UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

FACT SHEET

CONDUCTING SCREENING TESTS ON POTENTIAL STUDY PARTICIPANTS

A. GENERAL INFORMATION

To clarify any confusion that may exist regarding performance of screening tests on **potential** participants 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."

B. SCREENING RESEARCH PLAN (PROTOCOL)

Investigators have the option of submitting "Screening" protocols to the IRB for review and approval. For more information or guidance in submitting an application of this type, please contact HRPP at (858) 657-5100 or visit the website at irb.ucsd.edu.