IMPORTANT NOTICE TO ALL APPLICANTS: (Updated: 8/29/2002)

Reviewers of NIH applications are instructed (http://grants.nih.gov/grants/peer/hs_review_inst.pdf) to evaluate plans for the Protection of Human Subjects from Research Risk, the Inclusion of Women in Clinical Research, the Inclusion of Women in NIH-Defined Phase III Clinical Trials, the Inclusion of Minorities in Clinical Research, the Inclusion of Minorities in NIH-Defined Phase III Clinical Trials, the Inclusion of Children in Human Subjects Research, Data and Safety Monitoring in Clinical Trials and the care and use of Animals Subjects in Research. The outcome of these evaluations may affect the priority score that reviewers assign for the overall scientific and technical merit of each application.

If you believe that your application as submitted is deficient in any of the elements identified above, contact the Scientific Review Administrator who is identified in the assignment notice that you received about providing the required material. Any information that you send should be clearly labeled with your name and application number, and should be as concise as possible for the benefit of the reviewers.

1. HUMAN SUBJECTS RESEARCH.

a. Protection of Human Subjects from Research Risks:

If you propose the use of Human Subjects at any time during the project period, Section e, "Human Subjects", of the Research Plan must address the human subjects risk and protection issues that were required by the PHS 398 grant application instructions. **Inadequately addressing these issues will negatively affect your priority score, while failure to address the issues will result in your application not being evaluated.**

If you claim an exemption from human subjects regulations, this must be explained and justified in the application as required by the instructions in the PHS 398 grant applications instructions.

Note: NIH policy no longer requires documentation of Institutional Review Board (IRB) approval at the time of the initial peer review (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html).

b. Data and Safety Monitoring Plan (applies if you have proposed a clinical trial):

As of the October 2000 receipt date, applicants must supply a general description of the Data and Safety Monitoring Plan for **ALL** clinical trials; this must be included in the application (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html). The degree of monitoring should be commensurate with risk. NIH Policy for Data and Safety Monitoring requires establishment of formal Data and Safety Monitoring Boards for multi-site clinical trials involving interventions that entail potential risk to the participants. The absence of this information will negatively affect your priority score.

c. Plans for Inclusion of Women and Minorities:

The NIH Revitalization Act of 1993 (Public Law 103-43) requires inclusion of women and minorities as subjects in clinical research unless there is appropriate justification for not including them (see NIH Policy Page on the Inclusion of Women and Minorities). The most recent "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html) were published in the NIH Guide on August 2, 2000. **ALL** research involving human subjects is covered by this NIH policy. Each project of a multi-project application must individually be in compliance with the policy. Lack of adequate plans for inclusion of women and minorities will negatively affect your priority score.

If an NIH-defined Phase III Clinical Trial is proposed, applicants must include a description of plans to conduct valid analyses to detect differences in the intervention effect.

d. Inclusion of Children:

NIH requires that children (i.e., individuals under the age of 21) must be included in all human subjects research conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them (see NIH Policy Page on the Inclusion of Children) . This policy (http://grants.nih.gov/grants/guide/notice-files/not98-024.html) applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accord with Sections 101(b) and 401(b) of 45 CFR 46 - Federal Policy for the Protection of Human Subjects. Therefore, applications for research involving human subjects must include a description of plans for including children. If children will be excluded from the research, the application must present an acceptable justification for the exclusion. Lack of adequate plans for inclusion of children will negatively your priority score and result in a bar to award

2. ANIMAL SUBJECTS RESEARCH

If you propose the use of animals at any time in the project period, Section f, "Vertebrate Animals", of the Research Plan must address the **five points on the planned use of vertebrate animals** reproduced below (see the PHS 398 grant application instructions for more detail). Lack of complete information will negatively affect the evaluation of your application and absence of the information will result in the application not being reviewed.

The PHS 398 grant application instructions provides the following instructions:

Vertebrate Animals. If you have marked Item 5 on the Face Page of the application "Yes," address the following five points. In addition, when research involving vertebrate animals will take place at collaborating site(s) or other performance site(s), provide this information before discussing the five points. Although no specific page limitation applies to this section of the application, be succinct.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

3. Provide information on the veterinary care of the animals involved.

4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

3. GLOSSARY OF TERMS