



2012 CALL FOR PROPOSALS ACVIM Foundation / Waltham Canine and Feline Clinical Investigation Grants

Background: The ACVIM Foundation is a non-profit organization, affiliated with the American College of Veterinary Internal Medicine (ACVIM). The ACVIM Foundation provides funds to support investigations that have direct application to improving the diagnosis, treatment, understanding, or prevention of disease in animals.

Eligibility: Principal Investigators must be active Diplomates of the American College of Veterinary Internal Medicine (ACVIM). For Resident Proposals, residents enrolled in ACVIM-approved residency programs and have a minimum of one year left in their training program at the time of award should act as Co-Principal Investigator. Collaboration with investigators who are not ACVIM Diplomates as co-investigators is encouraged. Submission by Diplomates in private practice is strongly encouraged, and collaboration between Diplomates in private practice and those in academia is strongly encouraged.

Awards: Applicants may request up to \$27,000 total (**direct costs only**) for projects focused on clinical studies involving dogs and cats; **The WALTHAM Foundation will not support any study that harms any animal** (details can be found in *Guidelines for Grant Proposal Submission: ACVIM Foundation / Waltham, Canine and Feline Clinical Investigation Grants*, under Statement of Animal Welfare on page 1). Proposals may request up to the total amount and multi-year projects up to 3 years will be considered, subject to annual non-competitive renewal based on demonstration of adequate progress on the project. **The ACVIM Foundation must receive a summary report within 3 months after the completion of a project. Failure to submit a final report may make investigators ineligible to receive future funding from the ACVIM Foundation.**

Criteria for Awards: Proposals will be reviewed by the ACVIM Foundation Scientific Review Committee and ad hoc reviewers who are experts in the field of individual proposals. This program is intended to encourage studies with direct clinical application. Specific criteria used in consideration of proposals will include:

- Potential of the study to enhance the diagnosis, treatment, and/or prevention of disease in animals.
- Relevance of the proposal to existing scientific knowledge.
- Feasibility of the study, including likelihood of success in achieving study aims and appropriateness of the study design.
- Qualifications of the investigators, including adequacy of facilities, training record, productivity and other available resources.

Application Process: To be considered, grant proposals must follow the *Guidelines for Grant Proposal Submission: ACVIM Foundation / Waltham, Canine and Feline Clinical Investigation Grants*, and arrive in the ACVIM Foundation Office by the close of business on **Friday, April 20, 2012**.



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The Guidelines for Grant Proposal Submission, as well as further information about the ACVIM Foundation and its Grant Program, may be obtained at the ACVIM Foundation's website, www.ACVIMFoundation.org. For more information, contact the ACVIM Foundation's Donor Services Associate at Juliebeth@ACVIM.org.

The mission of the ACVIM Foundation is to eliminate animal and human disease by supporting discovery, education, and partnerships throughout the global community of medicine.



Guidelines for Grant Proposal Submission

ACVIM Foundation / Waltham Canine and Feline Clinical Investigation Grants

Overview: The ACVIM Foundation is a non-profit organization, affiliated with the American College of Veterinary Internal Medicine (ACVIM). The ACVIM Foundation provides funds to support investigations that have direct application to improving the diagnosis, treatment, understanding, or prevention of disease in animals. Due to the generosity of WALTHAM, up to \$27,000 (direct costs only) may be awarded to clinical studies involving dogs or cats.

Eligibility: Principal Investigators must be active Diplomates of the American College of Veterinary Internal Medicine (ACVIM). For Resident Proposals, residents enrolled in ACVIM-approved residency programs and have a minimum of one year left in their training program at the time of award should act as Co-Principal Investigator. Collaboration with investigators who are not ACVIM Diplomates as co-investigators is encouraged. Submission by Diplomates in private practice is strongly encouraged, and collaboration between Diplomates in private practice and those in academia is strongly encouraged.

Statement of Animal Welfare: Waltham has provided guidelines for a required **Statement of Animal Welfare** that is to be included with the proposal, and is to be strictly adhered to in conjunction with, and where necessary, beyond the requirements of the ACVIM Foundation's Guidelines.

If animals or animal tissues are included in the study, state:

- The number of animals involved in the study and the statistical validity of this number. Explain any alternatives to animals considered and why they were rejected. Describe how the impact of the study on any animal involved will be minimized.
- The source of the study animals (*e.g.*, client-owned, university resource, shelter animals)
- Housing and husbandry conditions, including diet and supplements being fed
- The fate of the animals at the end of the study. **The WALTHAM Foundation will not support any study that harms any animal.**
- How sufficient clinical cases will be obtained

Where animals are client-owned, the protocol should clearly indicate that owners will need to provide written consent for their pet's participation in the study and that they are fully aware of all procedures their pet (or samples from their pet) will undergo.

Preparation of the proposal: Proposals should be printable on white 8.5" x 11" paper. Text should be single-spaced, using a font that can be read easily. The use of a specific font is not required but font size must be 12 point or larger. An example of a satisfactory font in MS Word is 12 point Times New Roman. The page margins should be set at 0.75" on all sides and pages should be numbered consecutively with the page number appearing in the bottom center of each page. The cover page is counted as page 1, but the cover page should not be numbered. Begin page numbering with the abstract page (page 2), which immediately follows the cover page.

Submission: Complete proposal package including signed and dated cover sheet, checklist page, and other documents must be submitted as a single file in PDF format. **If the PDF is the product of a document scanning device, ensure that the scan settings are adjusted to minimize file sizes. Scans that adopt the highest available resolution result in extremely large files that are difficult to manage during review.** Proposals will be accepted by mail or email. *It is strongly recommended the applicant send the completed proposal packet via guaranteed delivery with tracking number. Be sure to keep all receipts of guaranteed delivery in the event your package does not arrive as scheduled.*

Deadline for submission is April 20, 2012.

Proposal package should be submitted to:

Juliebeth@ACVIM.org

OR

ACVIM Foundation – Grant Submissions
Attn: Juliebeth Pelletier
1997 Wadsworth Boulevard
Lakewood, CO 80214



Acknowledgement of receipt: The Principal Investigator will be notified by email of the arrival of the proposal from Juliebeth@ACVIM.org. Please mark this address as an approved sender to your email account, to avoid missing updates and notifications.

Recognition of the ACVIM Foundation and Waltham: The investigators are required to recognize the funding support of the ACVIM Foundation and Waltham in all publications that result from the project.

Outline of the proposal: The proposal should be organized as outlined below. *Strict adherence to these guidelines is required.* Proposals that fail to adhere to these guidelines may be rejected without further consideration. Note that page limits are maximums, and it is not necessary to fill them if the needed information can be provided in less space.

Title Page

Proposal Title - Limit title to 75 characters, including spaces.

Proposal Type - Diplomate or Resident (if applicable).

Principal Investigator - List name, degree(s), position.

Co-Principal Investigator - List name, degree(s), position.

Co-investigator(s) - List name, degree(s) and position of each co-investigator.

Contact information - Mailing address, e-mail, and telephone and FAX numbers for Principal Investigator.

Institutional Representative - Contact information for the individual who is authorized to accept payment for the institution/practice. Clearly indicate how a check should be made out and the address to which a check should be mailed, in the event of an award.

Amount requested - Annual and total amount of funds requested from this program. Maximum available funds (total costs to the Foundation) is \$27,000 (direct costs only).

Signatures and date - The PI, Co-PI, collaborators, and the Institutional Representative must sign and date the proposal. Include (in PDF format) in the electronically submitted proposal package or mail separately by submission deadline.

Abstracts (1 page maximum)

Scientific abstract - Write an abstract of the proposal in language suitable for the scientific reviewers. (Maximum length 250 words)

Lay abstract - Write an abstract of the proposal in language suitable for lay people. (Maximum length 250 words)

Hypothesis and specific aims (1 page maximum) - The **Hypothesis** and **Specific Aims** of the proposed project should be precisely stated. It is important to have clearly defined **Specific Aims** that can be achieved within the scope of the proposal. The expected time period to achieve each **Specific Aim** should be indicated.

Background, Design, Methods, and Analysis (5 page maximum)

- **Background and significance** - The background section should be concise and thorough. The information provided should be sufficient to allow reviewers to judge the merits of the proposed project. Information from previously published literature on the topic and relevant recent investigations should be included and referenced. The significance of the proposed research to veterinary pharmacology should be discussed.
- **Preliminary data** - Preliminary data that support the proposal, either by providing support for the overall hypothesis or by demonstrating the ability of the investigators to perform the proposed experiments, should be reported. The use of photos, tables, figures and other graphics is encouraged.
- **Study Design, Methods, Statistical and Data Analysis**

Study design - Provide precise details about the study design. Information such as the number of study groups, the expected number of animals in each group, and details about treatment, samples to be taken, and monitoring should be included here. Studies that involve enrollment of client-owned animals should provide documentation that the caseload is sufficient to provide opportunities to enroll the expected number of animals.

Methods - Describe the methods that will be employed to achieve the Specific Aims of the project. Provide sufficient detail to allow reviewers to judge the feasibility of the proposed methods for achieving the stated objective.

Statistical and data analysis - Describe how the results of the study will be analyzed, including information about statistical methods that will be used. Sample size must be justified by the use of statistical techniques.

NOTE: The following sections are not included in the 5 page limit



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Budget (1 page maximum) - Provide a detailed budget for how the funds will be used. For multi-year studies provide a detailed budget for the first year and an estimated categorical budget for the remaining years. Provide a short justification for each budget item. Clearly indicate the amount of funds requested for each budget category listed and the total amount requested for the project.

Allowable costs –Funds from this grant may not be used to pay for faculty or resident salaries or travel / meeting costs (unless the travel is for the purposes of data collection). Purchase of major equipment (defined as any non-perishable item that costs over \$5000) is permitted but must be cost-shared with the sponsoring institution and well-justified. Up to 20% of the total direct costs for the project can be used for technical or student salaries. Indirect costs **will not** be covered.

References (1 page maximum) - Provide complete reference information for all literature cited. List references in the reference format used by the *Journal of Veterinary Internal Medicine* (available at <http://www.ACVIM.org/wwwfp/jvim/jvim.htm>).

Facilities description (1 page maximum) - Describe the environment of each institution/practice where the project will be performed. Include specific information about the clinical and scientific equipment and facilities available to the investigators. When determining the feasibility of a proposed project, it is important for the reviewers to know whether the major equipment and facilities needed to complete the project are available to the investigators.

Supporting Documents - Letters of collaboration from each co-investigator, collaborator, and consultant listed in the proposal are NOT required. Instead, these individuals must sign the cover page along with the P-I and Co-PI (see above).

Institutional/other party commitments and assurances -A letter must be included from an individual who can indicate the institution's commitment to the PI to perform the project, use of any equipment and facilities, and any matching funds. In academic institutions this will usually be from a department chair or associate dean for research. In a private clinical practice, a letter from the practice owner or hospital administrator is appropriate. For proposals that involve multiple institutions, separate letters from each institution / practice are required. Documentation must include assurances that the specific aims of other grants are not duplicated in the proposal submitted to the ACVIM Foundation.

Disclosure statements - A disclosure statement is required of the PI and each co-investigator listed on the cover page of the proposal and should specifically include: disclosure of any business or financial interests the investigator has in the proposed project or its results; a statement about whether the proposed investigation(s) is intended to produce results that will form, wholly or in part, the basis for a patent application; the existence of any agreements or contracts that may interfere or prohibit the distribution, publication, and reporting of the study results; and any other information that could impact the timely facilitation and completion of the proposed studies.

Biographical sketches - A short biographical sketch is required for the PI, Co-PI and collaborators who contribute significantly toward the generation of data (for example, the diplomate and resident, and the basic scientist collaborator who will be performing bench-side analysis, or experiments using the material provided by the clinician). Each biographical sketch should be **limited to 2 pages** and include the following information:

- **Education** - Describe the investigator's educational background; list all degrees obtained.
- **Professional training** - Describe the investigator's professional training. Internships, residencies, fellowships, postdoctoral positions and similar training after the doctoral degree should be listed here.
- **Employment** - List current and previous positions held by the investigator beginning with the current position.
- **Honors and awards** - List all honors, awards and other distinctions earned by the investigator in the past 3 years.
- **Publications** - List all of the investigator's publications for the past three years in chronological order. Earlier publications may be listed if they are relevant to the proposed project but these should be indicated as such.
- **Investigator's role and % effort on proposed project** - Describe the investigator's role in the project. For an investigator from an academic institution, indicate % effort on the proposed project. For an investigator in a private practice, indicate % of total daily effort to be spent on proposed project.
- **Active and pending research support** - List all of the investigators' active and pending research support, including intramural support. Include the project title; the source of funding; project duration; objectives and specific aims; and, annual direct costs. If this or a closely related proposal will be, or has been, submitted to other funding sources, list those sources as pending. Clearly indicate all alternate sources of support for this project, including potential budgetary overlaps.

Institutional Animal Care and Use Committee (IACUC) and Institutional Biosafety approvals - Studies involving laboratory animals must be approved by the Institutional Animal Care and Use Committee (IACUC) of the institution where the work is to be done. **Documentation of approval by the IACUC must be provided in the event funding is awarded.** Since funding will not be released until approved animal care forms are received by the ACVIM Foundation, it is strongly advised that IACUC and Biosafety panel approvals be submitted with the proposal, as this will expedite release of grant funds. ***The use of laboratory or experimental animals is not allowed for this grant***

Projects that involve the use of recombinant DNA, viral vectors, and / or radioactivity must be approved by the Institutional Biosafety Office of the institution where the work is to be done. A copy of the Institutional Biosafety Office approval must be provided in the event funding is awarded. If the proposed project does not require IACUC or Institutional Biosafety approval, please include a statement that indicates that the proposed project is exempt and explains why.



Funds will not be released until the ACVIM Foundation receives proof that final institutional approval for the project has been obtained.

Guidelines for Clinical Investigation – All studies must meet the ACVIM Foundation Guidelines for Clinical Investigation (below). A statement of assurance that these Guidelines will be adhered to must be included.

Assurance of appropriate care for pet animals - Studies involving pet (client-owned) animals must meet the ACVIM Foundation Principles for the Humane Involvement of Pet Animals in Veterinary Clinical Investigations (below). A statement of assurance that these Principles will be adhered to must be included. In addition, a copy of the Client Informed Consent Form to be used for the study must be included. A sample informed consent form is available from the Foundation.

The Foundation also requests that studies involving veterinary patients be approved by an Institutional Animal Care and Use Committee (IACUC) and that documentation of this approval (or pending approval) must be provided in the event funding is awarded. If there is no applicable IACUC approval process available to an applicant for a study involving veterinary patients, the statement of assurance accompanying the proposal should indicate this and provide clarification.

Previous ACVIM Foundation funding - Indicate whether the PI has received previous funding from the ACVIM Foundation. List the project title and dates of previous funding and any abstracts and/or publications that directly resulted from the project.



ACVIM Foundation

Principles for the Humane Involvement of Pet Animals in Veterinary Clinical Investigations*

The development of new knowledge in veterinary internal medicine often requires clinical investigation in veterinary patients (pets, client-owned animals). Such investigation must always be carried out by a highly skilled veterinarian, whose first responsibility is to the well-being of the individual patient, in the setting of the veterinarian / client - patient relationship. In addition, the ACVIM Foundation has developed the following principles for investigations involving pet animals. The Foundation requires the responsible Institutional Representative to ensure that these principles will be adhered to when veterinary clinical investigations are conducted using Foundation-granted funds. A statement of assurance that the principles will be adhered to must accompany grant proposals for studies involving pet animals.

1. Animals must always be treated according the highest standards of medical and compassionate care in specialty veterinary medicine. The objectives of the investigation must never take precedence over the well-being of the patient.
2. Whenever an animal would otherwise suffer severe or chronic pain or distress that cannot be relieved, the veterinarian should recommend to the owner / guardian that the pet be euthanized.
3. Investigators and other personnel shall be appropriately qualified and experienced for working with veterinary patients.
4. Procedures involving animals should be designed and performed with due consideration of their relevance to animal health and the advancement of knowledge.
5. The animals selected for an investigation should be of an appropriate species and quality and the minimum number required to obtain valid results. Alternatives to the use of animals such as mathematical models, computer simulation, and *in vitro* biological systems should be considered.
6. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
7. Procedures that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia.
8. Housing conditions should be appropriate for the species and contribute to the animals' health and comfort. The housing, feeding, and care of all hospitalized animals must be directed by a veterinarian.
9. The transportation, care, and use of animals should be in accordance with applicable portions of the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal laws, guidelines, and policies.
10. Where exceptions are required in relation to these Principles, the decisions should not rest with the investigators but should be made by an appropriate review group such as an Institutional Animal Care and Use Committee.
11. The Foundation also requests that studies involving veterinary patients be approved by an Institutional Animal Care and Use Committee (IACUC) and that documentation of this approval (or pending approval) be included with the grant proposal. If there is no applicable IACUC approval process available to an applicant for a study involving veterinary patients, the statement of assurance accompanying the proposal should indicate this and provide clarification.

*Adapted from U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training



ACVIM Foundation Guidelines for Clinical Investigation

Overview:

The ACVIM Foundation improves the health and well-being of animals by funding humane studies and communicating information about this work to the veterinary community and the general public. We support leading veterinary scientists as they take on a range of critical animal health issues within the specialties of small and large animal internal medicine, cardiology, neurology, and oncology. This work, in turn, holds promise for better preventive care, better nutrition, and more sensitive screening and improved treatment for such devastating diseases as cancer, epilepsy, cardiomyopathy, and kidney failure.

Our main goal is to support research that leads to new diagnostic, treatment, and prevention techniques. Guided by our Scientific Review Committee, we fund only the most relevant and humane animal health studies.

Guidelines:

- 1) Relevance** All studies will be designed and carried out with consideration for their relevance to animal health and the advancement of knowledge.
- 2) Compassion** In accordance with good scientific technique, every animal shall have compassionate care, comfort, and protection from abuse and unnecessary pain.
- 3) Humaneness** Use of animals shall be humane and consistent with laws and regulations that have been approved by local governing bodies whose function is the regulation of animals in research (e.g., foreign country, veterinary practice, animal ranch/sanctuary, wildlife preserve, etc.) ACVIM Foundation will require the review of the proposed animal use by an established collaborating institution's IACUC or require the applicant to seek review from a willing institution that has an established IACUC. All animal care, husbandry procedures, and IACUC member structure shall meet or exceed the guidelines set forth in U.S. government's Animal Welfare Act (Title 9 CFR Subchapter A – Animal Welfare) and the National Research Council's Guide for the Care and Use of Laboratory Animals (1996), and/or further required regional regulations. ACVIM Foundation requires IACUC approval from the submitting institution for all clinical trials involving animals even though such approval may not be a requirement of the institution.
- 4) Informed Owner Consent** ACVIM Foundation shall require informed owner consent in all clinical trials involving client-owned animals. An informed owner consent form of minimum standards shall be provided to the foundation as part of the grant review process and executed by the Principal Investigator or appropriate officer under their authority.
- 5) Statement re: Disease Induction, Euthanasia Restrictions, and Management of Discomfort**
 - A. ACVIM Foundation shall not fund health studies on an animal which require the induction of disease or injury, unless 1) the nature of the disease or condition to be studied is of such significance for improving animal health that induction of disease is justified and 2) meaningful information can be obtained no other way (i.e. alternative models have been thoroughly evaluated). Investigators shall be required to address introduction of disease in all ACVIM Foundation grant applications.
 - B. ACVIM Foundation shall not fund any study in which euthanasia is required or otherwise controlled or influenced by the investigator unless compelling justification is made and no alternatives exist.



C. ACVIM Foundation shall not fund any study that induces or allows pain or distress, other than short-term, minor pain or distress that can be controlled by appropriate anesthetic, analgesic or tranquilizing drugs.

6) Study Termination ACVIM Foundation reserves the right to terminate a study if there are concerns about animal well-being.

7) Extraordinary and Unpredictable Circumstances ACVIM Foundation recognizes that, in upholding the Veterinarian's Oath, the following extraordinary and unpredictable circumstances may influence the funding of studies which would otherwise be rejected as unacceptable. These circumstances may include but are not limited to disorders associated with:

- A. severe morbidity/mortality
- B. economic or humanitarian crises
- C. clear or present threats to the public health

8) Modifications ACVIM Foundation will remain open to input from the professional and lay community regarding worthwhile modifications to this document as appropriate to help achieve the highest ideals of the Foundation.



2012 Grant Proposal Submission Checklist - Waltham

Fill out and include a copy of this checklist page with the proposal.

Proposal Title _____

Principal Investigator _____

1. **Title Page**
 - Proposal Title and Proposal Type** (Diplomate or Resident-if applicable).
 - Principal Investigator, Co-Principal Investigator, and Co-investigator(s)** - Name, degree(s) and position.
 - Contact information** - Mailing address, e-mail, and telephone and FAX numbers for Principal Investigator.
 - Institutional Representative** - Contact information and check information, in the event of an award.
 - Amount requested** – Annual and total amount of funds requested from ACVIM Foundation.
 - Signatures and date** - The PI, Co-PI, collaborators, and the Institutional Representative must sign and date the proposal (scan into PDF document or mail separately. If mailing, it must be received by the submission deadline).
2. **Abstracts (1 page maximum)**
3. **Hypothesis and specific aims (1 page maximum)**
4. **Background, Design, Methods, and Analysis (5 page maximum)**
 - Background and significance
 - Preliminary data
 - Study Design, Methods, Statistical and Data Analysis
 - *Study design* - Provide precise details about the study design.
 - *Methods* - Describe the methods that will be employed to achieve the Specific Aims of the project.
 - *Statistical and data analysis* - Describe how the sample size was determined and how data will be analyzed.
5. **Budget (1 page maximum) - Provide a detailed budget with a short justification for each item.**
6. **References (1 page maximum)**
7. **Facilities description (1 page maximum)**
8. **Biographical sketches - A short biographical sketch is required of PI, Co-PI, and collaborators who contribute significantly toward the generation of data.**
9. **Supporting documents - Include a signature from each co-investigator, collaborator, and consultant on the cover page.**
10. **Residency status – Letter from Co-PI verifying status of resident.**
11. **Institutional/other party commitments and assurances- Include a letter from the institution for each investigator.**
12. **Disclosure statements - A disclosure statement is required of PI and each co-investigator.**
13. **Institutional Biosafety Approval or statement that study is exempt and why. This is required only in the event funding is awarded, but it is strongly advised that it be included in the proposal in order to expedite release of grant funds.**
14. **Studies involving laboratory animals: Copy of Institutional Animal Care and Use Committee (IACUC) approval. This is required only in the event funding is awarded, but it is strongly advised that it be included in the proposal in order to expedite release of grant funds. *The use of laboratory or experimental animals is not allowed for this grant***
15. **Studies involving pet animals:**
 - Statement of assurance that the ACVIM Foundation Guidelines for Clinical Investigation will be adhered to.
 - Statement of assurance that the ACVIM Foundation Principles for the Humane Involvement of Pet Animals in Veterinary Clinical Investigations Principles will be adhered to.
 - Waltham's Statement of Animal Welfare is included
 - Copy of the Client Informed Consent form.
 - Copy of Institutional Animal Care and Use Committee (IACUC) approval or statement indicating that there is no applicable IACUC approval process available. **This is required only in the event funding is awarded, but it is strongly advised that it be included in the proposal in order to expedite release of grant funds.**

Submission: Complete proposal package including signed and dated cover sheet, checklist page, and other documents must be received as a PDF in electronic format (via email, CD-R or DVD-R) at the ACVIM Foundation office by close of business on Friday, April 20, 2012. **Please combine all documents into a single PDF file.**



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