

Human Subjects Protocol for Full IRB Review

(Please type)

1. Type of Project:

2. Name of Principal Investigator:

Signature of Investigator: _____ Date

Address: _____ Phone

Qualifications of Investigator:

List the name, rank, and major departmental appointment of other investigators participating in this project, if any. Use a separate sheet of paper if necessary.

NONE _____ OTHERS

If medical supervision is necessary, give the name of the physician who will be responsible for the supervision:

Phone

3. If this study is part of a grant, please indicate the following:

Grant Title:

Principal Investigator of Grant:

4. Source of Funds: State specific name of funding source.

Governmental
Agency or Agencies

Foundation(s)

Corporation(s)

Organization(s)

Individual(s)

Other

None ()

5. Location of Study:

Name of Institution

Type of Room

If the project is a field study, describe the community on the lines below. If the study is to be undertaken within a school, business, or other institution that does not have a review board, attach a statement of any contacts with the appropriate officials.

6. Drugs:

A. Is this study a phase I, II, III, or IV drug study? If yes, please indicate:

Phase I

Phase II

Phase III

Phase IV

B. Does this project involve the use of an investigational new drug?

YES

NO

If yes, attach the Pharmacy Department Release Form and provide the name of the drug and the IND number:

Name of Drug

IND Number

Date of end of 30-Day Expiration or Waiver

If an investigational new drug is involved, but an IND number has not been issued, what are the plans of the Principal Investigator for securing an IND from the FDA?

C. Have other review boards reviewed this project (including departmental review committees who authorize the uses of their patient populations)?

YES

NO

If yes, provide the name of the review board and the date of approval:

If the study was rejected, give the reasons:

9. Number and Type of Subjects and Controls:

A. Number of Subjects and Controls:

B. Type of Subjects and Controls:

C. Population from which derived:

D. Indicate which of the following special populations will be involved in the Project:

Prisoners

Fetuses

Abortuses

Pregnant women

Minors under
14 years of age

People with mental illness

None of the above

People with mental retardation

If any special populations listed above are involved, state reasons for using the special populations:

List any persons who will be at risk other than those directly involved in the study:

E. Will any of the subjects be from a Veteran's Administration Hospital?

YES

NO

10. Duration of Study

- A. Probable duration of entire study
- B. Total amount of time each subject will be involved:
- C. Duration of each phase in which the subject will be involved:

11. Purpose, Background, and Study Methodology: (items 11-14 should be discussed on separate sheets of paper).

- A. Purpose of Project or Activity in LAY LANGUAGE.
- B. Background: Describe past experimental and/or clinical findings leading to the formulation of this study. Include and past or current research by the principal Investigator.
- C. Study Methodology:
 - 1. Describe the study methodology that will affect the subjects, particularly in regard to any inconvenience, danger, or discomfort.
 - 2. List the procedures, the length of time each will take, and the frequency of repetition.
 - 3. Attach a copy of any interview or questionnaire that will be used.

12. Risks and Precautions

- A. Possible Risks - Physical, Psychological, and Social:
 - 1. Estimate their frequency, severity, and reversibility.
 - 2. Describe any alternative treatments.
 - 3. Describe any withholding of normal treatment.
 - 4. What is the risk-benefit ratio?
- B. Special Precautions:

1. Describe precautions that will be taken to avoid hazards and the means for monitoring to detect hazards.
2. State the point at which the experiment will be terminated if hazards materialize. Differentiate between the point for termination of the involvement of an individual subject and for the termination of the entire study.
3. Describe the method of screening potential subjects and controls, and the factors that will be the basis for excluding potential subjects from the study.
4. If an agent or therapy is being assessed, indicate the point at which the differences in outcomes between subjects and controls will be considered sufficiently significant to eliminate the need for additional subjects, or to require modification of the disclosure made to continuing and prospective subjects because of greater information concerning relative risks.
5. State whether the potential subject will be, or will have been, in a stressful, painful, or drugged condition. If yes, describe the proposed precautions to overcome the effect of the condition on the consent process.
6. If the time period between informing the subject and soliciting a decision is less than twenty-four hours, describe the time sequence desired and the reasons why the twenty-four hour minimum would handicap the effective conduct of the study or would be disadvantageous to the subject.

13. Procedures to Maintain Confidentiality

- A. Will any information derived from this study be given to any person or group, including the subject? If yes, describe to whom the information will be given and the nature of the information.
- B. Describe the procedures for maintaining confidentiality.

14. Other Information