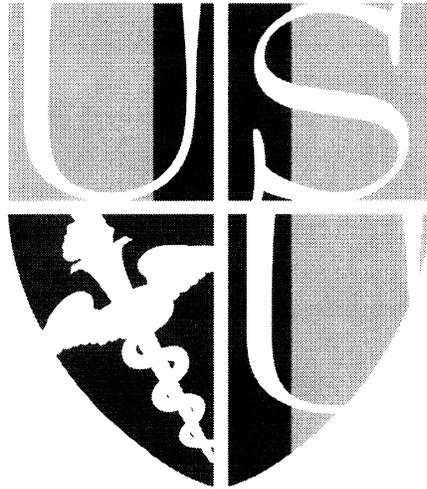


**USUHS
INSTRUCTION
3200**





UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES



SUBJECT: Research and Clinical Investigation

Instruction 3200

SEP 30 1997

(REA)

ABSTRACT

This Instruction establishes policies, responsibilities, and procedures to be followed concerning the submission, scientific review, and funding consideration of Uniformed Services University of the Health Sciences (USUHS) research and clinical investigation proposals.

A. Reissuance and Purpose. This Instruction reissues USUHS Instruction 3200^a and establishes policies, responsibilities, and procedures concerning the submission, scientific review, funding consideration, and conduct of USUHS research/clinical investigation proposals.

B. References. *See Enclosure 1.*

C. Applicability. The provisions of this Instruction apply to all USUHS research/clinical investigation activities supported by the USUHS budget or by extramural funding agencies.

D. Definitions. *See Enclosure 2.*

E. Policy. The USUHS policy regarding research/clinical investigation is outlined as follows:

1. Research/Clinical investigation projects may be conducted by USUHS faculty members using USUHS resources, to include both intramural funds (received by direct appropriation) and extramural funds (grants, grant agreements, and

contracts to include funds provided by other Federal and non-Federal agencies), resources of others through collaborative arrangements, and through approved agreements with the Henry M. Jackson Foundation (HMJF);

2. Patient care, service, or teaching activities performed in connection with research/clinical investigation must be documented as part of the investigational projects;

3. Funds awarded in pursuit of all research/clinical investigation activities at the USUHS will be administered by the Office of Research (REA) or the HMJF. All proposals as well as grant agreements with the HMJF are submitted through REA;

4. All research/clinical investigation projects conducted by USUHS employees must be approved. USUHS projects must be approved by the Vice President, Research Office (VPA) unless otherwise stated in this Instruction. Any USUHS

faculty member working on research/clinical investigation projects will be named on the official copy of all the project documents for the projects on which he/she is working. If a billeted USUHS faculty member serves as an investigator using the USUHS affiliation and/or spends an estimated 5% or more of his/her time on a research/clinical investigation project, a project document must be written, reviewed, approved by the VPA, and filed in REA;

5. Research activities such as literature searches, records review, and manipulation of existing data that do not involve human volunteers, laboratory animals, controlled substances, hazardous materials, and those that are not covered by DoD Directive 5230.9^b, may be approved by the Department Chair in which the faculty member has his/her primary appointment. All other research projects, after approval by the Department Chair, must be submitted to REA for the coordination of the review and approval process;

6. Individuals desiring to use the USUHS laser equipment must do so under the auspices of an approved protocol. Investigators from outside the USUHS must write a short description of the proposed research before being allowed access to the equipment. Initially, a proposal should be reviewed by the Director, Biomedical Instrumentation Center (BIC). Once approved, the Principal Investigator (PI) would then submit the proposal to REA for the clearance process;

7. A USUHS research project funded by an extramural funding agency

(including those funded through the HMJF) must meet the following conditions:

a. Publication rights. A funding agency will not be allowed to censor a manuscript or prevent its publication. A funding agency may request a short review period (generally no more than 30-60 days) prior to the submission of the manuscript for publication in a scientific journal,

b. Proprietary information. The rights to proprietary data will be set out in the research agreement and will be determined by applicable regulations. For example, if the research is accomplished by means of a contract, the appropriate clause from the DoD FAR^c will be inserted. Researchers are advised that they should consult with the USUHS General Counsel (OGC) in order to determine the proper ownership of research data,

c. When investigators leave the USUHS, permission to remove research data must be sought from the Department Chair, the USUHS OGC, other appropriate USUHS officials, and the HMJF, if they are involved,

d. Civilian personnel billets. Additional non-permanent manpower billets may be assigned through REA to a department when a faculty member in that department has received extramural funds from an agency that specifically provides funding for personnel. These billets will be identified at the time proposal applications are forwarded to REA for review and will be allocated upon the awarding of the grant. Such billets will be designated as reimbursable and will be deactivated upon termination of the grant. A person hired on the reimbursable billet will be appointed for the award period of the grant, subject to the annual funding review of the awarding agency and satisfactory performance by the employee.

Moreover, such an employee is not considered as a tenured track employee within the USUHS. The USUHS position supported by extramural funds may be a Schedule A, excepted position. Schedule A appointments are authorized by the Civilian Human Resources (CHR) when special qualifications and employment factors make it impractical to recruit through the competitive Civil Service procedures. If the employee is to be located at a site other than the USUHS for two or more days each week, the request must be reviewed by the Extramural Funded Billet Review Panel. If the billets are to be counted against the work year ceiling, the President, USUHS, will make the billet allocation decision. Such an appointment may be terminated for the following reasons:

- (1) voluntary resignation,
- (2) lack of work and/or funds,
- (3) disciplinary reasons,
- (4) job abolishment, and
- (5) manpower or budgetary

purposes,

e. Patent policy will be determined as described in USUHS Instruction 5537^d,

f. With appropriate procedures, faculty research projects may be funded by for-profit funding sources. The requirements of DoD 5500.7-R^e will be observed in all such actions. Negotiations must be completed by personnel of the HMJF. Investigators may only have informal discussions about the science to be done with the for-profit funding source,

g. The employees of a funding agency specifically designated in an approved research project may volunteer their services to the USUHS pursuant to Title 10, USC, Section 2113^f. These

individuals will be covered for work-related injuries and tort described in Title 10, USC, Section 2113^f,

h. Research projects involving human volunteers will include an indemnification agreement by the funding source, as approved by the USUHS,

i. Copyright policy. Pursuant to Title 17, USC, Section 105^g, copyright protection is not available for any work of the U.S. Government when that work is prepared by an officer or employee of the U.S. Government as part of that person's official duties, and

j. Requests for gifts will not be initiated by USUHS employees. The HMJF may request and accept gifts, but a Government employee may not solicit them nor may a Government employee solicit gifts on behalf of the HMJF. To obtain experimental animals or chemicals from industry, a Material Transfer Agreement (MTA) should be established through the HMJF;

8. Billed civilian and active duty military faculty members at USUHS with Full, Associate, or Assistant Professor titles, any of which may be in the tenure, non-tenure, Clinical Educator, or Research pathways, are eligible to be PIs on extramural and/or intramural research/clinical investigation projects. Specifically:

a. faculty members deriving 50% or more of their salaries from USUHS-appropriated funds and expending 50% or more of their effort at USUHS are eligible to receive both extramural and all intramural funding types, and

b. civilian faculty members deriving more than 50% of their salaries from extramural sources are not eligible for intramural funds.

Nonbilleted USUHS faculty members with the above-named faculty appointments who are assigned to a military teaching hospital or research facility associated with training USUHS medical or graduate students and are making a significant contribution to the USUHS teaching and/or research programs are eligible for extramural and Standard intramural funds. Application guidelines for extramural research support through the USUHS are found in *Enclosure 3*. Applications for Standard intramural funding must include a memorandum clearly explaining the faculty member's involvement at the USUHS and shall be approved on an individual basis by the Dean, School of Medicine (DEN) or the Dean, Graduate School of Nursing (GSN), as appropriate, based on the recommendation of the respective Department Chair and the VPA.

A faculty member who has been denied tenure by the USUHS does not qualify for research support;

9. All USUHS PIs must seek extramural funding. Investigators who have received an initial 3 years of Standard intramural funding (as described in paragraph F.2.(c)) and seek continued intramural support must have demonstrated good faith efforts to acquire extramural support by submitting at least one credible grant application to an extramural funding source through REA during the previous project period. This test will apply at each competing review by the Research Proposal Merit Review Committee (MRC) or the Nursing Research Proposal Merit Review Committee (NMRC) from information provided by REA (to include both new standard and competing continuation

proposals). Failure to meet this requirement is sufficient to preclude continued intramural funding;

10. All proposals requiring REA approval, both funded and cost-free (no dollars requested), must be submitted to REA and approved by the VPA before research/clinical investigation may be started or supplies and equipment ordered. This requirement also applies to applications to extramural agencies for salary stipends. Appeals may be directed to the Executive Vice President, Academic Affairs (presently the DEN);

11. If applicable, all proposals for research will be assessed by REA for scientific merit and resource requirements, and reviewed by USUHS assurance committees for compliance with regulations concerning the use of human volunteers, laboratory animals, radioactive material, radiation producing machines, biohazardous material, controlled substances, and other potentially dangerous materials;

12. Allocation of USUHS Research, Development, Test, and Evaluation (RDT&E) or Clinical Investigation (CI) funds will be based upon the order of scientific merit (assigned by the MRC or the NMRC) and mission relevance and will be subject to the availability of resources, which include funds, space, and personnel. See *Enclosure 4* for specific guidance regarding intramural funding;

13. A USUHS investigator may be a PI on more than one USUHS-funded protocol, provided the total intramural funding level does not exceed the authorized ceiling as stated in *Enclosure 4*. The total percentage

of effort by the PI (including effort expended on any extramural project) may not exceed 100%; and

14. Prior to approval, information contained in a research proposal is not subject to disclosure under the provisions of the Freedom of Information Act (FOIA). Any requests for disclosure of research information will be referred to the USUHS OGC through the Vice President, Administration and Management (VAM).

F. Types of Funding.

1. Intramural Funding. The intramural research funding program is supported with constrained funding from the USUHS appropriation. The purpose of the program is to promote excellence in faculty research and scholarship at the USUHS, conduct militarily relevant research, and to aid in the recruitment and retention of quality faculty. The program is also intended to encourage the initiation of a research program that will be extramurally competitive. The program serves basic and clinical science faculty and nursing faculty at all levels within the USUHS, and may be used for multiple purposes including:

- a. Support of new investigators;
- b. Encouragement of high quality research activity by clinical scientists;
- c. Fostering innovative research by established investigators; and/or
- d. Support for pilot projects and creative research initiatives which subsequently are likely to attract extramural research support.

2. Intramural Funding Awards.

Qualified faculty members may apply for support through the following programs:

a. Starter Awards. Newly appointed faculty members may submit proposals for Starter funds from the USUHS up to 18 months from the date of their initial appointments at the USUHS. The period of funding may not exceed 1 year; the funding limit is found in *Enclosure 4*. These proposals may not be renewed and are designed to provide a minimum of delay in the development of the data necessary for the investigator to compete successfully for an initial Standard project or for extramural funding support. Funds for these proposals may be requested only for supplies and personnel, and may not be used for major equipment (\$5,000 or greater per item) or travel. Receipt of other intramural funding or funding from extramural sources precludes eligibility for Starter funds. Should a Starter proposal be awarded and other funds subsequently become available, unspent Starter funds will be terminated. An exception for discontinuing Starter funds may be given by the VPA if certain resources are not available through extramural funding, and this unavailability prevents the initiation of research. In such a case, funds may be made available through the Starter award process in order to supplement the extramural funding. Each case will be evaluated individually. USUHS Form 3201 and appropriate USUHS assurance supplements are required;

b. Starter Awards for Short Term Military Faculty and Research Fellows. Newly appointed short-term military faculty (whose USUHS assignments are less than 24 months) and research fellows may submit proposals for USUHS Starter funds up to 12 months from the date of their initial appointment at the USUHS. In rare instances, time restrictions may be waived at the discretion of the DEN or the Dean, GSN. The period of funding may not exceed 2 years and the funding limit is found in *Enclosure 4*. These proposals may not be renewed. They are designed to provide a minimum of delay in the execution of a research project, thereby enhancing the research career of these individuals. The applications should indicate how the research would be directed and accomplished. Funds for these proposals may only be used for supplies and personnel. USUHS Form 3201 and appropriate USUHS assurance supplements are required;

c. Standard Awards (Initial and Competing Continuation). Initial projects will be approved for no more than 3 years. Competing continuation projects may be funded for up to 5 years for PIs whose existing principal funding is derived from extramural sources. PIs with no extramural funding may receive competing continuation funding for up to 3 years provided they have demonstrated a good faith effort to acquire extramural support (see paragraph E.9). USUHS Form 3201 and appropriate assurance supplements are required. Should a Standard proposal be awarded and other funds subsequently become available for the same research, unspent Standard funds will be terminated;

d. Noncompeting Continuation Awards. Annual continuation reviews for ascertaining progress are conducted by REA. Should a question arise regarding the possible discontinuation of a protocol, it will be submitted to the USUHS MRC or the NMRC for review. USUHS Form 3211 and appropriate USUHS assurance supplements are required;

e. Special Awards. This category of investigation is reserved for short-term, one-time protocols for PIs who do not qualify for a Starter protocol or whose proposals are inappropriate to append to an existing protocol. The period of funding may not exceed one year; the funding limit is found in *Enclosure 4*. This procedure will not be used to circumvent the submission of a Standard proposal. USUHS Form 3201 and appropriate USUHS assurance supplements should be used. In addition, a cover memorandum to REA will be included with a full justification for submission;

f. Pilot Awards. Pilot studies are those requiring only a minimal number of laboratory animals and/or supplies on a one-time basis. Requests for unusually expensive species, larger numbers of animals, or those requiring special logistical support require the submission of a Standard proposal. Laboratory animals acquired through a Pilot award are subject to all animal use regulations. The funding limit is found in *Enclosure 4*. A faculty member may have only one Pilot project active at any time. Requests for Pilot studies will be submitted in memorandum format, addressed to REA, and must be sufficiently detailed in order to permit proper evaluation. All appropriate USUHS assurance supplements must accompany any proposal;

g. Instructional Development Awards. This program is designed to support the development of instructional techniques and teaching methods. The period of funding may be for 2 years, and the funding level is found in *Enclosure 4*. USUHS Form 3201 and appropriate USUHS assurance supplements are required. These proposals are reviewed and priority ranked by the Teaching Laboratories Evaluation Committee (TLEC);

h. Dissertation Awards. Graduate students seeking a doctoral degree in the School of Medicine whose programs have progressed to the dissertation level may apply for funding support. Such support normally will not exceed eight academic quarters. Under exceptional conditions, the USUHS Graduate Education Committee may recommend an additional year (four quarters) of support. The level of support may vary from year to year. Such funding, when available, will be limited to doctoral students who have completed two years of full-time graduate study or who have been advanced to candidacy for the doctoral degree and are devoting a majority of their time to dissertation research. An abbreviated form (USUHS Form 3202) may be used to request funding for research activity that is a direct extension of a currently active protocol; otherwise, USUHS Form 3201 should be used. The Office of Graduate Education (GEO) may be contacted for forms and assistance for such applications;

i. Medical Student or Physicians Assigned for Graduate Medical Education Project Awards. Under the sponsorship of a qualified faculty member, a medical student or a physician assigned to the USUHS for a Graduate Medical Education (GME) may apply for research support.

The funding limit is found in *Enclosure 4*. An abbreviated form (USUHS Form 3202) may be used to request funding for research activity that is a direct extension of a currently active protocol; otherwise, USUHS Form 3201 should be used;

j. Phase-Down Awards. These awards are made to PIs whose competing continuation proposals for ongoing research are approved by the MRC but have not met the funding payline. Funding is limited to 50% of that requested (up to a maximum total of \$3,000 per period for two six-month periods) and are made to "phase-down" ongoing projects within one year. These awards are not given for proposals for new research. Phase-down awards are granted from funds distributed by the President, USUHS, upon recommendation of the DEN, or the Dean, GSN, according to total funds available and the number of approved, but not funded, proposals within the USUHS;

k. Close-Out Awards. These awards are made to PIs whose continuation proposals for ongoing competing research are not approved by the MRC or NMRC. These projects will be terminated within 2 months of notification. Funding is limited to 2 months at 1/6 of the previous annual budget;

l. National Institutes of Health/ National Science Foundation Bridge Awards. USUHS faculty who submitted competing continuation proposals to the National Institutes of Health (NIH) or the National Science Foundation (NSF), who had awards approved but did not meet the NIH/NSF payline and failed to receive bridge funding from the HMJF, may submit their proposals to USUHS for consideration for up to one year of funding support. An intramural award may be held concurrently with a bridge grant. The PI

will provide REA with a copy of the cover letter and the critique sheet from the NIH/NSF, the original proposal, a revised budget adhering to the USUHS funding guidelines (which may not exceed the dollar amount established for a Standard proposal by an established investigator), and a revised one-page work scope. The request will be reviewed by the MRC. The PI must resubmit the proposal to the NIH or the NSF within 12 months; and

m. Graduate Nursing Students.

Masters level nursing students will submit proposals through their Department Chairs to the NMRC.

3. Collaborative Research. USUHS investigators who plan to participate in collaborative efforts with PIs from other institutions must first obtain approval from their Department Chair if significant time is involved (5% or greater). They must also provide REA with a description of the proposed work. USUHS assurance committee review may be required, depending upon the nature of the assurance reviews at the other institution and where the work is being conducted. If patients, human volunteers, or clinical investigations are involved, or if an exchange of funds or equipment is contemplated, an approved and executed memorandum of understanding between the USUHS and the other institution must be completed prior to the initiation of the collaborative research.

4. Extramural Funding. Extramural research/clinical investigations are defined as research with funding support that is not provided from USUHS appropriated funds. The grantor is the extramural agency providing the funds. The USUHS or the HMJF may be the grantee institution responsible for administering the project

and assuring compliance with the respective Federal, DoD, and grantor requirements.

a. Faculty wishing to apply for extramural research support should contact REA for assistance. All applications require USUHS or USUHS and HMJF approval prior to submission to the extramural agency. It is the responsibility of the faculty member to deliver the requisite number of copies of the proposal to the granting agency.

b. REA will review, with the PI, and coordinate the submission of any proposal through the USUHS or the HMJF.

c. Many USUHS faculty at affiliated USUHS institutions play an important role in the scholarly pursuits of the USUHS by teaching USUHS medical and graduate students and/or by contributing to the service and research capabilities of the USUHS departments. *Enclosure 3* describes the guidelines to be followed concerning faculty status for using the HMJF for the administration of extramural grants through the USUHS.

G. Responsibilities.

1. The Vice President, Research shall:

a. Approve and allocate funding for all USUHS funded research and clinical investigation proposals;

b. Act as the final approving authority on all USUHS proposals that compete for extramural funding; and

c. Report periodically to the President, USUHS concerning research funding approved.

2. The Director, Research Programs shall:

a. Serve as the Executive Secretary to the MRC, the Institutional Review Board (IRB), and the NMRC;

b. After assurance committee and administrative approvals have been received, forward all Standard (initial and/or competing continuation) proposals competing for USUHS intramural funds, to the MRC or the NMRC;

c. Notify the PI and the Department Chair of the final action regarding proposals competing for intramural or extramural funds; and

d. Review all noncompeting intramural continuation proposals in order to ascertain progress.

3. The Director, Grants Administration shall:

a. Administer all USUHS research/clinical investigation funds, as well as those awarded to the USUHS from extramural sources;

b. Monitor grant agreements with the HMJF or with other institutions to which grants have been awarded;

c. Assign a routing number and the type of funds (RDT&E or CI) to be used for approved, intramurally funded proposals;

d. Direct proposals through assurance committees and administrative reviews appropriate to the specific requirements of each (e.g., use of human volunteers, use of laboratory animals, University Information Systems (UIS));

e. If appropriate, coordinate follow-up if review committees do not meet their suspense dates and forward approvals to the HMJF; and

f. Provide the continual coordination of information with the PI, the Department Chair, and the VPA throughout the duration of each research/clinical investigation project.

4. Department Chairs shall:

a. Review and approve all proposals from PIs who hold primary appointments in their Departments;

b. Review the adequacy of the experimental design of those proposals involving the use of human volunteers and/or laboratory animals in order to minimize risks and maximize the acquisition of meaningful data, the overall benefit/risk ratio; and, in the case of human volunteers, assure the quality of the informed consent;

c. Approve participation by investigators within his/her department who plan to take part in collaborative efforts with PIs from other departments, other institutions, or DoD agencies if significant time is involved (5% or greater);

d. Approve participation by co-investigators or staff from other departments if significant time is involved (5% or greater);

e. Confirm availability of resources, including equipment, to conduct the research project; and

f. Approve all manuscripts submitted for publication which result from intra- and extramural funding for scientific accuracy.

5. Directors of Special Activities (e.g., University Information Systems, Financial Management, Facilities) shall review and approve proposals when appropriate.

6. Faculty Members, USUHS shall:

a. Prepare typed proposals using the prescribed formats as required by the USUHS or the appropriate affiliated institution. A proposal is required for a USUHS research/clinical investigation project whether or not funds are requested.

This applies also to applications to extramural agencies for salary stipends. All proposals for intramural or extramural support should be accompanied by the appropriate USUHS assurance supplements:

- (1) use of human volunteers (USUHS Form 3204),
 - (2) use of laboratory animals (USUHS Form 3206),
 - (3) radioactive material and/or radiation-producing machines (USUHS Form 3205),
 - (4) biohazard, controlled substances, and dangerous materials (USUHS Form 3207),
 - (5) Biomedical Instrumentation Center (USUHS Form 3220), and/or
 - (6) use of computer resources (USUHS Form 7900);
- b. Obtain approval from the appropriate Department Chair(s);
 - c. Obtain approval from the appropriate agency official should the proposed project or part of that project require support (e.g., laboratory space or technical help) from an agency outside of the USUHS;
 - d. Request approval from the Food and Drug Administration (FDA) for proposals involving the use of new drugs, biologics, or devices in human volunteers. This action must be coordinated with REA;
 - e. Submit progress reports and requests for project continuation to REA when specified;
 - f. Complete a "Work Unit Information System Worksheet" for those projects funded with RDT&E funds upon request by REA;
 - g. Ensure that appropriate credit be given on all publications resulting from USUHS sponsored research/clinical investigation, including publications that

originate from extramurally funded studies. Per USUHS Instruction 7700^h, these credit statements should include appropriate disclaimers; and

- h. Deliver the proposal to the granting agency.

7. The USUHS Research Proposal Merit Review Committee shall:

- a. Review all USUHS Standard (initial and competing continuation) proposals for intramural funding consideration on a priority score basis;
 - b. Following merit review, the Executive Secretary (Director, Research Programs) will forward the Committee's recommendations for funding through the Chair, MRC, to the VPA and the DEN;
 - c. Forward summary statements of all applications, including priority scores of approved proposals, to the VPA for funding consideration;
 - d. Review and approve any no-cost protocol extension requests; and
 - e. Assure that all proposals (excluding Standard and Instructional Development, which are reviewed by the MRC and TLEC, respectively) will be evaluated by a subcommittee of the MRC, which will include the Chair, MRC, the Director, Research Programs and the VPA.
- For more information about the MRC see *Enclosure 5*.

8. The USUHS Nursing Research Proposal Merit Review Committee shall review clinical investigations and Master level nursing student proposals for intramural funding consideration on a priority score basis.

For more information about the NMRC see *Enclosure 5*.

9. USUHS Assurance Committees

The chair or representative from each assurance committee/administrative review area will promptly inform REA of its findings. If problems are encountered, the chair or representative will contact the PI directly for clarification and/or revision. Once the investigator makes the appropriate changes to the proposal, those in the assurance committee/administrative area will give their approval/disapproval to REA.

a. The Institutional Review Board shall review all research/clinical investigation proposals involving the use of human volunteers. The responsibilities, structure, and procedures of this committee are defined in 45 CFR, Part 46ⁱ, 32 CFR, Part 219^j, DoD Directive 3216.2^k, and USUHS Instruction 3201^l.

b. The Laboratory Animal Review Board shall review all research/clinical investigation proposals involving the use of laboratory animals. The responsibilities, structure, and procedures of this committee are defined in a Joint Regulation^m and USUHS Instruction 3204ⁿ.

c. The Radiation Safety Committee shall:

(1) Review all research/clinical investigation proposals involving the use of radioactive materials or radiation-producing machines. The Chief, Radiation Safety, is a member of this committee and acts as its representative in the initial review process of USUHS proposals utilizing ionizing radiation sources. The responsibilities, structure, and procedures for this review are incorporated into USUHS Instruction 6402-M^o; and

(2) Ensure that radiation training requirements for all personnel associated with the proposal have been satisfied once a proposal utilizing ionizing radiation

sources has been approved for funding, regardless of the funding agency. After all requirements have been met, this committee shall grant the PI the authorization to use radioactive materials/radiation producing machines. This authorization must be obtained prior to the procurement and/or use of radioactive materials. Although the Chief, Radiation Safety, coordinates these training and authorization actions, per USUHS Instruction 6402-M^o, it is the responsibility of the PI to initiate these procedures with the Office of Environmental Health and Occupational Safety (EHS).

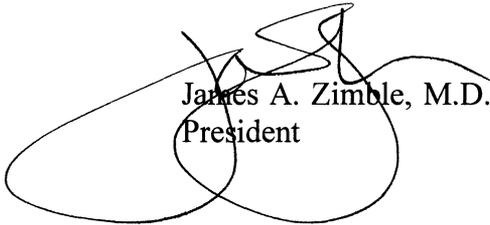
d. The Biohazards, Controlled Substances, and Dangerous Materials Review Committee shall review all research/clinical investigation proposals involving the use of biohazardous agents, controlled substances, and dangerous materials (e.g., microorganisms, recombinant DNA, chemical carcinogens, and toxins). The responsibilities, structure, and procedures for this committee are defined in USUHS Instruction 6401^p and USUHS Instruction 6404^q.

10. The Biomedical Instrumentation Center shall review all research/clinical investigation protocols involving the use of facilities (such as lasers, electron microscopes, confocal and deconvolution microscopes, oligonucleotide/polypeptide synthesizers, or fluorescence-activated cell sorters) listed on USUHS Form 3220.

11. The Equipment and Unfunded Requirements Review Committee shall review all major equipment requirements (greater than \$5,000 per item) requested for USUHS initial, competing continuation, and/or noncompeting continuation Standard proposals.

H. Forms. *See Enclosure 6.*

I. Procedures. *See Enclosure 7.*



James A. Zimble, M.D.
President

Enclosures:

1. References
2. Definitions
3. Guidelines for Research Support for USUHS Faculty at Affiliated Institutions
4. Guidance for USUHS Intramurally Funded Research
5. Appointment of USUHS Research Proposal Merit Review Committee and Nursing Research Proposal Merit Review Committee
6. Forms
7. Procedures

REFERENCES

- (a) USUHS Instruction 3200, "Research and Clinical Investigation: Submission, Review, and Funding," dated December 18, 1996 (hereby cancelled)
- (b) DoD Directive 5230.9, "Clearance of DoD Information for Public Release," dated April 9, 1996
- (c) DoD Federal Acquisition Regulation Supplement, Subpart 27.4 ...(page 3)
- (d) USUHS Instruction 5537, "Submission of Invention Disclosures and Preparation of a Patent Application," dated August 24, 1989
- (e) DoD 5500.7-R, "Joint Ethics Regulation (JER)," dated August 1993
- (f) Title 10, United States Code, Section 2113, "Subject Matter of Copyright: United States Government Works"
- (g) Title 17, United States Code, Section 105, "Board of Regents"
- (h) USUHS Instruction 7700, "Publication Costs," dated June 24, 1986
- (i) 45 Code of Federal Regulations, Part 46, "HHS Regulation - Protection of Human Subjects"
- (j) 32 Code of Federal Regulations, Part 219, "DoD Regulation - Protection of Human Subjects"
- (k) DoD Directive 3216.2, "Protection of Human Subjects in DoD-Supported Research," dated January 7, 1983
- (l) USUHS Instruction 3201, "The Use of Human Volunteers in Research at the Uniformed Services University of the Health Sciences," dated November 2, 1989
- (m) Joint Regulation, AR 70-18, SECNAVINST 3900.38B, AFR 169-2, DARPAINST 18, DNAINST 3216.1B, "The Use of Animals in DoD Programs," dated June 1, 1984
- (n) USUHS Instruction 3204, "Supplement to USUHS Instruction 3203, The Use of Animals in DoD Programs," dated October 23, 1989
- (o) USUHS Instruction 6402-M, "Radiation Safety Guide," dated September 12, 1989
- (p) USUHS Instruction 6401, "Biohazard and Dangerous Materials Guide," dated May 15, 1987
- (q) USUHS Instruction 6404, "Management of Controlled Substances, Alcohol and Alcoholic Liquors, Syringes, and Hypodermic Needles, Precursor/Essential Chemicals, and Anabolic Steroids," dated June 28, 1991
- (r) SOM-DPM-162-90, "Acceptance of Grants with Less than Full Indirect Costs by USUHS," dated October 1, 1990

DEFINITIONS

1. Scientific Research. A systematic, studious inquiry undertaken to produce knowledge and conducted in a way that provides a rational basis for its conclusions. At the USUHS this includes inquiry termed "clinical investigation." The result of the planned inquiry could reasonably be expected to be published in the scientific literature.
2. Investigators. USUHS faculty members conducting work in pursuit of the aims of a research/clinical investigation project. Investigators are expected to conduct all research according to accepted scientific and resource management principles.
3. Principal Investigator. The investigator who is responsible for directing a project.
4. Material Transfer Agreement. Private companies use this vehicle to transfer material to other laboratories for study. The agreement defines the rights of the company and the investigator. Normally, the agreement will be between the company and the HMJF with the PI signing as "acknowledged by," thereby avoiding the complication of the Government accepting gifts from private companies. After execution of the agreement, the material will be delivered to the investigator's laboratory.
5. The Henry M. Jackson Foundation or Other Not-For-Profit Organization. Under special circumstances and with the permission of the VPA, each time the term HMJF is used in this document, the name of another not-for-profit organization may be substituted for the HMJF.

**GUIDELINES FOR RESEARCH SUPPORT OF USUHS FACULTY AT
AFFILIATED INSTITUTIONS**

The USUHS is unique in its mission and in its organizational and staffing structure to support that mission.

Recognizing the importance USUHS faculty billeted at affiliated institutions play in the scholarly pursuits of the mission of the USUHS, the following guidelines are established for research support:

1. An affiliated institution is one which has an executed current affiliation agreement with the USUHS;

2. USUHS faculty must hold a current faculty appointment within a USUHS Department. Such an appointment must only be given for recognized continuous contributions to the Department. The Department Chair shall so designate such contributions to the Dean of the appropriate school, on the appointment or reappointment request;

3. The Dean of the appropriate school shall seek the advice of the Chair on all matters dealing with such appointments. The Dean shall ensure that the criteria are consistent, given the mission of each Department, to ensure that appointments meet the needs of the USUHS and the affiliated institution;

4. The Chair shall report to the affiliated institution the progress of research or significant teaching contribution of a non-billeted faculty member so that said information can be reflected on performance evaluations;

5. All requests for research support by faculty must demonstrate how such support directly affects the mission of the USUHS. Said request shall be certified by the Department Chair who shall specifically comment on the contribution of the research or teaching to the Department's mission. Said comments are to be project specific and not general in nature;

6. All requests for research support by affiliated institutions are to be forwarded by the Chair to the Grants Administration. Copies will be made and distributed to the OGC, the VPR, the VPA, and the DEN or the Dean, GSN. The appropriate Dean will make the final decision. The Chair shall be apprised of concerns of any of the above. The Chair shall apprise the faculty member of any changes needed;

7. Investigators with Standard protocols who have been funded at the beginning of the fiscal year are required to spend their total annual budget in a timely fashion. The following obligation schedule must be observed:

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- a. 25% by December 31,
- b. 50% by March 31,
- c. 75% by June 30, and
- d. 100% by September 30.

Investigators are expected to spend all funds awarded during the fiscal year by September 30; there will be no carry over of funds. If 50% are not obligated by March 31, excess funds will be removed from affected budgets by the VPA. If a protocol requires an alternative funding schedule, an exception can be made upon specific written justification and approval by the Director, Grants Administration; and

8. At no time are USUHS resources to be used as a conduit for non-related HMJF enterprises with nonaffiliated entities that are unrelated to the mission of the USUHS. Any existing endeavor that does not conform to these guidelines will be phased out in the most expedient manner possible.

GUIDANCE FOR USUHS INTRAMURALLY FUNDED RESEARCH

<u>Type of Project</u>	<u>Maximum Dollar Limit</u> (Subject to availability of funds)
Starter	13,200
Short Term Military or Research Fellow Standard	3,000
(a) New investigator	27,000
(b) Established investigator	16,200
Instructional Development	7,500
Dissertation	2,500
Pilot	1,200
Special	4,500
Medical and billeted resident physician projects	1,000
Phase-Down	6,000 per year or 50% of requested amount, whichever is less
Bridge Grants	16,200
Close-Out	1/6 of prior annual award
Nursing Research (inclusive of graduate students) that go to NMRC	Variable

(a) New investigator: faculty member is eligible to receive the maximum \$27,000 funding limit each year for 36 months.

(b) Established investigator: faculty member is eligible for the lower limit of \$16,200 after receiving the maximum funding limit for 36 months.

1. Starter awards must be submitted within 18 months of the eligible faculty member's arrival at the USUHS.
2. PIs who have received 3 years of Standard intramural funding support and wish to continue receiving intramural funding support must demonstrate application of extramural funding support

within the previous 3 years. Demonstration of attempts to receive extramural funding would be reviewed at each Standard new or competing continuation review cycle by the MRC or NMRC. Failure to demonstrate this requirement will prohibit the receipt of future intramural research support.

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3. Major equipment (>\$5,000 per item) purchases are not permitted on intramural protocols. PIs, in collaboration with their Department Chairs, may submit major equipment requests when advised to do so by the VPR. These requests will be reviewed by the EURRC.

4. Support personnel costs not exceeding 50% of the total award may be included on Starter and Standard USUHS intramural research/clinical investigation proposals. Requests to reprogram funds for personnel costs will require justification.

5. Any request for travel must be justified as being mission essential and will be critically reviewed by REA.

6. It is advised that budgets include funds for publication costs and equipment maintenance.

7. Investigators with Standard protocols who have been funded at the beginning of the fiscal year are required to spend at least 40% of their total budget by April 1 (60/40 rule). If a protocol requires an alternative funding schedule, an exception can be made upon specific written justification and approval by the Director, Research Programs. Excess funds are removed from affected budgets by the VPA. PIs are expected to spend all funds awarded during the fiscal year by September 30.

**USUHS Research Proposal Merit Review Committee and
Nursing Research Proposal Merit Review Committee**

The USUHS MRC is appointed by the Executive Vice President, Academic Affairs. The Committee consists of approximately 12 voting members selected from the School of Medicine faculty. The Executive Secretary to the MRC is the Director, Research Programs.

The USUHS NMRC is appointed by the Dean, GSN. The committee can be either a standing committee or an ad hoc committee of at least three members, who are experts in topics related to the Nursing research to be considered. The Director, Research Programs serves as the Executive Secretary and will coordinate the process. The NMRC reviews nursing research proposals seeding nursing specific intramural research funding from the GSN.

FORMS

The following list of forms can be found in the Office of Research (REA).

USUHS Form 3201, "Intramural Research Protocol - New or Competing Continuation"

USUHS Form 3202, "Student Research Protocol"

USUHS Form 3204, "Research Involving Human Subjects"

USUHS Form 3205, "Use of Radioactive Material/Radiation-Producing Machines"

USUHS Form 3206, "Animal Study Protocol"

USUHS Form 3207, "Biohazards, Controlled Substances, and Dangerous Materials"

USUHS Form 3211, "Intramural Research Protocol - Non-Competing Continuation"

USUHS Form 3220, "Biomedical Instrumentation Center - Services and Equipment"

USUHS Form 7900, "Use of Computer Resources"

PHS Form 398, "PHS Grant Application Packet"

PROCEDURES

Proposal Routing and Handling.

1. All proposals for intramural or extramural funding will initially be submitted through REA. All correspondence regarding a proposal or a funded project will also be coordinated through REA.

2. Preproposals for extramural agencies are to be reviewed within the USUHS prior to submission and coordinated through REA, which will prepare a cover letter to the extramural funding agency. REA will return the preproposal to the PI for submission to the funding agency.

3. Dissertation research proposals, following departmental approval, will be submitted to the GEO.

Times for Proposal Submission.

1. Eligible faculty may submit proposals (excluding Standard and Instructional Development) any time during the year. Funding will occur when appropriate review is completed.

2. Standard and Instructional Development proposals are funded twice a year on the following schedule:

a. For Initial and Competing Continuation Proposals

<u>Submission Deadline</u>	<u>Funding Date</u>
June 15	October 1
December 15	April 1

b. For Noncompeting Continuation Proposals

<u>Submission Deadline</u>	<u>Funding Date</u>
July 1	October 1
January 1	April 1

Processes for Proposal Submission.

1. Investigators must obtain their Department Chair's approval before submitting proposals to REA. Investigators with projects that are carried out entirely or partially at a performance site other than the USUHS must first obtain the necessary approval from the appropriate agency official of the site of the research before obtaining their Department Chair's approval. Proposals should then be submitted to REA. These procedures are applicable regardless of the funding source.

2. The Department Chair or representative from each assurance committee/administrative review area will promptly inform REA of their findings. If problems are encountered, the Department Chair or representative will contact the PI directly for clarification and/or revision. Once the PI makes the appropriate changes to the proposal, the assurance committee/administrative area will forward their approval/disapproval to REA.

5. Supplemental requests for additional funding for both extramural and USUHS supported projects, as well as requests for reprogramming, extensions, and revisions without additional funding, must be fully justified by the PI and co-signed by the appropriate Department Chair before submission to REA for action (and if appropriate, forwarding to the HMJF).

Inter-institutional Transfer of Extramurally Funded Research Projects and Related Resources.

1. Individual grants/contracts may be considered for transfer from the USUHS to an eligible institution provided such transfer does not jeopardize an existing USUHS program or programs.

2. Transfers of individual projects must comply with all funding agency regulations and are coordinated through REA.

3. A grant/contract transfer must have approval from and be in compliance with all procedures of both institutions. If the HMJF is the grantee, then the Office of Sponsored Programs at the Foundation must be consulted. If other not-for-profit organizations are used, they must be consulted.

4. Transfer of equipment, supplies, and books from the USUHS that have been purchased with extramural funds will be allowed only if the project under which the items were purchased, or a directly related project, is also transferred. Approval of the original funding agency will be obtained in some instances.

5. A PI will submit an itemized list of the equipment to be transferred to another institution through his Department Chair to REA 90 days prior to the proposed move. The list must include the USUHS or the HMJF property management tag number for each piece of equipment. No equipment may be transferred from the USUHS without the approval of REA or REA and the HMJF. Once the transfer is approved, it is the responsibility of the PI to coordinate the property transfer between institutes with the USUHS Logistics Division (LOG).

6. Transfer of USUHS funded program grants/contracts will not be allowed.

Attachments:

1. Guidelines for Non-DoD Extramural Projects-Preaward and Postaward
2. Guidelines for DoD Extramural Projects-Preaward and Postaward

**GUIDELINES FOR NON-DOD EXTRAMURAL PROJECTS
PREAWARD AND POSTAWARD**

A. Initial grant preparation and possible submission through the HMJF should be coordinated as early as possible through REA.

B. All proposals should be in REA at least 15 days prior to their due date at the funding agency. If the funding agency requires either human or animal use assurance prior to submission, the proposal must be in REA 5 weeks before the due date.

C. Equipment maintenance costs should be included in the budget for all proposals. Investigators may contact the USUHS Technical Services Branch, LOG for guidance regarding the cost of the maintenance services for specific equipment, but a general guideline is 6% of the total direct costs.

D. PIs with extramural grants/contracts who request reprogramming of funds, extension of budget periods with and without additional funds, and other revisions, must submit a reprogramming request (forms available in REA) to REA through their Department Chair. This should include a detailed justification for the requested action.

E. Support Cost Recovery (SCR) will be required on all proposals in accordance with SOM-DPM-162-90^r.

F. No salary or fringe benefit payments may be made from Public Health Service (PHS) grant funds to career, career-conditional, or other Federal employees (civilian or military) with permanent appointments provided for under existing position ceilings of a given Federal component. Temporary employees specifically hired to assist in the conduct of a sponsored PHS assistance program may, if authorized by the grant award, be reimbursed from grant funds.

G. Publications resulting from joint USUHS and HMJF efforts must include a statement that the project is a cooperative research project of the Henry M. Jackson Foundation for the Advancement of Military Medicine and the Uniformed Services University of the Health Sciences pursuant to Public Law 98-36.

3. The MRC or the NMRC will review all initial and competing continuation Standard proposals only after all assurance committee (except the IRB) and administrative reviews have been satisfactorily completed. Review of the use of human volunteers for intramurally funded proposals should be performed after a proposal has been reviewed by the MRC or NMRC and recommended for funding.

4. Upon completing the MRC or NMRC review, REA will prepare critiques based on the review process. The critiques and a recommended funding cut-off point (payline) will be forwarded by REA through the VPA to the appropriate Dean for funding consideration and payline approval. A notification memorandum with a proposal critique and a Notice of Fund Approval (NOFA) will be sent to each PI whose protocol scores above the payline. A copy of the memorandum will be sent to the Department Chair.

5. Critiques of proposals that are approved but do not meet the payline, or that are disapproved, will be sent to each PI. Notices of Phase-down and Close-out funding awards will accompany critiques of ongoing projects. These notices will also be sent to Department Chairs.

6. PIs may appeal the decision rendered. The appeal must be received in REA within 20 working days of decision notification. Appeals and related pertinent materials will be forwarded by REA to the VPA and the appropriate Dean for final action.

7. Any revised proposal that is resubmitted to the MRC or NMRC should include a one-page summary that responds to the criticisms in the previous critique. Changes within the text of the Research Plan should be highlighted and noted by lines in the margin. Any work accomplished since the previous submission may be incorporated into the Progress Report/Preliminary Studies section.

8. Work may be accomplished under approved, but unfunded, proposals provided other "in-house" funds are transferred for that purpose. Requests for fund transfers will be considered:

a. If submitted by the Department Chair in which the PI has his/her primary appointment; and

b. If the source of funds within the department are identified.

The continuation of these projects will be contingent upon the continued availability of funds identified by the Department Chair.

9. PIs submitting initial proposals to extramural sources should observe established submission deadlines and deliver their proposals to REA 15 days before the official deadlines. PIs should refer to the "Guidelines for Non-DoD Extramural Projects-Preaward and Postaward" and the "Guidelines for DoD Extramural Projects-Preaward and Postaward" for additional information on submissions to extramural agencies.

10. Proposals to be submitted for extramural funding may be forwarded, with the Department Chair's approval, before

the completion of the USUHS administrative and assurance committee review. If a subsequent administrative or assurance committee review reveals that a proposal is inappropriate, the USUHS will withdraw the proposal from the granting agency.

11. Upon the receipt of funding award notices from extramural funding agencies, REA or the HMJF will forward a NOFA to the PI with a copy to his/her Department Chair.

Major Equipment Submission.

1. Department Chairs should submit their major equipment requests (\$5,000 or greater per item) for their departments when advised to do so by the Vice President, Resource Management (VPR). The EURRC will then review and prioritize all requests.

2. The allocation of major equipment is made to the department in which the PI is located. This is in contrast to supply funds for a protocol which are directly allocated to the PI.

Protocol Continuation and Progress Reports.

1. Noncompeting continuation proposals of USUHS intramural protocols should adhere to the submission deadlines outlined in Paragraph 2.b. Proposals should be submitted on USUHS Form 3211. Provided the protocol does not significantly deviate from the original, assurance committee and administrative area reviews are not necessary, with the exception of protocols involving human volunteers and laboratory animal use, which always require an annual review.

Each noncompeting continuation receives a review by REA to ascertain its progress. These protocols will not be sent to the MRC or NMRC unless there is some question about continuation. If this is the case, the proposal will be assigned a primary and secondary reviewer and receive a full MRC or NMRC review.

2. Competing continuation of USUHS intramural protocols should adhere to the submission deadlines outlined in paragraph 2.a. Investigators should use USUHS Form 3201 and appropriate USUHS supplement forms.

3. USUHS protocols funded with RDT&E funds, (R prefixed cost code) have an additional reporting requirement. The report entitled "Work Unit Information System Worksheet" must be completed by the investigator when requested by REA. This form is required both at the start and the completion of a project, or when noteworthy change or progress has been made. However, in no instance will a summary report be submitted later than 12 months after the previous report.

4. Protocol reviews and progress reports for extramurally funded grants and contracts will be submitted in accordance with instructions from the funding agency and if appropriate, must be received by REA 15 days prior to the submission due date so that both REA and the HMJF have adequate time to review the proposal. If the extramural agency requires USUHS approval for the use of human volunteers or laboratory animals prior to submission, the application must be in REA at least 5 weeks prior to the submission date.

**GUIDELINES FOR DOD EXTRAMURAL PROJECTS
PREAWARD AND POSTAWARD**

A. If approved for funding, these proposals may result in a research agreement (grant or contract) between USUHS and the HMJF. In order to expedite the development of the required research agreement, the proposal should contain the information that follows. Even if the proposal is only partially funded, it may be the preference of the USUHS to write a research agreement for the entire project, conditional upon the receipt of subsequent funding.

B. Applications for research to be administered through a research agreement with the HMJF must state the length of time required to complete the entire project. In no event should the proposal cover more work than the PI can reasonably expect to accomplish within a five-year period. Research objectives should be clearly spelled out for each year of the proposed effort.

C. If any portion of the research is dependent upon the support to be furnished by an individual(s) outside the USUHS department of the PI, a letter of collaboration agreeing to provide such support must accompany the proposal.

D. An estimate of the total research project budget, with a break-out of the direct and indirect costs by category and

year, must be submitted. A listing of costs for year 1 accompanied by an escalation rate statement for subsequent years is not sufficient unless required by the agency procedures (e.g., "Just in Time"). Otherwise, the actual, proposed costs for each year must be shown.

E. Either the budget estimate or an accompanying justification must include the following detailed information. Failure to provide complete information may result in a delay of the contract or grant process.

1. Salary - Costs must be proposed in accordance with current HMJF and USUHS pay scales. Proposals must also state:

a. The current or projected annual salaries for each individual for whom funding support is requested;

b. The percent effort that each individual will devote to the project each year;

c. The prorated amount of salary for which reimbursement is sought; and

d. The names and/or positions of individuals who will work on the project, but will not require funding support and the annual estimated percent effort each will devote to the project.

2. Fringe Benefits should be based on the average bid and billing rate for the USUHS and/or the HMJF.

Enclosure 7
Attachment 2

3. Equipment, Supplies, Travel, Consultants - Follow the guidelines of the agency granting money (e.g. PHS Grant Application Packet (Form 398)). The basis for all equipment and supply costs will be included. Costs associated with each major category will be shown. Justify any exceptional costs or categories.

4. Subcontract Costs - The estimated subcontract work must be supported by documentation indicating the specific items or portion of the work to be subcontracted; the type of subcontract anticipated; the name of the subcontractor, if known; and a detailed cost summary.

5. Other Expenses - Use guidelines in PHS Grant Application Packet (Form 398). In addition, if equipment maintenance is an itemized category, the specific items of equipment to be covered must be listed and the percentage of time each item will be employed on the project must be stated. If an item is not 100% dedicated to the research project, maintenance costs should be prorated to reflect estimated usage.

6. Indirect Costs - The current Defense Contracting Audit Agency (DCAA) approved rate will be charged. Indirect costs will be calculated and reviewed in REA.