

IMPORTANT NOTICE TO APPLICANTS

IF YOUR APPLICATION DOES NOT ADDRESS SOME REQUIRED POINTS IT WILL NOT BE REVIEWED

Please check your recently submitted grant application to ensure that it conforms to NIH policies regarding **human subjects and vertebrate animals**. Detailed instructions about these policies can be found at http://grants.nih.gov/grants/peer/hum_anim_notice.pdf

If you find that some information is missing, you have 15 working days from the mailing date of the notice of study section assignment (this mailing) to provide the required information. Send your response directly to the Scientific Review Administrator identified in the assignment notice.

Issues to Double-Check:

Human Subjects:

If your application does not address all of these points it will not be reviewed:

- **Protection of human subjects from risk:** Discussion of risks and protection is required for all projects involving human subjects for which an exemption does not apply. **All clinical trials** require a Data and Safety Monitoring Plan.
- **Inclusion of women:** Discussion of your plans to include women is required for all projects involving human subjects (except those for which exemption 4 applies), including sex-specific studies.
- **Inclusion of minorities:** Discussion of your plans to include minorities is required for all projects involving human subjects (except those for which exemption 4 applies).
- **Inclusion of children:** Discussion of your plans to include children is required for **all** projects involving human subjects, **including** those for which exemption 4 applies and studies that involve only age-specific groups (e.g., Alzheimer's Disease).

If an exemption is claimed, a justification of the exemption **must** be provided.

Vertebrate Animals:

If your application does not address this point it will not be reviewed:

- **Use of vertebrate animals:** If you propose the use of animals at any time in the project period, the Research Plan must address the five points on the planned use of vertebrate animals described in the PHS 398 grant application instructions.

If your organization has an approved Animal Welfare Assurance on file with OLAW and your application does not address the following point, it will not be reviewed:

- **IACUC approval:** The NIH must have your animal welfare approval from the Institutional Animal Care and Use Committee (IACUC) before your application can be reviewed. Within 60 days of the application receipt date, IACUC approval must be received by the Scientific Review Administrator named in the assignment mailer.

Note: While NIH is proposing a Just in Time receipt of IACUC approvals, for now material must be submitted as noted above.