FRIENDS RESEARCH INSTITUTE, INC.
1040 Park Avenue, Suite 103
Baltimore, MD 21201

Subject: Vulnerable Populations
Division: IRB
Date: March 1, 2012

IRB Policy 109.1: VULNERABLE RESEARCH SUBJECTS

Policy

Not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Some persons are in need of extensive protection, even to the point of excluding them from activities that may harm them. Other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequences. Indeed, some types of research may, in and of themselves, create a vulnerable group – that is, the subjects lose their autonomy or are exposed to unknown risks. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations. The IRB will have appropriate subject advocate representatives present at the meeting.

Potentially vulnerable groups may include Prisoners; Children; Pregnant women and fetuses; decisionally impaired (such as mentally limited, substance abusers); and other vulnerable groups.

Prisoners

IRB Policy 109.2

Children

IRB Policy 109.3

Pregnant Women, Human Fetuses, and Neonates

IRB Policy 109.4

Other Vulnerable Groups

Although federal regulations list vulnerable groups, other vulnerable groups may include mentally impaired persons, employees of the Sponsor or Investigator, terminally ill patients, and the very elderly. The IRB will determine special protections for these groups on a case-by-case basis, taking into account the risks and benefits and other protections afforded by institutional policies and state and federal law.

Subjects in "Treatment IND" Studies

Informed consent is especially important in treatment use situations because the subjects are

desperately ill and particularly vulnerable. They will be receiving medications which have not been proven either safe or effective in a clinical setting. Both the setting and their desperation may work against their ability to make an informed assessment of the risks involved. The IRB must ensure that potential subjects are fully aware of the risks involved in participation.

The IRB should also pay particular attention to Treatment INDs in which the subjects will be charged for the cost of the drugs. The question here is one of equitable selection and the involvement in research of vulnerable populations, particularly economically disadvantaged persons [21 CFR 56.111(a)(3)]. If subjects will be charged for use of the test article, economically disadvantaged persons would likely be excluded from participation. The stated purpose of the Treatment IND exemption is to facilitate the availability of promising new drugs to desperately ill patients while obtaining additional data on the drug's safety and effectiveness. Charging for participation may preclude economically disadvantaged persons as a class from receiving access to test articles. The IRB will need to balance this interest against the possibility that unless the Sponsor can charge for the drug, it will not be available for treatment use until it receives full FDA.

Cognitively Impaired Subjects

Studies involving subjects who are decisionally impaired may take place over extended periods. The IRB should consider whether periodic re-consenting of individuals should be required to ensure that a subject's continued involvement is voluntary. The IRB may require that Investigators re-consent subjects after taking into account the study's anticipated length and the condition of the individuals to be included (e.g., subjects with progressive neurological disorders). Additionally, the IRB should consider whether, and when, it should require a reassessment of decision-making capacity.

Responsibility

IRB Administrators are responsible for maintaining up-to-date review tools for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines, and for ensuring the IRB members are apprised of new and evolving regulations and guidelines pertaining to vulnerable populations. IRB members are responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources.

Applicable Regulations and Guidelines

The Belmont Report
45 CFR 46
21 CFR 56.111
OHRP IRB Guidebook