

## GENERAL INFORMATION AND INSTRUCTIONS

Institutional Review Committees for Basic Research

(Animal, DNA, Biohazards, Radioactive Drug Research)

Lifespan Office of Research Administration

### GENERAL INFORMATION

If a Lifespan affiliate staff member is conducting research either on-site or off-site, that requires committee review, she/he must register the project with Lifespan Office of Research Administration (ORA) by completing a research application for basic research (non-clinical). Research is defined as "a systematic investigation, including research and development, testing and evaluation, designed to develop or contribute to generalizable knowledge." All research proposals, whether unfunded or funded by an outside agency or by the institution, must be submitted to the Committees and Communications Section of the Office of Research Administration(ORA).

The investigator must complete the required forms according to these instructions. Type the application using single spaced type. Check with ORA for availability of Microsoft templates for IBM and Macintosh. Review committee forms are also available on the Lifespan homepage on the Internet ([www.lifespan.org/research/](http://www.lifespan.org/research/) ). Include the "Notification of a Receipt of a Research Project Application" as the last page. This form will be returned to you to acknowledge the receipt date of the application, the committee number that has been assigned to it, the status of processing, and review committee information. Please note that forms from other organizations which show the same information as requested on the Lifespan forms can be substituted.

Completed applications and appropriate number of copies from either RIH or TMH investigators (see Quick Preparation Reference) must be submitted no later than 4:30PM on the deadline date (see list of deadline dates) to the Committees and Communications Section of ORA, Aldrich Building 5th floor. The original application should be delivered to the Manager, Committee Coordinator or Committee Assistant. Copies should be left in the basket at the front desk. Generally speaking, committee approval takes 4-6 weeks after submission to the ORA. Should you need to call to inquire about your research project, please have the title and/or application/committee number ready. This information will expedite the search for information. For general information please call, Kathy Handshaw, Manager, (444-5843), Jacqui Poore, (444-2093) Committee Coordinator, or Shirley Minor, Committee Assistant, (444-6246).

### SPECIFIC INSTRUCTIONS

#### **A. Request for Research Committee Review**

1. Affiliate is the “home” institution of the investigator/mentor.
2. Principal Investigator/Mentor is that individual who is responsible for the scientific and administrative conduct of the research project. This individual may not actually be the person who conducts the research, but rather sponsors an individual who is not a member of the institutional staff, or who does not have full staff privileges (i.e. resident, fellow, student, etc.)
3. Principal Researcher is that individual who actually conducts the research.
4. Project Title Please use the complete title as it appears on the sponsor protocol or funding agency application. The short title is for data entry purposes so you may create what ever short title you feel is appropriate.
5. Sponsoring Agency is the support source for the project (i.e. NIH, American Heart Association, Whitaker Foundation, hospital department funds). Agency submission deadline is necessary to determine how quickly committee review is needed. Check funded if you are receiving monetary compensation..
6. Committee Considerations: Federal and Hospital regulations require specific consideration by special committees for all aspects of the research methodology. The review and approval of these committees should be concurrently sought as no project will be activated until all appropriate review committee approvals and clearances have been obtained and documented.
7. Administrative endorsements The proposed application must be reviewed and approval indicated by the following individuals of the Hospital prior to submission for committee review:
  - a. Department Head/Chief - signature is required prior to submission, to indicate that this individual has reviewed the proposal for scientific merit and adequacy and is an appropriate use of the investigator’s departmental time and effort.
  - b. Peer Review (if applicable) - Some departments have peer review mechanisms that certify the appropriateness and merit of the proposed research. In these cases the signature of a responsible peer reviewer is needed prior to submission for committee review.
  - c. Departmental Administrator/Business Manager(if appropriate) - for review and endorsement regarding the relationship of the proposal to approved departmental plans and resources.

**B. Attachments**

1. Biographical Sketch should contain current pertinent research/clinical information and should not exceed two pages. This form may be omitted if the investigator(s) have previously filed a sketch in the ORA, within the past year.
2. Research Plan (A research plan that has been submitted to a sponsor may be substituted)

All information for the research plan should be typed. Organize the plan to answer these questions: (A) What do you intend to do? (B) Why is the work important? (C) What has already been done? (D) How are you going to do the work?

Include sufficient information in the plan to facilitate an effective review without reference to any previous application. Be specific and informative and avoid redundancies. Reviewers often consider brevity and clarity in presentation as indicative of a principal investigator/program director's approach to a research objective.

When a revised application is submitted, provide a statement specifying what significant changes have been made. Include additions, deletions, revisions, and any responses to criticisms in the previous summary statement.

The suggested format for a research plan is as follows:

Specific Aims. State concisely and realistically what the research described in this application is intended to accomplish and/or what hypothesis is to be tested.

Significance. Briefly sketch the background to present proposal, critically evaluate existing knowledge, and specifically identify the gaps which the project is intended to fill. State concisely the importance of the research described in this application by relating the specific aims to longer-term objectives.

Progress Report/Preliminary Studies. New applications may use this section to provide an account of the principal investigator/program director's preliminary studies pertinent to the application, and/or any other information that will help to establish the experience and competence of the investigator to pursue the proposed project. Continuation applications would use this section to list the accomplishments on the research project during the reporting period. The titles and complete references to appropriate publications and completed manuscripts may be listed. Supplementary background graphs, diagrams, tables, and charts relevant to the progress report/preliminary studies may also be submitted.

Experimental Design and Methods. Discuss in detail the experimental design and the procedures to be used to accomplish the specific aims of the project. Describe the protocols to be used and the tentative sequence or timetable of the investigation. Include the means by which the data will be analyzed and interpreted. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed

procedures and alternative approaches to achieve the aims. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

3. Animals. If animals have been identified on the face sheet, an IACUC Form (Animal Care and Use Protocol - ACUP) must be attached. Complete detailed instructions accompany that form. All new investigators must meet with the chairperson of the IACUC for an orientation session and complete the Central Animal Facility orientation prior to beginning the work on their animal protocol. Contact the CAF at ext. 45788 to schedule orientation/training.
4. Recombinant DNA If you are using recombinant DNA in your research protocol, please read the DNA information sheet and complete the DNA forms.
5. Radioactive Drug Research and Biohazards There are no special forms for these committees. The research plans should contain specific and sufficient information for a review by these committees (see Regulations Governing Research at the end of these instructions. Information concerning the use of radioactive material can be obtained from the Radiation Safety Committee at extension 45961.
6. Application Receipt form should be completed(top part only). You will receive this form when your application has been processed for committee review.

## REGULATIONS GOVERNING RESEARCH

### **Animal Research**

PHS and Lifespan policies require that studies proposing the use of animals be carefully evaluated to assure that consideration is given to alternatives to animal use, the rationale for using animals, the appropriateness of the species selected and numbers to be involved, and that no unnecessary discomfort, pain or injury is suffered. NIH Study Sections will take these concerns into account when reviewing application for grant funding. Applicants using animals in projects or other activities are personally responsible for the proper care and humane treatment of animals to be used in their projects. Lifespan affiliates must assure the Public Health Service (PHS) in writing, that it is committed to following the standards established by the Animal Welfare Act 9 CFR Subchapter A, Parts 1, 2, and 3, and by the documents entitled "Public Health Service Policy on Humane Care and Use of Laboratory Animals" and "Guide for the Care and Use of Laboratory Animals". These are available from the Office for Protection from Research Risks, National Institutes of Health, Bethesda, MD 20205. and in your "Lifespan Central Animal Facility Policy and Procedure Manual".

If animals are involved, the protocol must be reviewed by the Lifespan Institutional Animal Care and Use Committee (IACUC). The principal investigator and/or his/her designate will be required to attend the meeting to present the protocol and to describe the nature of the study as it impacts on animals. The committee will primarily review the proposal for considerations of alternative models; for the justification for using animals; the appropriateness for the species selected and numbers to be used; the methods for their use; the methods outlined for analgesic, anesthetic, and tranquilizing drugs to prevent unnecessary pain and suffering; and methods of euthanasia. If approval is conditionally granted, recommended changes to the IACUC forms must be resubmitted to the Committees and Communications Section for final approval (no research activity involving animals may be initiated until a letter of IACUC approval is received by the principal investigator). It is the responsibility of the investigator to forward appropriate IACUC approval certification to the sponsoring agency. Please call ext. 46246 with any questions you may have in relation to your review status.

### **Recombinant DNA Research**

The current "NIH Guidelines for Research Involving Recombinant DNA Molecules", "Laboratory Safety Monograph ", and announcements of modifications and changes to the "Guidelines", are available from the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, MD 20892. All research involving recombinant DNA techniques that is supported by the National Institutes of Health must meet the requirements of these guidelines. Copies of the Guidelines and Safety Monograph are available from ORA. The Lifespan Recombinant DNA Committee (RDC) is responsible for reviewing and monitoring all recombinant DNA research performed at any Lifespan affiliate. All protocols using recombinant DNA methodology at biosafety level II, will require continuing review including submission of an inventory of all biological agents classified biosafety level II. Research involving class III and IV agents is not allowed at any Lifespan affiliate. Appropriate forms for DNA research are included in the research application packets available in the ORA. Please call the Committee Coordinator, in the ORA at extension 42093, if you need further information.

### **Radioactive Drug Research**

FDA requires institutional committee review and approval of research protocols using radioactive drugs designed to obtain basic information regarding metabolism (e.g. kinetics, distribution and localization) and human physiology, pathology, or biochemistry. All such research must be conducted in accordance with federal regulations 21 CFR part 361.1. This review is conducted by the Radioactive Drug Research Committee. Further information regarding this committee can be obtained from the Committees and Communications section of the Office of Research Administration, extension 46246.

### **Biohazardous Research**

The Biohazards and Laboratory Safety Committee is responsible for reviewing and approving all research protocols involving the use of hazardous materials. The Committee will assess the risk to property and to the population within the institution and will make recommendations for minimizing such risk. Further information regarding this committee can be obtained from the

Committees and Communications section of the Office of Research Administration, extension 42093 or the Safety Office at extension 48357.