Medication Survey Form Instructions MSR Version F, 12/08/2008 QxQ Date: 01/26/2009

I. GENERAL INSTRUCTIONS

The Medication Survey Form (MSR) is completed during the screen/baseline combination visit or the randomization visit and at clinic follow-up visits. The MSR is completed after the Medication Listing Form (MSL) has been administered. It is intended to classify medications used by each participant based on the FAVORIT medication thesaurus.

During each visit the MSR must be filled out completely (i.e., do not update the previous MSR). If medications are listed on the MSL that were prescribed but they are currently not being taken by the participant (i.e., not taken during the past month), then these medications should not be recorded on the MSR. Please note if the participant is taking aspirin regularly, it should be recorded on the MSR even if it is not prescribed.

The FAVORIT medication thesaurus is located directly behind the MSR in the Manual of Procedures (MOP). This thesaurus includes the generic names, trade names and manufacturer for all medications of interest to the FAVORIT study. This thesaurus will be periodically updated for both the United States and Canada. The order of medication categories, subcategories, and individual medication on the FAVORIT medication thesaurus and the MSR are identical. Information from the MSL form and the FAVORIT medication thesaurus must be used simultaneously when transferring data from the MSL form to the MSR form.

Interviewers must be familiar with and understand chapter 14: Administrative Procedures, in the MOP, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTIONS

If any medications are listed on the MSL but are not on the FAVORIT medication thesaurus then they should **not** be recorded on the MSR. If a new medication is not listed on the medication thesaurus but you believe it should be included, contact the DCC.

A. Class, Subclass, or Specific Drug

1-56. These items deal with the medication(s) used by the participant based on drug class, subclass, or specific drug name. Record the source of information on each medication exactly as indicated on the MSL. Record "No" if the medication is not on the MSL.

Aspirin (item 33): FAVORIT is interested in regular aspirin use, regardless of whether it is prescribed or not. "Regular" is defined as at least once a week for several months. Do **not** include Tylenol, Advil, or other NSAIDS (non-steroidal anti-inflammatory drugs) that do not contain aspirin.

B. Hypertension Medication Use

57. Treatment for Hypertension:

- a. If over the past month the patient has been undergoing treatment for hypertension with one or more specific anti-hypertensive medications (i.e., the participant was given a prescribed medication, regardless of whether they are taking it or not) record "Yes" then continue to item 57b. If the patient is not currently under this treatment, record "No" then go to item 58.
- b. Indicate the source of information that the participant is undergoing treatment for hypertension in item 57a. If the source is from the participant's medical record/chart, record "A". Otherwise, if the participant provided this information, record "B"

- 58. Record the date of the visit when information was obtained using the US order (Month/Day/Year). Record numbers using leading zeroes where necessary to fill all boxes.
- 59. Record whether the data was collected directly into the date entry system on the computer or whether it was recorded on a paper form.
- 60. Record the examiner's initials using the 3 digit initials of the person completing this form. If he/she only has two initials, then record the 1^{st} name initial in the first box, the last name initial in the 2^{nd} box and leave the third box blank.

Medication Survey Form Instructions MSR Version E, 08/11/2008 QxQ Date: 08/11/2008

I. GENERAL INSTRUCTIONS

The Medication Survey Form (MSR) is completed during the screen/baseline combination visit or the randomization visit and at clinic follow-up visits. The MSR is completed after the Medication Listing Form (MSL) has been administered. It is intended to classify medications used by each participant based on the FAVORIT medication thesaurus.

During each visit the MSR must be filled out completely (i.e., do not update the previous MSR). If medications are listed on the MSL that were prescribed but they are currently not being taken by the participant (i.e., not taken during the past month), then these medications should not be recorded on the MSR. Please note if the participant is taking aspirin regularly, it should be recorded on the MSR even if it is not prescribed.

The FAVORIT medication thesaurus is located directly behind the MSR in the Manual of Procedures (MOP). This thesaurus includes the generic names, trade names and manufacturer for all medications of interest to the FAVORIT study. This thesaurus will be periodically updated for both the United States and Canada. The order of medication categories, subcategories, and individual medication on the FAVORIT medication thesaurus and the MSR are identical. Information from the MSL form and the FAVORIT medication thesaurus must be used simultaneously when transferring data from the MSL form to the MSR form.

Interviewers must be familiar with and understand chapter 14: Administrative Procedures, in the MOP, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTIONS

If any medications are listed on the MSL but are not on the FAVORIT medication thesaurus then they should **not** be recorded on the MSR. If a new medication is not listed on the medication thesaurus but you believe it should be included, contact the DCC.

A. Class, Subclass, or Specific Drug

1-55. These items deal with the medication(s) used by the participant based on drug class, subclass, or specific drug name. Record the source of information on each medication exactly as indicated on the MSL. Record "No" if the medication is not on the MSL.

Aspirin (item 33): FAVORIT is interested in regular aspirin use, regardless of whether it is prescribed or not. "Regular" is defined as at least once a week for several months. Do **not** include Tylenol, Advil, or other NSAIDS (non-steroidal anti-inflammatory drugs) that do not contain aspirin.

B. Hypertension Medication Use

56. Treatment for Hypertension:

- a. If over the past month the patient has been undergoing treatment for hypertension with one or more specific anti-hypertensive medications (i.e., the participant was given a prescribed medication, regardless of whether they are taking it or not) record "Yes" then continue to item 56b. If the patient is not currently under this treatment, record "No" then go to item 57.
- b. Indicate the source of information that the participant is undergoing treatment for hypertension in item 56a. If the source is from the participant's medical record/chart, record "A". Otherwise, if the participant provided this information, record "B"

- 57. Record the date of the visit when information was obtained using the US order (Month/Day/Year). Record numbers using leading zeroes where necessary to fill all boxes.
- 58. Record whether the data was collected directly into the date entry system on the computer or whether it was recorded on a paper form.
- 59. Record the examiner's initials using the 3 digit initials of the person completing this form. If he/she only has two initials, then record the 1^{st} name initial in the first box, the last name initial in the 2^{nd} box and leave the third box blank.

Medication Survey Form Instructions MSR Version D, 11/08/2007 QxQ Date: 11/22/2007

I. GENERAL INSTRUCTIONS

The Medication Survey Form (MSR) is completed during the screen/baseline combination visit or the randomization visit and at clinic follow-up visits. The MSR is completed after the Medication Listing Form (MSL) has been administered. It is intended to classify medications used by each participant based on the FAVORIT medication thesaurus.

During each visit the MSR must be filled out completely (i.e., do not update the previous MSR). If medications are listed on the MSL that were prescribed but they are currently not being taken by the participant (i.e., not taken during the past month), then these medications should not be recorded on the MSR. Please note if the participant is taking aspirin regularly, it should be recorded on the MSR even if it is not prescribed.

The FAVORIT medication thesaurus is located directly behind the MSR in the Manual of Procedures (MOP). This thesaurus includes the generic names, trade names and manufacturer for all medications of interest to the FAVORIT study. This thesaurus will be periodically updated for both the United States and Canada. The order of medication categories, subcategories, and individual medication on the FAVORIT medication thesaurus and the MSR are identical. Information from the MSL form and the FAVORIT medication thesaurus must be used simultaneously when transferring data from the MSL form to the MSR form.

Interviewers must be familiar with and understand chapter 14: Administrative Procedures, in the MOP, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTIONS

If any medications are listed on the MSL but are not on the FAVORIT medication thesaurus then they should **not** be recorded on the MSR. If a new medication is not listed on the medication thesaurus but you believe it should be included, contact the DCC.

A. Class, Subclass, or Specific Drug

1-46. These items deal with the medication(s) used by the participant based on drug class, subclass, or specific drug name. Record the source of information on each medication exactly as indicated on the MSL. Record "No" if the medication is not on the MSL.

Aspirin (item 33): FAVORIT is interested in regular aspirin use, regardless of whether it is prescribed or not. "Regular" is defined as at least once a week for several months. Do **not** include Tylenol, Advil, or other NSAIDS (non-steroidal anti-inflammatory drugs) that do not contain aspirin.

B. Hypertension Medication Use

47. Treatment for Hypertension:

- a. If over the past month the patient has been undergoing treatment for hypertension with one or more specific anti-hypertensive medications (i.e., the participant was given a prescribed medication, regardless of whether they are taking it or not) record "Yes" then continue to item 46b. If the patient is not currently under this treatment, record "No" then go to item 47.
- b. Indicate the source of information that the participant is undergoing treatment for hypertension in item 46a. If the source is from the participant's medical record/chart, record "A". Otherwise, if the participant provided this information, record "B"

- 48. Record the date of the visit when information was obtained using the US order (Month/Day/Year). Record numbers using leading zeroes where necessary to fill all boxes.
- 49. Record whether the data was collected directly into the date entry system on the computer or whether it was recorded on a paper form.
- 50. Record the examiner's initials using the 3 digit initials of the person completing this form. If he/she only has two initials, then record the 1^{st} name initial in the first box, the last name initial in the 2^{nd} box and leave the third box blank.

Medication Survey Form Instructions MSR Version C, 02/22/2005 QxQ Date: 03/02/2005

I. GENERAL INSTRUCTIONS

The Medication Survey Form (MSR) is completed during the screen/baseline combination visit or the randomization visit and at clinic follow-up visits. The MSR is completed after the Medication Listing Form (MSL) has been administered. It is intended to classify medications used by each participant based on the FAVORIT medication thesaurus.

During each visit the MSR must be filled out completely (i.e., do not update the previous MSR). If medications are listed on the MSL that were prescribed but they are currently not being taken by the participant (i.e., not taken during the past month), then these medications should not be recorded on the MSR. Please note if the participant is taking aspirin regularly, it should be recorded on the MSR even if it is not prescribed.

The FAVORIT medication thesaurus is located directly behind the MSR in the Manual of Procedures (MOP). This thesaurus includes the generic names, trade names and manufacturer for all medications of interest to the FAVORIT study. This thesaurus will be periodically updated for both the United States and Canada. The order of medication categories, subcategories, and individual medication on the FAVORIT medication thesaurus and the MSR are identical. Information from the MSL form and the FAVORIT medication thesaurus must be used simultaneously when transferring data from the MSL form to the MSR form.

Interviewers must be familiar with and understand chapter 14: Administrative Procedures, in the MOP, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTIONS

If any medications are listed on the MSL but are not on the FAVORIT medication thesaurus then they should **not** be recorded on the MSR. If a new medication is not listed on the medication thesaurus but you believe it should be included, contact the DCC.

A. Class, Subclass, or Specific Drug

1-45. These items deal with the medication(s) used by the participant based on drug class, subclass, or specific drug name. Record the source of information on each medication exactly as indicated on the MSL. Record "No" if the medication is not on the MSL.

Aspirin (item 33): FAVORIT is interested in regular aspirin use, regardless of whether it is prescribed or not. "Regular" is defined as at least once a week for several months. Do **not** include Tylenol, Advil, or other NSAIDS (non-steroidal anti-inflammatory drugs) that do not contain aspirin.

B. Hypertension Medication Use

46. Treatment for Hypertension:

- a. If over the past month the patient has been undergoing treatment for hypertension with one or more specific anti-hypertensive medications (i.e., the participant was given a prescribed medication, regardless of whether they are taking it or not) record "Yes" then continue to item 46b. If the patient is not currently under this treatment, record "No" then go to item 47.
- b. Indicate the source of information that the participant is undergoing treatment for hypertension in item 46a. If the source is from the participant's medical record/chart, record "A". Otherwise, if the participant provided this information, record "B"

- 47. Record the date of the visit when information was obtained using the US order (Month/Day/Year). Record numbers using leading zeroes where necessary to fill all boxes.
- 48. Record whether the data was collected directly into the date entry system on the computer or whether it was recorded on a paper form.
- 49. Record the examiner's initials using the 3 digit initials of the person completing this form. If he/she only has two initials, then record the 1^{st} name initial in the first box, the last name initial in the 2^{nd} box and leave the third box blank.

Medication Survey Form Instructions MSR Version B, 03/13/2003 QxQ Date: 03/13/2003

I. GENERAL INSTRUCTIONS

The Medication Survey Form (MSR) is completed during the randomization visit and at clinic follow-up visits. The MSR is completed after the Medication Listing Form (MSL) has been administered. It is intended to classify medications used by each participant based on the FAVORIT medication thesaurus.

During each visit the MSR must be filled out completely (i.e., do not update the previous MSR). If medications are listed on the MSL that were prescribed but they are currently not being taken by the participant (i.e., not taken during the past month), then these medications should not be recorded on the MSR. Please note if the participant is taking aspirin regularly, it should be recorded on the MSR even if it is not prescribed.

The FAVORIT medication thesaurus is located directly behind the MSR in the Manual of Procedures (MOP). This thesaurus includes the generic names, trade names and manufacturer for all medications of interest to the FAVORIT study. This thesaurus will be periodically updated for both the United States and Canada. The order of medication categories, subcategories, and individual medication on the FAVORIT medication thesaurus and the MSR are identical. Information from the MSL form and the FAVORIT medication thesaurus must be used simultaneously when transferring data from the MSL form to the MSR form.

Interviewers must be familiar with and understand chapter 14: Administrative Procedures, in the MOP, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTIONS

If any medications are listed on the MSL but are not on the FAVORIT medication thesaurus then they should **not** be recorded on the MSR. If a new medication is not listed on the medication thesaurus but you believe it should be included, contact the DCC.

A. Class, Subclass, or Specific Drug

1-45. These items deal with the medication(s) used by the participant based on drug class, subclass, or specific drug name. Record the source of information on each medication exactly as indicated on the MSL. Record "No" if the medication is not on the MSL.

Aspirin (item 33): FAVORIT is interested in regular aspirin use, regardless of whether it is prescribed or not. "Regular" is defined as at least once a week for several months. Do **not** include Tylenol, Advil, or other NSAIDS (non-steroidal anti-inflammatory drugs) that do not contain aspirin.

B. Hypertension Medication Use

46. Treatment for Hypertension:

- a. If over the past month the patient has been undergoing treatment for hypertension with one or more specific anti-hypertensive medications (i.e., the participant was given a prescribed medication, regardless of whether they are taking it or not) record "Yes" then continue to item 46b. If the patient is not currently under this treatment, record "No" then go to item 47.
- b. Indicate the source of information that the participant is undergoing treatment for hypertension in item 46a. If the source is from the participant's medical record/chart, record "A". Otherwise, if the participant provided this information, record "B"

- 47. Record the date of the visit when information was obtained using the US order (Month/Day/Year). Record numbers using leading zeroes where necessary to fill all boxes.
- 48. Record the examiner's initials using the 3 digit initials of the person completing this form. If he/she only has two initials, then record the 1st name initial in the first box, the last name initial in the 2nd box and leave the third box blank.

Medication Survey Form Instructions MSR Version A, 02/18/2002 QxQ Date: 06/10/2002

I. GENERAL INSTRUCTIONS

The Medication Survey Form (MSR) is completed during the randomization visit and at clinic follow-up visits. The MSR is completed after the Medication Listing Form (MSL) has been administered. It is intended to classify medications used by each participant based on the FAVORIT medication thesaurus.

During each visit the MSR must be filled out completely (i.e., do not update the previous MSR). If medications are listed on the MSL that were prescribed but they are currently not being taken by the participant (i.e., not taken during the past month), then these medications should not be recorded on the MSR. Please note if the participant is taking aspirin regularly, it should be recorded on the MSR even if it is not prescribed.

The FAVORIT medication thesaurus is located directly behind the MSR in the Manual of Procedures (MOP). This thesaurus includes the generic names, trade names and manufacturer for all medications of interest to the FAVORIT study. This thesaurus will be periodically updated for both the United States and Canada. The order of medication categories, subcategories, and individual medication on the FAVORIT medication thesaurus and the MSR are identical. Information from the MSL form and the FAVORIT medication thesaurus must be used simultaneously when transferring data from the MSL form to the MSR form.

Interviewers must be familiar with and understand chapter 14: Administrative Procedures, in the MOP, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTIONS

If any medications are listed on the MSL but are not on the FAVORIT medication thesaurus then they should **not** be recorded on the MSR. If a new medication is not listed on the medication thesaurus but you believe it should be included, contact the DCC.

A. Class, Subclass, or Specific Drug

1-43. These items deal with the medication(s) used by the participant based on drug class, subclass, or specific drug name. Record the source of information on each medication exactly as indicated on the MSL. Record "No" if the medication is not on the MSL.

Aspirin (item 31): FAVORIT is interested in regular aspirin use, regardless of whether it is prescribed or not. "Regular" is defined as at least once a week for several months. Do **not** include Tylenol, Advil, or other NSAIDS (non-steroidal anti-inflammatory drugs) that do not contain aspirin.

B. Hypertension Medication Use

44. Treatment for Hypertension:

- a. If over the past month the patient has been undergoing treatment for hypertension with one or more specific anti-hypertensive medications (i.e., the participant was given a prescribed medication, regardless of whether they are taking it or not) record "Yes" then continue to item 44b. If the patient is not currently under this treatment, record "No" then go to item 45.
- b. Indicate the source of information that the participant is undergoing treatment for hypertension in item 44a. If the source is from the participant's medical record/chart, record "A". Otherwise, if the participant provided this information, record "B"

- 45. Record the date of the visit when information was obtained using the US order (Month/Day/Year). Record numbers using leading zeroes where necessary to fill all boxes.
- 46. Record the examiner's initials using the 3 digit initials of the person completing this form. If he/she only has two initials, then record the 1st name initial in the first box, the last name initial in the 2nd box and leave the third box blank.