CRITERIA FOR IRB APPROVAL OF RESEARCH

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied. This includes all initial approvals (full-board review or expedited review), considerations for amendments to ongoing studies, and re-approval applications:

A. Risks to subjects are minimized
   1. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
   2. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes

B. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

C. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, mentally disabled persons, or economically or educationally disadvantaged persons.

D. Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by 45CFR46.116 and/or 21CFR50.

E. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45CFR46.117 and/or 21CFR27.

F. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

G. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

H. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, handicapped, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Data Monitoring

The IRB must determine that the research plan is appropriate in making adequate provisions for monitoring data to ensure the safety of participants. The IRB might consider provisions such as:

Safety information to be collected, including serious adverse events; how it will be collected (e.g., with case report forms, at study visits, by telephone calls with participants); the frequency of data collection, including when collection starts; the frequency or periodicity of review of cumulative safety data. The plan
might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor, including the frequency of reporting. For studies that do not have or are not required to have a data monitoring committee and are blinded, have multiple sites, enter vulnerable populations, or employ high-risk interventions, the IRB will carefully review the data and safety monitoring plan and determine whether a data monitoring committee is needed. If the study is not using a data monitoring committee, and if applicable, statistical tests will be employed for analyzing the safety data to determine whether harm is occurring. The IRB will determine provisions for the oversight of safety data (e.g., by a data monitoring committee) and conditions that trigger an immediate suspension of the research, if applicable.

Expedited versus Full-Board Review

Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the IRB. The FDA’s IRB regulations [21CFR56.110] and OHRP regulations [45CFR56.110] permit, but do not require, an IRB to review certain categories of research through an expedited procedure if the research involves no more than minimal risk. A list of categories was last published in the Federal Register on November 9, 1998 [63 FR 60364-60367]. The list may be found at http://www.hhs.gov/ohrp/policy/expedited98.html. LSUHSC-NO adopts the expedited review procedures as its own.

The IRB may also use the expedited review procedure to review minor changes in previously-approved research during the period covered by the current approval.

Under an expedited review procedure, review of research may be carried out by the IRB chairperson or by one or more experienced members of the IRB designated by the chairperson. The Chair appoints experienced IRB members to conduct reviews of new studies, changes to approved studies, unanticipated problems, and re-approval applications using the expedited procedure. “Experienced” in this context refers to IRB members who have served for a number of years and have reviewed diverse types of research, addressing issues which require extensive knowledge of regulations and policies. The reviewer(s) may exercise all the authorities of the IRB, except disapproval. Research may only be disapproved following review by the full committee. Approval criteria for expedited review are the same as those for full-board review.

The LSUHSC-NO HRPP does not review new research applications involving prisoners by the expedited procedure. Any such new applications received by the LSUHSC-NO IRB are reviewed at a convened meeting of the IRB. This includes research involving interaction with prisoners, as well as research that does not involve interaction with prisoners. For DHHS-funded research, the IRB Chair certifies to OHRP that the duties of the IRB have been fulfilled regarding Subpart C determinations.

Minor modifications to research involving prisoners may be reviewed using the expedited procedure, by either of the two procedures described as follows, based on the type of research.

- Minor modifications to research involving interaction with prisoners may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied. The prisoner representative must concur with the determination that the research involves no greater than minimal risk, and must review the research as a reviewer, designated by the chair, or consultant. This may be as the sole reviewer or in addition to another reviewer, as appropriate.
• Minor modifications to research that does not involve interaction with prisoners may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied. Review by a prisoner representative is not required, but the prisoner representative may review the research as a reviewer or consultant if designated by the IRB chair.

All members are advised of research studies or other action items that have been approved by expedited review during the preceding month through the Monthly Report of Expedited activities, which is made available to Board members before and during the IRB meeting and at any time thereafter.