Nova Southeastern University
Standard Operating Procedure for GCP

Title: Equitable Selection of Subjects		Version # 1
SOP Number: OCR-RR-001	**Effective Date: August 2013**	**Page 1 of 2**

PURPOSE: The Belmont Report calls for "Justice", or the equal distribution of research burdens and benefits. Targeting specific populations over others without scientific justification is neither better nor worse then excluding the same population from participation. Both result in inadequate representation and thus, the research findings will be skewed as such.

POLICIES:

1. The demographics of individuals targeted for and participating in research should be representative of the population that would benefit from the research. Any skewing of definable classes within the population should be due only to randomness and not due to any systematic overutilization or underutilization of that class (regardless if it is intentional or unintentional).
   1.1. Classes are not limited to typical demographics such as sex, race, age etc. They may also include things such as diabetics, hypertensives, specific neighborhoods, patients of a certain clinic, indigent patients only, etc.
2. Subjects that may otherwise directly or indirectly benefit from the research should not be systematically over-utilized or under-utilized simply because of their ease of availability, their compromised position or their manipulability.
3. The Center/College should not place additional barriers to participation (i.e. additional inconveniences, discomforts, embarrassments etc) on any individuals or class of individuals over others (i.e. only returning phone calls from certain subjects or class of subjects would not demonstrate equitable selection).
4. Exclusion of certain individuals or class of individuals should only be due to medical necessity.
5. When protecting certain individuals or a class of individuals, the Center/College shall not be unduly paternalistic.
   5.1. Unless otherwise determined incompetent, the mentally ill have the right to self-determination.

5.2. Subjects may volunteer for research projects as often as they wish, provided that there is no scientific or medical justification for excluding them (i.e. cannot be on more than one investigational drug at any given time).

6. Refusal to participate shall not cause any individuals or class of individuals to lose any rights to which they would otherwise be entitled.
   6.1. A subject has the right to treatment within the limitations of the Center/College as if they appeared there in the absence of a study.
7. Any potential subject that is also a patient of one of the investigators has the right to discuss their situation with another physician.

Procedure to Assure Equitable Selection

1. The Center/College shall submit information to the IRB that details the following:
   1.1. the purposes of the research
   1.2. the setting in which the research occurs
   1.3. inclusion criteria
   1.4. exclusion criteria (if any)
   1.5. consideration of the scientific and ethical justification for including vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons
2. The integrity of any randomization procedure in the IRB approved protocol must be maintained.
   2.1. Any randomization procedures should not be tampered with
   2.2. Individual subjects should not be scheduled for randomization based on a perceived "cracking" of the code