

**UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN SUBJECTS PROGRAM
FACT SHEET**

SCREENING TESTS PRIOR TO STUDY ENROLLMENT

It has come to the attention of the Human Subjects Program Office that there is some confusion among researchers regarding performing screening tests on **potential** participants **before** obtaining consent for a study. The following is the FDA's position on this issue as stated in their FDA Information Sheet:

"For some studies, the use of screening tests to assess whether prospective subjects are appropriate candidates for inclusion in studies is an appropriate pre-entry activity. While an investigator may discuss availability of studies and the possibility of entry into a study with a prospective subject without first obtaining consent, **informed consent must be obtained prior to initiation of any screening procedures that are performed solely for the purpose of determining eligibility for research.**

Procedures that are to be performed as part of the practice of medicine and which would be done whether or not study entry was contemplated, such as for diagnosis or treatment of a disease or medical condition, may be performed and the results subsequently used for determining study eligibility without first obtaining consent. On the other hand, informed consent must be obtained prior to initiation of any screening procedures that are performed solely for the purpose of determining eligibility for research. When a doctor-patient relationship exists, prospective subjects may not realize that screening tests performed solely for research enrollment are not required for medical care. Physician-investigators should take extra care to clarify with their patient-subject why certain tests are being conducted.

Screening procedures for research eligibility are considered part of the subject selection and recruitment process, and therefore, require IRB oversight. IRB review and approval should not be too burdensome for either IRBs or investigators, as screening may qualify as a minimal risk procedure [21 CFR 56.102(i)] and the IRB may choose to use expedited review procedures [21 CFR 56.110] to approve such screening. The IRB should receive a written outline of the screening procedure to be followed and how consent for screening will be obtained. The IRB may find it appropriate to limit the scope of the screening consent to a description of the screening tests and to the reasons for performing the tests including a brief summary description of the study in which they may be asked to participate. Unless the screening tests involve more than minimal risk or involve a procedure for which written consent is normally required outside the research context, the IRB may decide that prospective study subjects need not sign a consent document [21 CFR 56.109(c)]. If the screening indicates that the prospective subject is eligible, the informed consent procedures for the study, as approved by the IRB, would be followed."

Some UCSD/VAMC research units have submitted "screening" protocols to the IRB for review and approval. The Human Subjects Program Office would like you to be aware that this is an option that is available to you. If you would like more information or guidance in submitting such an application, please telephone the Human Subjects Program Office at campus extension 44520.