NOVA SOUTHEASTERN UNIVERSITY

Recruitment and Retention of Subjects

Overview, Regulatory Support and References

Recruitment marks the first step in the informed consent process and therefore must not be coercive or misleading. Although some forms of research may be retrospective, data from research such as clinical trials is completely dependent on prospective recruitment and retention of subjects. There are often other therapeutic relationships the subject may have with providers whose treatment plan must be respected. Even though these relationships exist, Respect for Persons includes recognizing their right to autonomy and self-determination. The primary goal should be to recruit quality subjects that meet all of the inclusion criteria and do not have any of the exclusion criteria for the clinical trial. Care should be taken to assure that the potential subject has the ability and is willing to complete the procedures and number of visits required for the clinical trial. Subjects should volunteer in an environment free of coercion and those persons considered vulnerable should have additional protections in this process to assure lack of coercion. Finally, there may be commercial pressures to enroll subjects that may either offer incentives or give the appearance of incentives to researchers to coerce subjects into studies. To avoid even the appearance of impropriety, certain practices that are seemingly unprofessional or coercive should not be condoned.

- 21CFR56.111(b)
- 45CFR46.111(b)
- ICH GCP 4.4.1; 5.8.3; 8.2.3; 8.2.7; 8.3.2; 8.3.3
- FDA Information Sheet (1998) "Recruiting Study Subjects" (http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting)
- FDA Information Sheet (1998) "Payment to Research Subjects" (http://www.fda.gov/oc/ohrt/irbs/toc4.html#payment)
- FDA Information Sheet (1998) "Screening Tests Prior to Study Enrollment" (http://www.fda.gov/oc/ohrt/irbs/toc4.html#screening)
- OHRP IRB Guidebook Chapter 3, Section C "Selection of Subjects" (http://www.hhs.gov/ohrp/irb/irb_chapter3.htm#e3)
- OHRP IRB Guidebook Chapter 6 "Special Classes of Subjects" (http://www.hhs.gov/ohrp/irb/irb_chapter6.htm)

- OHRP IRB Guidebook Chapter 3 "Incentives For Participation" (http://www.hhs.gov/ohrp/irb/irb_chapter3.htm#e7)
- OHRP IRB Guidebook Chapter 3 "Identification And Recruitment Of Subjects" (http://www.hhs.gov/ohrp/irb/irb_chapter4.htm#f12)
- Health and Human Services, Office of Inspector General—Recruiting Human Subjects- Sample Guidelines for Practice (http://oig.hhs.gov/oei/reports/oei-01-97-00196.pdf)
- Health and Human Services, Office of Inspector General—Report on Recruiting Human Subjects (http://oig.hhs.gov/oei/reports/oei-01-97-00195.pdf)