Institutional Review Board
Sample Guidelines

Colleges and universities have procedures for reviewing research proposals for feasibility, meaningfulness, human subjects' rights and safety, ethical issues, and informed consent.

If your organization does not have an Institutional Review Board, the project director, the staff director, and the board chairperson (or their equivalents) must review the research grant application in the following areas:

I. Feasibility

Can this project reasonably be expected to be completed by the personnel listed in the time frame given for the amount of money requested?

II. Meaningfulness

Is this project worth doing? Do the potential benefits justify the costs in money, staff time, and effort?

III. Human Rights

Are the research subjects fully informed concerning their role(s) in the project? Are their human rights and safety fully protected? Are all research procedures ethical, safe, legal, and respectful?

Are the research subjects and/or their written materials and records fully deidentified? Is confidentiality fully protected?

IV. Informed Consent

Informed consent is not required under certain circumstances (e.g. extraction of deidentified data from former patient's records). The Jerry M. Lewis, M.D. Foundation Director will consult with you on this issue at your request. If you decide informed consent is not required for your project, include a clear statement of explanation for this decision in your grant application.

An Informed Consent Form must include:

A. A statement that the project involves research, an explanation of the project, and a description of the subject's role(s) in the project;

B. A description of any reasonably foreseeable risks or discomforts to the subject;

C. A description of any benefits to the subject or to others which may reasonably be expected from the project;

D. A disclosure of any alternative procedures that might be advantageous to the subject;

E. A statement describing the procedures to be followed to protect and insure confidentiality of records and deidentification of data;

F. A statement indicating how the results of the project may be used (e.g. to improve services, better understand clients' needs, training of staff, preparation of professional or public presentations and publications). Cite all that apply;

G. Names and telephone numbers of the project director and staff director for the subjects to contact in the future regarding any questions or concerns about the project;

H. A statement that participation in the project is voluntary, that refusal to participate will involve no penalty or denial of services, and that the subject may withdraw participation and consent at any time without penalty or denial of services.

The Informed Consent Form must be signed and dated both by the project director and the research subject, and copies of the signed and dated forms provided to both.

Grant Application Procedure

- State in your grant application that you do not have an Institutional Review Board, but that you have fully addressed the issues described in the four areas covered by these Sample Guidelines.

- Include a copy of your Informed Consent Form with the grant application.

- Include a signed and dated copy of these Sample Guidelines with your grant application attesting that:

- We, the undersigned, have carefully reviewed the grant application and these Sample Guidelines, and feel the research project successfully addresses all the concerns listed in the Sample Guidelines.

_____	_____	_____
Project Director	Staff Director	Board Chairperson
_____	_____	_____
Name Typed	Name Typed	Name Typed
_____	_____	_____
Date	Date	Date