ADIRONDACK HEALTH

TITLE:	Advertising, Recruitment, and Screening of Study Subjects	POLICY #: SOP-12
FOLDER NAME:	Institutional Review Board (IRB)	PAGE: 1 OF: 2
PREPARED BY:	Patricia Druzba, Ph.D. Chair, Institutional Review Board (IRB)	
EFFECTIVE DATE: 8/15	REVIEWED/REVISED: 2/16	
APPROVED BY: Patricia Druzba, PhD (Chair, IRB) _____ Chandler Ralph (CEO/President) _____		

1. IRB approved studies will automatically be added to the hospital website along with the name and contact information of the Principal Investigator (PI).
2. The forms of advertising subject to IRB review include, but may not be limited to, flyers, posters, brochures, newspaper, radio, television, internet, recruitment letters (HIPAA Privacy Rule may apply), postcards, phone calls, and "support groups" conducted by the investigator or her/his staff.
3. The requirements for advertising in any and all media available to the general public may include:
    a. The name and address of the research facility (the investigator may also be named);
    b. The condition under study or the purpose of the research; the word "research" or "investigational" should be used in most cases involving a drug, biologic or device;
    c. In summary form, the criteria which will determine eligibility for the study, in the case of studies with a large number of inclusion or exclusion criteria, summarize the "deal-breakers";
    d. A brief list of participation benefits, for example, no-cost health examination with blood work;
    e. The time and other commitment(s) required for participation; and
    f. The person to contact for further information.
4. The IRB will be responsible for determining if the wording or phraseology of the ad is coercive or misleading or otherwise dishonest. The IRB will not approve any advertising that makes a claim for a new treatment, new medicine, new device, superiority to existing treatment; emphasizes compensation; or lists study benefits in an unbalanced way.
5. The IRB recommends that the script for taped ads (radio, TV, internet) be reviewed and approved before taping to avoid the re-taping expense and time, should the wording not be acceptable to the IRB. The final tape must also be compared to the original script which was provided to the IRB to be sure no changes were made to the script, the tone of voice of the announcer is balanced (not overly effusive), the announcer does not speak too fast, giving a sense of urgency, or is accompanied by soothing background music.
6. The use of in-person recruitment may be allowed after IRB review and approval of the script being used. This would include, but not limited to, calls to a toll-free

number as advertised in another media and cold calls to patients with the diagnosis under study.

7. Because of the very strong possibility of undue influence, investigators may not recruit from their own staff or their family members.
8. Performing "tests" for screening of subjects for possible entry into a clinical trial is permissible if the test being performed is considered "standard of care" that is the patient would have this test whether or not study entry was contemplated. Informed consent is not required for diagnosis, staging, or treatment of a condition considered as standard of care, even if the subject would then be eligible for the clinical trial. Consent is also not required if the screening is in the form of questionnaires.
9. A written "Screening Informed Consent" is required when screening tests are done solely for the purpose of determining study eligibility; this includes "wash-out" from a current medication. The requirements for a screening consent include:
    a. a list of the test(s) being done,
    b. a brief summary of the study, and
    c. how and by whom the screening consent will be obtained.
10. Written documentation of the screening consent process and a copy of the signed screening consent must be made part of the patient's permanent record.
11. If the test(s) required for determining eligibility is considered "minimal risk", the IRB may use an expedited review procedure, however, the IRB may limit the scope and/or number of the test(s) being done. The screening consent is good for one round of a test. If the subject fails screening and re-screening is approved by the sponsor, a second screening consent must be signed. Both consents must be part of the patient's medical record.
12. If the screening test normally requires a written consent before it is performed, the IRB may determine that the subject does not need to sign a written screening consent. That determination must be made in writing to the Principal Investigator.
13. Screening tests which include HIV testing can be performed on a consenting adult and New York State reporting regulations apply.
14. Studies under the auspices of DHHS may have different rules so contact the IRB Chair as applicable.

REFERENCES:

Office of the Inspector General OEI-01-97-00195
Privacy Rule Section 164.512 (i) (l) (ii)