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

Core Review Submission Checklist

CLINICAL TRIAL PROTOCOLS

Research Advisory Panel of California

The Research Advisory Panel requires a single or multicenter clinical drug trial protocols using Schedule II controlled substance as its main study drug, or substance abuse research clinical trials, to be submitted - by the sponsor conducting the study - to the Panel office for review and approval prior to the start-up of any sites in California. Below is a checklist of the items required for Panel review:

A. COVER LETTER

The cover letter should be in the form of a request letter, from the sponsor conducting the single or multicenter clinical trial study, for Panel review of the protocol to be used in the study. It should include:

- ❑ The title of the study
- ❑ An anticipated startup and completion time lines
- ❑ The number of California sites planned, and estimated number of subjects
- ❑ The name, mailing address, phone number, and e-mail address of a contact person of the sponsor or CRO.

B. PROTOCOL ☐ **One Copy of Clinical Trial Protocol Attached**

C. CONSENT ☐ **One Copy of Template Consent Attached**
☐ **Review the Consent Form Check List**

.

D. STUDY DRUG INFO ☐ **Monograph or Investigators Brochure Attached**

Note: Approval for single or multicenter clinical trial protocols is granted to the sponsor conducting the study, not the individual sites participating in the study. Hence the review and approval process is initiated by and granted to the sponsor conducting a single or multicenter study, and, accordingly, **applications will not be accepted from individual MD's or sites participating in a single or multicenter study.**