
GENERAL REVIEW AND ENFORCEMENT POLICIES

INITIATION AND APPROVAL OF RESEARCH PROJECTS

1. Purpose:

This guide describes the procedures for the initiation, evaluation, and approval of proposed research studies.

2. Procedures for Initiating Proposals for Intramural Research:

- a. Procedures for planning, initiating, monitoring, evaluating, and reporting intramural studies within the Office of Research (OR) are found in the OR Research Manual.
- b. Requests for research by CVM staff outside the Office of Research (either intramural or extramural) should be submitted in accordance with SIG Report 1.2.7. (See Attachment A.)

3. Research Proposals Involving Human Subjects:

- a. Agency review by the Research Involving Human Subjects Committee (RIHSC) is required.
- b. Guidelines for submission of proposed studies to the RIHSC for review are provided as Attachment B to this guide. These guidelines are applicable to intramural and extramural projects.

Attachment A

THE CVM RESEARCH PRIORITY REVIEW COMMITTEE

The Center for Veterinary Medicine Research Priority Review Committee (RPRC) is charged with evaluation of research ideas and needs developed or proposed by CVM professional staff members and from extramural sources. The Committee will be composed of equal numbers of representatives from ONADE, OSC, and OR. The review Committee will actively encourage the submission of research ideas and proposals, and will evaluate the needs and ideas in a manner which will encourage the development of effective research proposals. The Committee will actively communicate with the proposal author (Health Science Administrator for unsolicited proposals for extramural funds) so that the final product reviewed by the Committee accurately reflects the original concept of the proposal and contains sufficient information to be fairly judged on its merits. The Committee will develop guidelines that detail methods to be used to objectively judge the proposal's merits. The proposals will be reviewed in a timely manner by the Committee, with written reviews to the authors after final review. The Committee product will be a dynamic ranking of proposals that reflect Center research priorities. The Committee will prepare a quarterly list of all ideas and proposals, along with a ranking and priority score, and submit it to the Director, Office of Research, for final action. The committee will report to HFV-1. The Office of Research will determine whether the proposals will be funded with extra- or intramural funds, or result in other dispositions. The RPRC is to undergo a cost-benefit self assessment and receive CVM endorsement once every 3 years before it is rechartered.

The CVM Research Priority Review Committee

I. Composition

A. Committee composition

The committee will consist of a total of six (6) members. ONADE, OR, and OSC will be represented by two (2) members each. Any professional Staff member in these Offices is eligible for committee membership.

B. Committee assignment

1. First seated committee composition

Three (3) members of SIG 1.2.7 will be selected by this SIG to be members of the first seated committee to assure that the proposals of the SIG are implemented.

The other three (3) members of the first committee will be chosen by the member of SIG 1.2.7 from those individuals that apply, or are nominated,

in response to Center-wide solicitation, and who accept. This may be any professional staff member in ONADE, OR, and OSC, including other members of SIG 1.2.7 that were not initially selected.

2. First seated committee terms

The terms on the first seated committee will have to be staggered for consistency purposes. Three individuals will serve 2-year terms, and three will serve 3-year terms.

C. Subsequent Committees

1. Subsequent committee constitution

The Research Priority and Proposal Review Committee will post a Center-wide solicitation, and choose new members from responding eligible individuals on an annual basis.

2. Subsequent committee terms

Terms on the committee will be 3 years.

D. *Ad Hoc* Members

Some proposals may warrant additional expertise. Members who fulfill these needs may be added as needed. Their term will be limited to the consideration of the proposal requiring their expertise. *Ad hoc* members will not be voting members.

II. Routing of Research Proposals

A. System requirements

1. The Office of Management and Communications will

a. establish an e-mail distribution list entitled "Request for Research."
This distribution list will consist of the six members of the standing CVM Research Priority Review Committee.

b. identify a permanent mail code for hard-copy submissions,

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- c. provide support that will enable hard-copy submissions to be scanned and distributed electronically,
 - d. provide the standing committee with ‘computer’ support that will enable tracking of research proposals, accommodate updating of priorities and ranking, etc.
2. The committee chairperson will establish an e-mail distribution list that includes one person from each Branch/Team/Work Group located at the Office of Research. The committee chairperson will use this list to forward all research proposals that the chairperson deems to be complete.

B. Routing

1. Initial submissions:

Research Proposal Worksheets (see attachment 1) can be submitted either electronically or in hard-copy at any time throughout the year. If the proposal is submitted from outside CVM, a member of OR will serve as the author and prepare a research proposal worksheet for that proposal, to be submitted to the committee. The chairperson, or individual assigned by the committee, will notify the submitter that the proposal has been received, and the date of the meeting at which the proposal will be reviewed. The committee chairperson will forward all research proposals to the contact persons in the Office of Research. Each Branch/Team/Work Group located at the Office of Research will have the opportunity to read the proposals and provide comment on whether any proposals are addressed in current or proposed research plans within the Office of Research. The Office of Research branch of the routing is not part of the official review but merely a mechanism to quickly bring reviewers and researchers together on projects of mutual interest.

Reviews by the standing committee should occur at least quarterly and result in both a numerical and priority (high, moderate, low) ranking. Both the numerical and priority rankings should be dynamic, and may change with each quarterly review.

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2. Priority Listing

The Office of Research will be provided an updated numerical and priority ranking list quarterly. The Office of Research will be responsible for assigning personnel within the Office and resources to complete the projects.

3. Pending Prioritized Proposals

All research proposals will remain active from the date of review until research is initiated. The proposal will then be removed from the priority list. For each subsequent year for pending proposals, the submitter will be contacted by the standing committee to determine whether the research proposal should remain active for another year. The submitter will determine if the research proposal remains active. A decision to keep a research proposal active should not require the proposal to be resubmitted. However, the submitter may use this opportunity to update the information in the proposal.

III. Scheduling Research Proposal Reviews and Research Committee Meetings.

A. Feedback to Individuals Submitting Research Proposals

At the time a Research Proposal is received by the Committee at least one member of the Committee should do a preliminary review of the proposal to determine if it contains sufficient information, in an appropriate format, to allow the Committee to assign a ranking to it at the next meeting. If the proposal appears complete, the person submitting it should be informed of its receipt and the approximate date it will be reviewed by the Committee. If the proposal has deficiencies, it should be returned to the submitter with an explanation of the needed additions or corrections for resubmission.

Following prioritization of all current research proposals, all individuals submitting proposals, in addition to whatever regular distribution list is established, should be provided with a copy of the entire priority list.

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- B. Research proposals will come directly by e-mail to all committee members, and may come at any time of the year. Each member should review the 1-2 page proposal within 1 week of receipt. The committee will establish a mechanism to determine: 1) is the proposal described clearly enough to allow adequate evaluation; 2) should the proposal author be invited to the next committee meeting to further describe the proposal and answer questions; and 3) does the committee currently have sufficient expertise to properly evaluate the proposal or should *ad hoc* members be recruited to help the committee in its evaluation?

C. Meetings

The committee will have meetings on a quarterly basis. The committee will meet at the beginning of August, November, February, and May. The May meeting will be scheduled so that the information in the proposal will be available to OR in time for their annual research planning. The quarterly meetings will cover the review and prioritization of proposals submitted during the previous quarter. Additional committee meetings may be convened to address unusual or urgent situations.

The time, date, and place of all regularly scheduled committee meetings will be announced one month in advance to all CVM employees via e-mail so that employees will know when research proposals will be reviewed.

The ranking of research proposals will be distributed to all CVM employees after each meeting of the RPRC.

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Attachment 1

Research Proposal Submission

The Center for Veterinary Medicine initiates intramural and extramural research programs designed to provide a scientific basis for Agency decisions.

The primary objectives of the research activities are to provide:

- a. data necessary to establish and support Agency policies in regulating animal drugs, food additives, feeds, and medical devices,
- b. research addressing specific regulatory problems (*e.g.*, contamination of feedstuffs, drug disposition in animals, and development and validation of analytical methods for detection of drug residues in animal derived food products),
- c. projections of future problems or developments that may affect Center regulatory policies. Long range research plans are designed to provide the necessary science base required to support regulatory policies.

All levels of the Center can contribute to the development of research needs. It has been assumed that many ideas with merit have failed to come to the attention of research planners. Therefore, this research proposal process seeks to encourage and develop ideas from across the Center. This approach will contribute to research output that is consistent with our mission. It provides an open process for idea development, peer review for merit, and matching prioritized projects with research resource availability.

Solicitation of ideas

Ideas may be submitted from any member of the Center's professional staff and from extramural sources. Generally, these ideas result from problems or questions arising from one's work. The first stage of the process is the development of a brief research proposal. This consists of a project title, statement of objectives, background, proposed work, and importance to the Center (see attachment). For the initial proposal, content is to be limited but sufficient to communicate the idea and its attributes. It is anticipated that a few sentences within each section will suffice to

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create a 1- page proposal.

While not required, it is suggested that some short background development be considered prior to submission of the proposal. The Office of Research staff is available for assistance in developing your proposals. The Office of Research staff involvement will be determined by the nature of the problem, and its proposed solution. Collaboration is encouraged. The completed proposal should be forwarded to the committee electronically via [e-mail code] or hard-copy mail [mail-code].

Review process

The CVM Research Review Committee is charged with the evaluation of research ideas and needs developed and/or proposed by CVM staff members, whether from NADE, OSC, or OR, or from extramural sources. The Committee will be composed of equal numbers of representatives from NADE, OSC, and OR.

Proposals will be accepted at any time and reviewed quarterly. New proposals will be ranked, and incorporated into the established list. The Office of Research will be provided an updated numerical and priority ranking list quarterly.

If the Office of Research incorporates the proposal into its research plan, the sponsoring employee will be invited to participate in the development of the research protocol. If the employee wishes to take part in conduct of the project, then management is encouraged to enable the employee's participation.

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Research Proposal Worksheet

I. Title:

II. Objective and/or Hypothesis:

(State either what you think the project should accomplish or the hypothesis that you have developed.)

III. Background Statement:

(What events or processes have made you consider a research-based solution to your idea?)

IV. General Statement of Proposed Work:

(What general design are you considering now for implementing the project? What are the needs [animals, species, numbers, housing, equipment]?)

V. Why is this important to CVM?

(What do you see as a product from the project and how would this affect you or your customer's way of doing business?)

Submitter: _____ Date: _____ HFV- _____ Phone _____

E-Mail address: _____

Send completed form to HFV-500.

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CVM Committee to Prioritize Research Proposals Quarterly Evaluation (date) and Update

Ranking

A. High Priority

Rank within category: 1

Title: Drug use in aquaculture: tissue residues of chloramphenicol in catfish

Submitted by Dr. Cullison (HFV-521)

Reviewed by committee on 6/94

Status: research on-going at Beltsville

Rank within category: 2

Title: Salmonella transfer from feed to poultry

Submitted by Dr. Graber (HFV-220)

Reviewed by committee on 3/94

Status: pending

B. Medium Priority

Rank within category: 1

Title: Effect of rendering on drug levels in finished products

Submitted by Dr. Lovell (HFV-222)

Reviewed by committee on 3/94

Status: pending

C. Low Priority

Rank within category: 1

Title: Sulfamethazine transfer into poultry

Submitted by Dr. von Bredow (HFV-512)

Reviewed by committee on 12/93

Status: pending

cc:

Center Director/Deputy Center Director(s)

Office Directors/Deputy Office Directors

All Division Directors/ Team Leaders (?)

Beltsville Management

Beltsville Scientists

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Attachment B

GUIDELINES FOR SUBMISSION OF PROPOSED STUDIES TO THE RESEARCH INVOLVING HUMAN SUBJECTS COMMITTEE (RIHSC) FOR REVIEW

1. The function of the Committee is to review all studies involving human subjects sponsored by, conducted by, or distributed by the Food and Drug Administration (FDA). The Committee is primarily interested in the moral ethical issues of proposed studies and serves as the responsible agency authority to assure that appropriate procedures will be employed to protect the rights and welfare of subjects. This review includes considerations of risks and benefits associated with studies.
2. All submissions should be concise to facilitate review by the Committee.
3. Submissions which involve the following must be submitted for review:
 - a. Memorandum of Need both domestic and/or foreign (i.e., PL 480 funded) projects (see 4 below);
 - b. Individual protocols developed by grantees, awardees, contractors, or by FDA members for intramural use. These include studies of medical and/or psychological phenomena (see 5 below); and
 - c. Protocols which are distributed to or imposed upon investigators, sponsors, and/or industry by the FDA and which require volunteer participation (i.e., biologic availability protocols) (see 6 below).
4. The following information in support of 3(a) must be submitted to the Committee:
 - a. A statement establishing the scientific merit of the proposal, including its research design and the importance of the knowledge to be gained. This may be satisfied by a statement that an FDA research committee has approved the proposal;
 - b. If known, a description of the subject population to be used (i.e., prisoners, students, patients, etc.);
 - c. A full description of anticipated risks to which subjects may be exposed. The description should include risks due to drugs, medical procedures, physical

- procedures, or to mental stress;
- d. A description of benefits to the subject. If the subject will not benefit from the study, so indicate and briefly describe the benefits, if any, to be realized by medical science or by society;
 - e. If known, the qualifications of the responsible investigator;
 - f. If known, a description of the institution's review committee structure and its review procedures; and
 - g. If known, a description of the facilities available for use by the investigator.
5. The following information in support of 3(b) must be submitted to the Committee:
- a. A statement establishing the scientific merit of the proposal, including its research design and the importance of the knowledge to be gained. This may be satisfied by a statement that an FDA research committee has approved the research proposals;
 - b. A description of the subject population which will be used;
 - c. A description of the methods used to obtain informed consent. This should include specific risks (i.e., drug reactions, medical procedures, physical procedures, mental stress) described to the subjects as well as the benefits, if any, which they may anticipate. If there are no benefits to the subjects, are they so apprised and informed of the scientific importance of the research? A copy of the informed consent form to be used should be included;
 - d. A description of benefits to the subject. If the subject will not benefit from the study, so indicate, and briefly describe the benefits, if any, to be realized by medical science or by society;

- e. The qualifications of the responsible investigator(s) involved in the study;
 - f. A concise description of the facilities and other resources for the accomplishment of the study and the protection of the subjects. If pertinent to the review, a description of the availability of treatment facilities for emergencies, etc., should be included;
 - g. A description of the institution's review committee and its review procedures (this should include a brief outline of the qualifications of the members); and
 - h. If pertinent, descriptions of adverse reaction reporting and follow-up procedures should be outlined.
6. The following information in support of 3(c) must be submitted to the Committee:
- a. A statement establishing the scientific merit of the proposal, including its research design and the importance of the knowledge to be gained. This may be satisfied by a statement that an FDA research committee has approved the research proposal;
 - b. A description of the subject population required for the study. Include a copy of the informed consent form;
 - c. A full description of anticipated risks to which subjects may be exposed. The description should include risks due to drugs, medical procedures, physical procedures, or to mental stress;
 - d. A description of benefits to the subject. If the subject will not benefit from the study, so indicate, and briefly describe the benefits, if any, to be realized by medical science or by society; and
 - e. If pertinent, descriptions of adverse reaction reporting and follow-up procedures should be outlined.

7. Ten copies of the above information must be submitted to the Chairman of the Research Involving Human Subjects Committee (RFM-1). A minimum of ten working days will be required for Committee review.
8. In submitting material to the RIHSC particular attention should be focused on the following:
 - a. What are the risks (procedural, drug, technique, etc.) to which subjects may be reasonably expected to be exposed as a result of their participation?
 - b. What benefits, if any, may reasonably be expected to accrue to the individual participant? To society?
 - c. Can the data be obtained in ways which we do not require human subjects to participate?
 - d. Does the need for the data or information justify the potential risks to the subjects?
9. All studies involving humans (both intra- and extramural) will be reviewed and approved by the CVM Research Committee prior to submission to RIHSC.

