Research Advisory Panel of California
Office of the Attorney General
455 Golden Gate Avenue, Suite 11000
San Francisco, California 94102-7004

For RAPC Office Use Only

Date Received_____

PR#:_____

Application for Review

HUMAN RESEARCH
SCHEDULE I OR SCHEDULE II CONTROLLED SUBSTANCES

All applicable sections of the application must be completed within the form field provided. Please type or print legibly. Note that certain fields require supporting attachments. Incomplete fields or missing attachments will delay the application process.

A. TITLE AND DESCRIPTION OF STUDY. ☐ **Copy of Study Protocol Attached (Required)**

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B. PRINCIPAL INVESTIGATOR. ☐ **Copies of CV's of Principal Investigator and Sub-Investigators Attached (Required)**

Name: _____

Institution: _____

Mailing Address: _____

_____

_____

Direct Contact Phone Number: _____

C. LOCATION WHERE STUDY WILL BE CONDUCTED

D. STUDY AND COMPARATOR DRUGS (List study and comparator drug and dosages – attach monograph for each. Include placebo, if applicable)

STUDY DRUG	DOSE RANGE(S)

E. SOURCE OF STUDY DRUGS

F. PLAN FOR STORAGE AND ACCOUNTABILITY OF STUDY DRUGS

If pharmacy based - storage and accountability plan not required - provide name and location of pharmacy.

G. PLANNED NUMBER OF SUBJECTS

H. STUDY DURATION FOR EACH SUBJECT

I. ANTICIPATED STUDY START-UP AND COMPLETION DATES

J. SOURCE OF FUNDING

K. CONSENT ☐ **Copy Attached of Informed Consent Form to be used with Study (Required)**

L. NAME AND ADDRESSS OF IRB; IRB REVIEW STATUS

☐ **IRB approval Pending**

☐ **IRB approval Obtained (Copy Attached)**

M. *If Applicable* - **PROVISIONS FOR HANDLING OF MEDICAL EMERGENCIES**

If study drug is being administered at an onsite research lab, office, clinic, or hospital setting, a description of provisions for handling any medical emergencies that might occur is required. Attach description.

N. *If Applicable* - **PROVISIONS FOR DISPENSING OF TAKE HOME STUDY MEDS**

If study requires subjects to "take home" single or multiple doses of study meds, a description of provisions for the dispensing and labeling of these medications is required. Attach description. If pharmacy based - dispensing and labeling description not required - provide name and location of pharmacy.

O. ACKNOWLEDGEMENTS AND SIGNATURE OF PRINCIPAL INVESTIGATOR.

As the final step in completing this application, the principal investigator acknowledges that, upon receipt of Panel approval, he/she will comply with all Panel requirements, including prompt reporting of any emergent study drug-related SAE's and presentation of the California Research Subjects Bill of Rights to each subject at onset of the consenting process.

Signature **Date**

Print Form Clear Form