WAYNE STATE UNIVERSITY

Wayne State University Human Investigation Committee	
SUBJECT	Vulnerable Participants: Terminally Ill
Section	
Form Date	
Approvals	Steering Committee 12/9/98, All IRB Committees 3/26/99, Administrative Approval 7/12/99

Background

There are no specific federal regulations concerning the inclusion of terminally ill subjects in a research protocol.

Definitions

For the purposes of identifying subjects to whom this document applies, two categories of "terminally ill" subjects are defined below:

1. *Imminent death* - reasonably expected survival $\leq$ 1 week.
2. *Shortened life expectancy* - reasonably expected survival > 1 week but $\leq$ 6 months due to current recognized illness.

Issues

It is expected that research protocols that include terminally ill subjects (especially the "imminent death" category) will most often be specifically concerned with some aspect of the dying or death process in addition to terminal illnesses. However, it is also possible that a terminally ill patient (especially "shortened life expectancy") might participate in a protocol that includes other (nonvulnerable) types of research subjects. Terminally ill subjects have the same rights as other individuals to participate in research, but care must be taken to offer the alternative of NOT participating in a given protocol in order to avoid coercion. *Coercion* is of particular concern with this vulnerable group of subjects because of the possible feeling of desperation. Special care is necessary to ensure that the subject (or the legally authorized representative) understands and voluntarily gives consent to participate in research.

HIC Policy Procedures

When the protocol form indicates inclusion of "terminally ill" subjects, the investigator must describe any special precautions that will be taken to avoid coercion when obtaining informed consent. Additionally, the consent form must include the following:

- A statement should be included under "Alternatives" that the subject has the option of not participating in the research protocol (and/or the option of some other treatment, as appropriate)
- A statement of "Benefits" that are reasonably expected for the majority of participants, i.e. it should not inflate the possibility of the individual's benefit. A statement that the subject may not benefit directly from participation in the research should be included when appropriate. The consent form must have a line for a witness's signature, and must include a legally authorized representative's signature when the subject is not legally competent to sign.