KCMC Clinical Trials Unit	STANDARD OPERATING PROCEDURE	Effective Date	SOP-Number CTU 006-01
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Title: MANAGING STUDY MEDICATIONS

SOP References: Study Visits **Supersedes:** N/A

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	Review Date	Revision Date	Signature
Annual Review:			

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PURPOSE: To establish a procedure for the management of study medications by the clinical research coordinator (or research nurse designee).

POLICY: The clinical research coordinator (or research nurse designee) will collaborate with the Principal Investigator, study team, including research pharmacist, and primary care provider in the management of study medications for patients enrolled in clinical trials in accordance with the protocol, as well as Federal, Sponsor and \institutional regulations and guidelines.

RESPONSIBILITY: The clinical research coordinator is educated and trained to evaluate, monitor and manage study medications for patients enrolled clinical trials.

DEFINITIONS:

Adherence: Ability to follow prescribed treatment plan. Many factors can effect adherence, including: clear directions, scope of services, accessibility, adverse drug reaction, level of motivation, belief system, mental health, satisfaction with treatment, social support, number of pills, dosing frequency, and diet restrictions. Multi-disciplinary interventions and counseling, use of reminders, and education aids may improve adherence.

Adverse Drug Reaction (ADR): Any unintended response to medicinal product that causal relationship between the event and study product is reasonably possible, probable, or cannot be ruled out.

Blinded Therapy: A masking procedure in which one or more of the parties involved in the clinical research trial is kept unaware of the treatment assignment(s) in order to diminish any possible bias. Single-blinding usually refers to the subject(s) being unaware of which therapy he/she is receiving. Double-blinding usually refers to the subject(s), Investigator(s), research team, Monitor, and, in some cases, data analyst(s) and pharmacist being unaware of the treatment assignment(s). Blinded therapy is often achieved with the use of look-a-like placebos in addition to active study product.

Commercial Drug Supply: Approved medications that are not supplied by a research study.

Concomitant Medications: Medications taken by a clinical research participant in addition to study/investigational treatment. Concomitant medications include any prescribed or over-the-counter medications, folk and herbal treatments, vitamin supplements, and illicit drugs or agents acquired on the street to alter body or mind function.

Investigational Product: Any new pharmaceutical agent, or placebo being investigated for safety, effectiveness of treatment, and tolerability. Investigational product may include a drug previously approved by regulatory authorities (Food and Drug Administration) but in a new formulation or for a different indication for which it was approved.

Open-Label Study Medications: Study medications that are not blinded.

Placebo: A placebo is an inactive pill, liquid, or powder that has no treatment value. Placebos are used to eliminate bias that may be produced by the participant or research team in thinking one treatment is superior to another or simply anticipating effect. In clinical trials using investigational products, placebos are often used to compare the treatment's effectiveness. No acutely ill participant receives a placebo if there is a known beneficial treatment. Most studies compare the accepted standard treatment + investigational drug against the accepted standard + placebo-substitute for the investigational drug. Placebos may also be used when comparing various accepted regimens against one another.

Study Medications: Any drug or agent provided by the research study. Study medications may include investigational products, placebo, or drug products that have already received regulatory authority approval.

Tolerability:

B. PROCEDURES:

1. Medications: The clinical research coordinator (or designee) must document the initiation of all study medications and concomitant medications, changes and/or discontinuations on source document study note or flow sheet, or on a medication tracking log kept for each study subject and updated at each study visit in addition to records kept by the research pharmacy.

a. Study Treatment: The clinical research coordinator (or designee) will collaborate with the research pharmacist regarding initiating, dispensing, changing, or discontinuing study medications. The clinical research coordinator (or designee) will refer study patients to the pharmacist as necessary for counseling/education. The clinical research coordinator will review and document medication adherence and tolerability with the research subject during study evaluations as required by the protocol.

i. On-Study Treatment: The clinical research coordinator (or designee) must document the study agent, dose, route, and frequency for each study medication on the source document clinic note or visit flow sheet. If a medication log is used to capture this information, the source clinic note or flow sheet should note that information has been updated on the medication log at each study visit. Documentation of study medication on the clinic source note or flow sheet is required in addition to study documentation standards that the research pharmacy must keep. Clinical source documentation must include, adherence to prescribed dose, tolerability, counseling, and return and dispensation of new study drug supply. If required by protocol, the same information may also need to be captured on CRF. The Principal Investigator will review, sign and date the source document capturing study treatment.

ii. Dose Interruptions/Discontinuations: The clinical research coordinator (or designee) will initiate dose interruptions or

treatment discontinuation of study treatment in collaboration with the Principal Investigator, Study Team, and Primary Care Provider in accordance with protocol directives. Any changes or discontinuations of study treatment must document agent, dose, route, frequency for each study medication, and reason for discontinuation on the visit source document clinic note or flow sheet, or medication log. If a medication log is used to capture this information, the source clinic note or flow sheet should note that information has been updated on the medication log. Dose interruption or discontinuation must be confirmed and documented at each study visit. If the study subject re-initiates study medication in-between study visits, a source clinic note must document the date drug was re-initiated, including: study agent, dose, route, and frequency, as well as why the study drug was re-initiated. Changes, interruptions, discontinuations, and re-initiation of study treatment will be reported on CRF as required by the protocol and data management center. The Principal Investigator will review, sign and date the source document capturing study treatment.

b. <u>Concomitant Medications</u>: If the protocol requires documentation of concomitant medications, the clinical research coordinator (or designee) must document concomitant medications by listing the agent, dose, route, and frequency for each concomitant medication on the visit source clinic note or flow sheet, or medication log for every study visit as required by the protocol. If a medication log is used to capture this information, the source clinic note or flow sheet should note that information has been updated on the medication log at each study visit. The Principal Investigator will review, sign and date the source document capturing concomitant medications.

i. Dose Interruptions/Discontinuations: The clinical research coordinator (designee) will review concomitant medications at each study evaluation to identify changes or discontinuation of concomitant medication(s.) This information will be documented on the visit source clinic note or flow sheet, or medication log for every study visit (as described above). The clinical research coordinator will report concomitant dose interruptions or discontinuations on CRF as required by the protocol and the data management center.

ii. Exclusionary Medications: The clinical research coordinator (or

designee) will continuously check concomitant medications against exclusionary medications listed in the protocol. The clinical research coordinator (or designee) will counsel the study participant to check with the research team prior to initiating any concomitant medications for assessment of drug-drug interactions or exclusion on protocol. The clinical research coordinator (or designee) will work together with the research pharmacist in assessing compatibility of study agents with concomitant medications. If an exclusionary medication is noted, the clinical research coordinator (or designee) will work together with the research pharmacist, Principal Investigator, and Primary Care Provider to establish whether a non-exclusionary substitution exists that the clinical research subject may safely take. If no reasonable substitution exists and it is necessary for the study subject to receive concomitant therapy, the clinical research coordinator will notify the Principal Investigator and study team for course of action.

This SOP has been read and understood by:

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