

NATIONAL NAVAL MEDICAL CENTER  
ANNUAL REPORT SUBMISSION FOR  
THE FOOD AND DRUG ADMINISTRATION

IND # \_\_\_\_\_

Study Status

Clinical Investigation Program Research Project: # \_\_\_\_\_,  
entitled, "

Principal Investigator:

A) Study Information:

1) Provide a brief summary:

a) Study's purpose -

b) Identify the patient population -

c) Is the study complete? [ ] Yes [ ] No

2) Subject Enrollment: \_\_\_\_\_ Total # initially planned for inclusion.

\_\_\_\_\_ Total # enrolled to date;  
as of \_\_\_\_\_.

\_\_\_\_\_ Total # who completed the  
study as planned.

\_\_\_\_\_ # who dropped out for any  
reason.

3) Provide a brief description of any study results, if completed, or if  
interim results if available.

B) Summary Information: Provide

1) Information from previous year's clinical and non-clinical  
investigations:

2) A narrative or tabular summary of the most frequent and most serious  
adverse experiences by body system:

- 3) A summary of all IND safety requirements submitted during the past year:
  - 4) List any subjects who died during participation in the study and the cause of death for each subject:
  - 5) List of subjects who dropped out during the course of the investigation in association with any adverse experiences, whether or not thought to be drug related:
  - 6) Describe any pertinent information that has been obtained concerning the drug's actions; including for example, information about dose response, information, from controlled trails and information about bioavailability.
  - 7) List of the preclinical studies (including animal studies) completed or in progress during the past year and a summary of the major preclinical findings:
  - 8) List any significant manufacturing or microbiological changes during the past year:
- C) Provide a description of the general investigational plan for the coming year to replace that submitted one year earlier.
- D) If the investigator brochure has been revised provide a description of the revision and copy of the new brochure:
- E) Provide a description of any significant Phase I protocol modifications made during the past year and not reported to the IND in a protocol amendment:
- F) Provide a brief summary of significant foreign marketing developments with the drug during the past year; such as approval of marketing in any country or withdrawal or suspension from marketing in any country:

- G) If desired by the sponsor, a log of any outstanding business with respect to the IND for which the sponsor requests or expects a reply, comment, or meeting.

Principal Investigator Signature

Principal Investigator Typed Name

Date