

VAMHCS RESEARCH COMPLIANCE OFFICE

CLINICAL WARNING

REQUIRED (Complete all of the following):

Protocol Title:

Principal Investigator:

Phone Number:

Pager:

E-Mail:

Co-Investigators:

Study Coordinator:

Phone Number:

Pager:

E-Mail:

Important Information (including any FDA-approved medications and/or medical devices)

OPTIONAL (Complete the following as determined by the PI):

Persons Responsible For Prescribing Drugs For This Study:

1) All Designations For Drug #1

Generic Name:

Trade Name:

Dosage Forms and Strengths:

Source of Drug:

Expected Therapeutic Effects:

Usual Therapeutic Dose and Range for Study:

Route and Rate Of Administration:

Possible Adverse Effects, Known Side Effects and Toxicities:

Storage:

Special Handling Precautions For Pharmacists and Nurses (describe in detail):

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2) All Designations For Drug #2

Generic Name:

Trade Name:

Dosage Forms and Strengths:

Source of Drug:

Expected Therapeutic Effects:

Usual Therapeutic Dose and Range for Study:

Route and Rate Of Administration:

Possible Adverse Effects, Known Side Effects and Toxicities:

Storage:

Special Handling Precautions For Pharmacists and Nurses (describe in detail):