

GUIDELINES FOR PREPARING APPLICATIONS FOR USUHS INTRAMURAL RESEARCH FUNDS

NONCOMPETING CONTINUATIONS

In collaboration with the Research Proposal Merit Review Committee (MRC) and the assurance committees, the Office of Research (REA) has developed electronic versions of all grant-related forms to be used for intramural research protocols submission. **Form 3211 should be used to apply for out-year funding if your budget year starts October 1. For other out-year starting dates, use Form 3211a.** Guidelines for completing Form 3211 are described below; you can obtain guidelines for Form 3211a from the REA home page (<http://www.usuhs.mil/research/dnform.html>) or from the REA office in Room A1032.

If you are applying for funding for a new study or a competing continuation, you must use Form 3201. Guidelines for completing Form 3201 are now laid out in a separate document. If you need a copy of Form 3201 and/or guidelines for completing it, you can download them from REA's home page or pick them up in REA. Student researchers and physicians assigned for graduate medical education projects should use Form 3202, which has its own guidelines document.

All of the forms and guidelines you need for intramural funding are available for downloading from the REA home page. You have the choice of Word 6.0 for Windows or Portable Document Format (PDF). You can also pick up any forms you need from the REA office.

Grants management personnel in REA are available to assist you. REA is located in Building A, Room 1032. The general telephone number is (301) 295-3303. The office fax number is (301) 295-6771.

GENERAL REMINDERS:

1. You must submit a complete, signed original of your out-year packet, including Forms 3203, 3210, 3211, and whatever supplemental assurance forms, additional letters of collaboration, etc. are necessary for the work you propose in the coming year. **If you provide us with an electronic copy of your standard forms, we can make minor corrections (e.g., in the budget or project year, budget totals, etc.) that prove necessary.** Electronic copies may be submitted on a diskette or by e-mail to the Grants Management Specialist for your department.
2. **For the sake of the reviewers, you must use a 12-point throughout your progress report and budget request. Forms with other font sizes will be returned without further processing. Proposals should be single-spaced.**
3. Please do not staple any pages in your packet. Proposal packets should be secured with rubber bands or paper clips.
4. In addition to the budget proposal (Form 3211), your application packet must contain the following:
 - Completed Form 3210 (Progress Report)

- Completed Form 3203 (Assurance Supplement Form), even if your proposal does not require approval by any assurance committees. Please note that we have made a few changes to this document in order to eliminate Form 3200, which you no longer need to complete. **This form must be reviewed and signed by the chair of your department.**
- **Assurance forms for federally required review:** If you have modified your study plan since its last merit review (competitive or out-year) so that it requires approval by an assurance committee, you must include the appropriate form(s) with your progress report:
 - Institutional Review Board (IRB) – Form 3204 (**See below**)
 - Radiation Safety Committee (RSC) – Form 3205
 - Institutional Animal Care and Use Committee (IACUC) – Form 3206 (**See below**)
 - Biohazards, Controlled Substances & Dangerous Materials (BCD) – Form 3207
 - Biomedical Instrumentation Center (BIC) – Form 3220
 - University Information Systems (UIS) – Form 7900

IRB and IACUC approvals must be renewed annually. (See paragraphs below.) The other four committees require only an initial review and approval.

Institutional Review Board: Federal regulations require annual IRB review of studies that use any of the following:

- human subjects;
- human cell lines (primary or immortalized);
- pathological specimens (whether obtained specifically for the study or acquired from a bank);
- any human tissue, including but not limited to blood, era, excreta, saliva, placenta (whether obtained specifically for the study or acquired from a bank);
- physiological measurements;
- exposure to x-ray, microwave or other radiation;
- recordings via MRC, ECG, ERG, PET and/or ultrasound;
- drugs;
- medical devices;
- voice, video, digital, and/or image recordings;
- survey, interview and/or focus group procedures;
- human performance and/or behavior evaluations; and/or
- existing medical records (e.g., in a chart review) or data.

Complete **Form 3204a** if your study has already received IRB approval and you will make no changes to the sections that involve human subjects and/or tissue. If you plan (a) to add human subjects, human tissue, or records to your protocol, or (b) to modify or extend the sections of your plan that involve human subjects or tissue, you must complete **Form 3204**.

Institutional Animal Care and Use Committee (IACUC) -- Complete Form 3206 **if your project is (a)** entering its fourth year of animal use or **(b)** you plan to add animals to your protocol. Use **Form 3206a** if your study has received IACUC approval **in the last three years** and you will make no changes to the sections that involve animals. Use **Form 3206b** if IACUC has approved your protocol, but you plan to make significant changes. Significant changes include but are not limited to:

- a change in one or more of the overall aims or objectives of the study that would affect animal use;
- an increase in animal pain, distress, or discomfort;
- a change in principal investigator;
- a change in or addition to personnel with a role in the care or handling of animals as approved in the original proposal;
- a substantial change in the number of animals used in the project;
- a change in procedures, surgery or treatment; the addition of the use of hazardous or radioactive materials; or a change in species.