RESEARCH ADVISORY PANEL of CALIFORNIA

APPLICATION REQUIREMENTS AND GUIDELINES for NON-HUMAN Research Using Schedule I Controlled Substances

The Research Application may consist of a cover letter to supplement copies of previously prepared documents containing the pertinent information. The investigator should note, however, that Panel consideration and action will be most expeditious when applications are complete and well-organized. It is recommended that applications have a table of contents and numbered pages.

Because of the varied nature of the research applications which may come before it, the Research Advisory Panel of California (RAPC) may request additional information beyond that listed below before reaching a final decision.

The Research Application sections are outlined below:

1) Investigator:

a) Name, address, and DEA registration number or copy of application for same.

b) Institutional or other affiliation.

c) Qualifications, including curriculum vitae and relevant bibliography of the principal investigator and co-investigators where applicable.

2) Research Project:

a) Title of project.

b) The purpose, specific aims and significance of the research.

c) Name of the controlled substance(s) involved, reasons for using particular substance(s), the amount of each needed (amount per experiment and total number of experiments), and the source of the material.

d) Description of the research to be conducted, including experimental design, capabilities for chemical characterization of the controlled substances and where appropriate, number and species of research subjects, dosage and route of administration, and contemplated duration of project.

e) Location where research will be conducted and description of the facilities.

f) Statement of the security provisions for storing and dispensing the controlled substances in order to prevent diversion. Description of method for documenting use, including inventory form, and list of individuals who have access to drugs and their qualifications.

3) Authority:

a) Documentation of approval of the study by the head of department or institution.

b) If proposal was reviewed elsewhere, the nature of the review process.

c) Description of source(s) of funding.

SIMULTANEOUS APPLICATION

The Panel does not wish to delay activation of any research project. Since many projects will involve a multi-agency review, the requirements of other agencies should be carried out simultaneously with application to the Panel. For example, applicants should proceed simultaneously to satisfy both the requirements of state and federal regulations, e.g., those of the U.S. Food and Drug Administration (FDA) or the Drug Enforcement Administration (DEA).

If funds to support the research are to be sought from federal, state or local granting agencies, the investigator should make application to that agency simultaneously with the application to the Research Advisory Panel of California (RAPC). The Panel recognizes the capriciousness of federal funding and encourages investigators to proceed with as complete an application as possible to RAPC while awaiting the final word on funding. An amended application can often be expedited by the Panel once the broad project has been reviewed. Applicants should clearly indicate those aspects that are pending final resolution.

APPLICATION REVIEW PROCESS

Timing

The Research Advisory Panel meets in January, March, May, July, September and November. To be considered at a given meeting, **research applications, amendments, or revisions must be received by the twenty-fifth day of the month preceding a Panel meeting** and must be in conformity with these guidelines. One application copy is required. The Panel's staff will make 7 copies, which will be mailed out to the Panel members for review prior to the Panel meeting. Address submissions to:

Research Advisory Panel of California (415) 703-1373
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004

If applications are submitted well in advance of the meeting, the Executive Secretary of the Panel will review it for completeness, and advise the applicant of omissions so that supplemental materials can be submitted in time for the next Panel meeting.

Panel Actions

Research applications considered at Panel meetings are either approved, approved with conditions, or the investigator is notified by letter of objections, omissions and/or questions which conflict with the Panel's criteria for approval. Prompt attention to any such letter from the Panel assures the earliest possible consideration of amended applications. When appropriate, amended protocols will be considered between regularly scheduled meetings to expedite the approval process. A site visit may be required as a condition of approval.

Amendments must be submitted whenever substantive changes in an approved project are contemplated such as: An increase in the quantities of controlled substance already approved, the use of additional controlled substances, alterations in the time span of the study, modified or additional research objectives and significant changes in experimental methods. Although minor changes in ongoing projects do not require prior RAPC authorization, the principal investigator is obligated to apprise the Panel of such modifications, including personnel changes , modification of facilities, and updating of protocols.

TIMELY INITIATION OF STUDY

If an approved project is not initiated within six months after approval, the principal investigator is required to submit a re-application either by 1) letter of explanation, or 2) a new application.

ANNUAL REPORT REQUIRED

Each approved principal investigator must submit an annual progress report by January 15th for each prior year or a final project report if the project has been completed or discontinued. More frequent reporting may be required by RAPC. The Panel publishes a list of approved projects and summaries of research findings in its Annual Report to the Legislature and Governor. Research findings submitted to the Panel which the investigator wishes to remain confidential should be so marked in the investigator's annual report to the Panel.

CONFIDENTIALITY OF INFORMATION

All research applications to the Panel are confidential and confidentiality is maintained by members and staff. The Panel's policy in this regard is consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the Panel to promote frank internal deliberations in its review of applications. The Panel makes available to the public the Annual Report including the Panel's membership, review process, policy, objectives and an enumeration of all approved projects and summaries of research findings. In addition, a list of all protocols approved during the current year is also available to the public.

RAPC may conduct site visits. All records maintained for approved research projects may be inspected by members of the Panel and/or the Executive Secretary. The Panel's above outlined standards on confidentiality will likewise apply to any site visits.