

**THE PROJECT REVIEW PANEL**

(USE INTERDEPARTMENTAL LETTERHEAD)

**TO:** (Name), Chair, IRB

**FROM:** Investigator's Name

**SUBJECT:** Project Panel for Review of (Name of Study)

**DATE:**

I wish to propose the following people for service on the Project Panel for review of the proposed study entitled "Name of Study."

1. Name, credentials (to be Executive Secretary of Panel), qualifications
2. Name, credentials, qualifications
3. Name, credentials, qualifications

Sincerely,  
Investigator's Name

Signature of IRB Chair

Date

Approved

Not Approved

## REPORT OF PROJECT REVIEW PANEL

(PLEASE TYPE)

Name of Principal Investigator

Title of Project

1. Type of Proposal or Activity

New                      Renewal - Date of last IRB Approval  
Renewal is required every 12 months. Should there be changes to the protocol before expirations of the 12 months period, an amendment should be requested.

2. Indicate concurrence or nonconcurrence with the human subjects protocol prepared by the investigator:

Concur                      Do not concur (If do not concur, explain reasons in an addendum).

3. Date of Project Review Panel Approval of this project

4. Did the full Project Review Panel meet personally in a face-to-face conference with the principal investigator of this project?

Yes      Date of Meeting

No      If no, why not?

**NOTE:** It is a requirement of the IRB that the panel members meet face-to-face with the investigator. Although the IRB may waive this requirement under certain circumstances, the investigator risks deferral of his/her protocol for failure to meet personally with the Panel.

5. If the research is to involve children, please answer the following questions, otherwise skip to question 6.

For research involving children, please indicate into which of the following four categories you would recommend that the proposed research be placed:

Research not involving greater than minimal risk. Research in this category requires both assent of the child and permission of at least one parent or guardian.

Research involving greater than minimal risk but of possible direct benefit to the child, in which the risk is at least as favorable to the subject as that presented by available alternative approaches. This requires both the assent of the child and permission of at least one parent or guardian.

Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the disorder or condition, in which the risk is minor relative to the potential improvement in knowledge to be applied to general understanding. Permission must be obtained from both parents unless there is only one reasonably available parent. Guardian consent should be substituted for parental under appropriate legal constraints.

Research not meeting the specifications above, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of children. This category is considered so serious that it must be submitted for a ruling by the secretary of DHHS following consultation with an appropriate panel of experts.

6. Will human subjects be at greater than minimal risk?

Yes If yes, answer the following questions:

No If no, skip to number 7.

A. Are the risks to the subject so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept the risks?

Yes No

B. Will the rights and welfare of any subjects be adequately protected?

Yes No

C. Will the proposal be acceptable in terms of:

Organizational commitments and regulations?

Yes            No

Standards of professional conduct and practice?

Yes            No

Community attitudes?

Yes            No

D.      Comment on the risk-benefit ratio regarding human subjects.

E.      What benefits, if any, may accrue to the public at large?

7.      Will effective informed consent be obtained by adequate and appropriate means?

Yes                  No

8. Does the consent form for this project include the basic elements as required by the IRB?

Yes                  No

9. Is adequate provision made to preserve the anonymity of the subject?

Yes                  No

10. If this project is a renewal or a continuing application, indicate any changes proposed.

11. What is the significance of the project?

12. Does the Panel have any recommendations for the investigator relative to human use?

Please type panel members' names and provide signatures.

Signature

Signature

Executive Secretary's Signature

Date

# HUMAN SUBJECTS PROTOCOL

(PLEASE TYPE)

1. Title of Project

In the case of renewals, please indicate any previous title(s) under which this study may have been submitted:

2. Name of Principal Investigator

Signature of Investigator

Date

Campus Address: Department

Office

Phone:

Qualifications of the Investigator

In the case of renewals, please indicate any names or names of prior principal investigators on the protocol.

Note: Change of investigator requires a letter from the original investigator requesting the change.

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. Status of Proposal or Activity

New                      Renewal                      Date of last IRB Approval

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

Grant Title

Principal Investigator of Grant

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

Governmental Agency

Foundation(s)

Corporation(s)

Organization(s)

Individual(s)

Other

None

6. 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.

7. Drugs:

A. Is this study a Phase I, II, or III drug study? No

Yes                      Phase I                      Phase II                      Phase III

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

Yes                      No

If yes, provide the name of the drug and the IND number:

Name of Drug

IND Number

Date of End of 30-day Expiration or Waiver

In 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. Does this project involve the use of any commercially available drugs?

Yes                      No

If yes, please provide the drug names:

8. Devices:

A. Does this project involve the use of an investigational new device?

Yes                      No

If yes, provide the name of the device and the investigational device exemption (IDE) number:

Name of Device

IDE Number

For projects involving investigational new devices which are considered non-significant risk devices, attach a letter from the sponsor discussing the reasons for the classification.

9. Approvals:

A. Does this project involve the use of radioisotopes?

Yes                      No

If yes, has the Isotope Committee given approval?

Yes                      No                      Attach documentation of Isotope Committee approval.

B. Does this project involve the use of biopsy or surgical material?

Yes                      No

If yes, has the department providing the specimens given approval?

Yes                      No                      Attach documentation of departmental approval.

C.    Have other review boards reviewed this project?

Yes                      No

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

If the study was rejected, give the reasons:

10.    Number and Type of Subject 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:

None

Prisoners

Fetuses

Mentally Retarded

Abortuses

Mentally Disabled

Pregnant Women

Minors under 14 years of age

If special populations (minors, fetuses, pregnant women, prisoners, mentally retarded, or mentally disabled) are involved, state reasons for using the special populations:

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

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 12-15 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 any past or current research by the principal investigator.

- C. Study Methodology:
1. Describe the study methodology which 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 which 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 termination of the entire study.
3. Describe the method for 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