, participant's current/existing drug(s), dose(s) and start date(s) will print here. Verify each drug the participant is taking, as well as dose and start date for the *last period*. Make any necessary corrections. Check "participant confirmed" box to complete #3A, and document compliance in #3B.

#4. Next Period: This section refers to ACE+ARB the participant *will take* after the visit or date of action. Indicate if ACE+ARB will be initiated and/or modified and the reason(s). In 4C, write the drug name(s), dose(s) and start date(s) for the *next period*.

**OPEN-LABEL DRUGS:** This section captures open-label BP drugs not captured in the first two sections.

If the participant is on or will begin taking open-label BP drugs at this visit, check the first checkbox and complete this section. If the participant is not taking open-label drugs, or will not begin taking them at this visit, check the second box and skip to the next section.

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#5. Existing Drug/Dose: This question refers to open-label drugs the participant *has taken* up to the time of the visit or date of action. When generated, the participant's current/existing drug(s), dose(s) and start date(s) will print here. Verify each drug the participant is taking, as well as dose and start date for the *last period*, and make any corrections necessary. Check the "participant confirmed" box to complete #5A, then document compliance in #5B.

#6. Next Period: This section refers to open-label drugs the participant *will take* after the visit or date of action. Indicate if open-label drugs will be initiated and/or modified and the reason(s). In 6C, write the drug name(s), dose(s) & start date(s) for the *next period*.

**ALL STUDY DRUGS:** This section captures information about all study drugs listed in the first three sections.

#7. Dispensing: Indicate how drugs were dispensed, or check "N/A" if no drugs were dispensed.

#8. Comments: Include comments about drugs, dosing, etc. Comments are for clarification only and cannot be used in study analysis.