



Michelson Prize & Grant Program Overview

May 1, 2010

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Agenda for this Session

- Overview of Found Animals and Michelson Prize and Grant Program
 - Aimee Gibbreath, Executive Director
- Overview of the Michelson Grant Application Process
 - Katy Palfrey, Program Manager
- Overview of Animal Welfare Guidelines
 - Dr. Shirley Johnston, Director of Scientific Research
- Overview of Projects and Concepts
 - Dr. Shirley Johnston, Director of Scientific Research
- Q&A with the Full Panel

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What is the Found Animals Foundation?

www.foundanimals.org

A 501(c)(3) private operating foundation. . .

. . . founded and funded by billionaire surgeon/inventor and serial entrepreneur Dr. Gary Michelson. . .

. . . and dedicated to developing innovative programs to minimize shelter euthanasia



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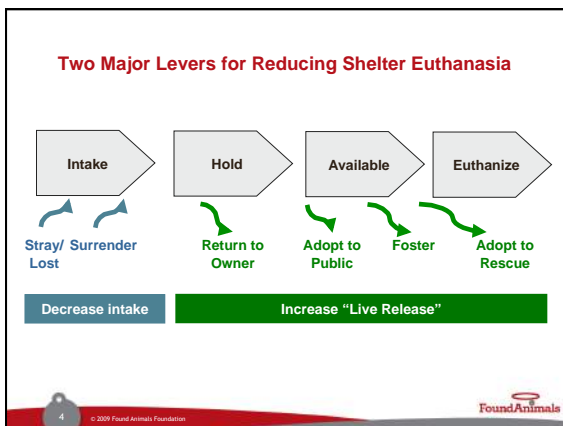
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Key Pet and Shelter Statistics

- **There are over 70 million dogs and 80 million cats in US households!**
 - 60% of US Households have pets
 - Only 56% have children under 18
 - Tens of millions more cats live on the streets feral and free roaming
- **Between six and eight million pets enter US shelters each year**
 - 1/3 or more are once wanted pets being surrendered by owners
 - ~25% of dogs in shelters are purebred
- **Only 50% of them go home alive, 3-4 million are euthanized**
 - Some for behavioral or health concerns, but most for simple lack of a home
 - An estimated 75% of the animals killed are cats
- **U.S. Municipalities spend over \$2B annually on animal care and control**
 - Approximately \$7 per person per year
 - Does not include amounts spent by private animal welfare groups

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Found Animals Programs Aligned Against Levers

Decrease intake	Increase "Live Release"	
Sterilization	Owner Resources	Adoption
<ul style="list-style-type: none"> • Low cost spay/neuter • Non-surgical research 	<ul style="list-style-type: none"> • Pet tips and tricks • Microchipping • Pet friendly housing 	<ul style="list-style-type: none"> • Shelter adoption events • Adoption promotions • Volunteer matchmakers
Education, Outreach, Policy		
<ul style="list-style-type: none"> • Live webcast variety show from shelter locations, 24/7 "kitty cam" • Social media promotions and contests • Pet licensing as a funding mechanism for subsidized spay/neuter 		

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What makes Found Animals stand out?



- Embrace of business principles for a social mission
- Focus on development of sustainable business models
- Emphasis on innovation, creativity, and experimentation
- No need for “tin cup” fundraising
- Run by business and medical professionals

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Media has started to notice Found Animals



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Current Status of Sterilization

- **Surgical spay/neuter is currently the standard for pet sterilization**
 - Surgery is very safe and effective
 - Eliminates reproduction and secondary sexual behavior
- **Most US pet owners already sterilize their pets via S/N**
 - ~70% of dog owners
 - ~80% of cat owners
- **But, S/N remains out of reach for populations that drive shelter intake**
 - Low income pet owners cite cost and access as barriers
 - 95+% of feral and free roaming cats are unsterilized
- **And studies show that most litters are still “accidents”**
 - 68% of the households that reported a litter of kittens born said it was unplanned, 47% of these households reported having more than one litter that year
 - 56% of households reporting a litter of puppies born, described them as unplanned with 21% having more than one litter

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Non-Surgical Sterilization Will Remove Barriers

Surgical spay/neuter procedures are not an ideal approach

- While quite safe and effective, S/N requires general anesthesia and an adequately equipped surgical facility
- This creates obstacles including high costs, transportation of animals and inherent health risks involved with surgery
- For many low income pet owners, surgical S/N is not accessible or affordable; also doesn't work well in developing nations

A single dose, non-surgical sterilant administered in the field at a reasonable cost would be an ideal solution

- Would extend the reach of sterilization to groups not currently well served by surgical approaches
- Would eliminate death and suffering for millions of companion animals worldwide

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The Michelson Prize and Grants

Announced October 2008

The Michelson Prize in Reproductive Biology:

\$25 million for innovation in non-surgical sterilization for cats and dogs

Found Animals will offer a \$25 million prize to the first entity to provide the Foundation with a safe, effective, and practical non-surgical sterilant for use in cats and dogs

The Michelson Grants in Reproductive Biology:

Up to \$50 million of grant funding available for research directed to achieving this goal

Found Animals will provide up to \$50 million in grant funding for promising research in pursuit of a safe, effective, and practical non-surgical sterilant for use in cats and dogs

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Why a Prize and Grant approach?

Animal health researchers have pursued non-surgical solutions for years, but a breakthrough product has yet to emerge

- Meanwhile, basic biology research has surged forward and many new technologies are on the horizon

Hope to encourage researchers from a variety of fields to take on the challenge of non-surgical sterilization for dogs and cats

- By attracting scientists who may have been unaware of pet issues to get involved, Found Animals hopes a solution will come to light quickly

We recognize that the research required to develop and test pharmaceuticals takes time and money

- Many interested parties may not have access to the resources needed to initiate and maintain this research
- The market for this product may not be commercially attractive

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Goal to Ensure an Effective Product Reaches the Market Priced for Maximum Impact

Goal is to see that a successful product is marketed widely at a reasonable price to meet its full potential in reducing unwanted litters

- Target segments include shelters, low income pet owners, feral and free roaming populations, and developing nations

Accordingly, Found Animals seeks licensing and/or intellectual property rights for products resulting from research it funds

- Prize & Grant terms and conditions address access to technology

Also expect involvement in the commercialization process of any viable products that develop from Prize & Grant program

- Found Animals is willing to fund and manage activities required to take product through the regulatory process and to ensure manufacturing and distribution

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Michelson Prize Details

The winning entry for the Michelson Prize in Reproductive Biology will have, at minimum, the following characteristics:

- Single dose, non-surgical sterilant
- Safe and effective in male and female, cats and dogs
- Suitable for administration in a field setting
- Viable pathway to regulatory approval
- Reasonable manufacturing process and cost

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Basic Prize Terms and Conditions

- Applicants must demonstrate safety, efficacy, at a "proof of concept" level in target species
- No expectation that applicant will have submitted for or received regulatory approval, but should be clear pathway
- Must have clear understanding of manufacturing process and cost, but no need for facilities
- \$25M Prize awarded in exchange for exclusive right to make and sell product worldwide
- May elect a royalty on eventual product sales instead of lump sum payment, if preferred
- Prize is open to any entity from any country (some details may vary based on entity and geography)

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Michelson Grant Details

- Multiple multi-year grants available for promising research in pursuit of non-surgical sterilization for dogs and cats
- Proposed research is **not** required to generate results which meet all of the Prize criteria in order to be funded
- However, preference will be given to projects with the potential to produce a Prize winning product or technology
- Grant recipients eligible to make Prize claims if research generates a product that meets all of the Prize criteria
- Prize and Grants open to commercial and academic entities from any country

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Basic Grant Terms and Conditions

- Must submit quarterly progress reports and a final grant report
- Must comply with animal welfare guidelines and host annual scheduled site visits and intermittent (unannounced) animal welfare visits
- Must agree that Foundation will have
 - first right of refusal to an exclusive license (with right to sublicense) to make, sell, and use product(s) in areas of interest to the Foundation
 - rights to the background intellectual property required to exercise a license on product(s) resulting from funded research
- Foundation will compensate the licensor with a royalty or comparable compensation structure if a product is approved for sale

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Our Website is a Great Resource

The screenshot shows the FoundAnimals website with a navigation bar and a sidebar. The main content area features the title "The Michelson Prize & Grants in Reproductive Biology" and a sub-header "The Michelson Prize in Reproductive Biology". Below this, there is a paragraph of text and a list of bullet points. The website also includes social media icons for Twitter, Facebook, and LinkedIn.

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Join Michelson Prize & Grant Mailing List for Updates!



The screenshot shows the FoundAnimals website with a 'Mailing List' sign-up form. The form includes fields for Name, Email, and Phone, and a 'Sign Up' button. There are also social media icons for Twitter, Facebook, and YouTube at the top right of the page.

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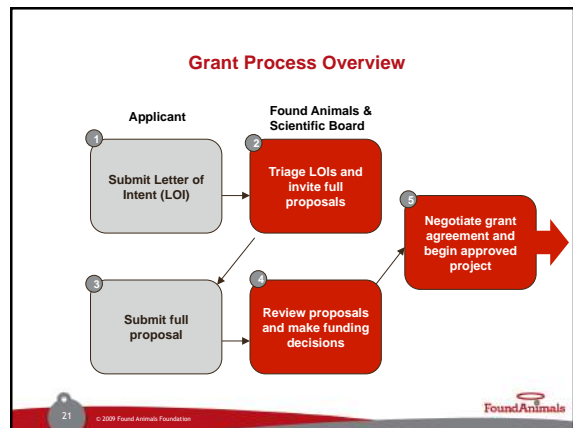
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Got a Great Idea?



A cartoon illustration of a person with their arms outstretched, looking up at a glowing lightbulb above their head, symbolizing a great idea.

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LOI is First Step in Grant Application Process

Research team submits Letter of Intent to Found Animals which includes:

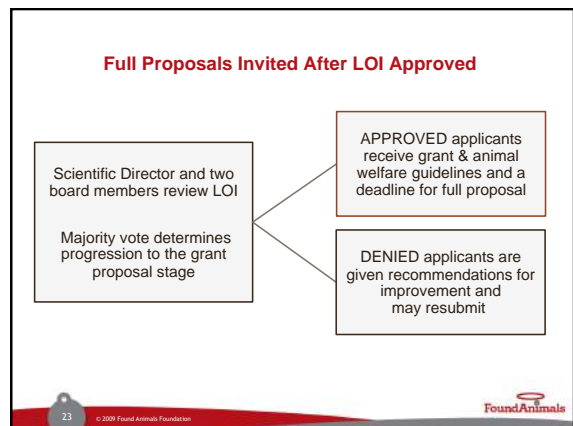
- Rationale for approach
- Summary of required research
- Explanation of how research will facilitate achievement of goal

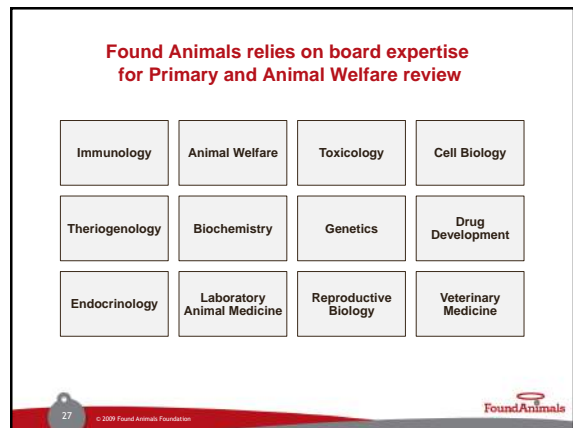
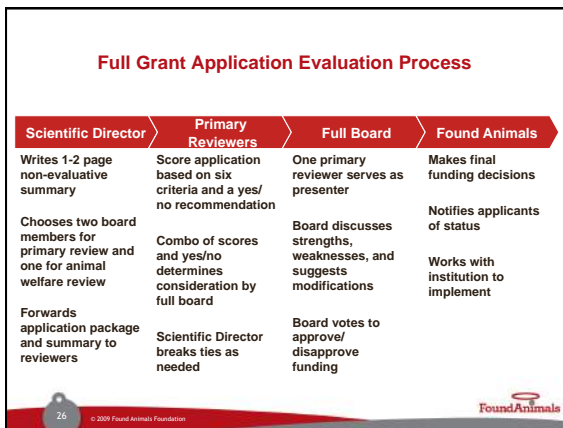
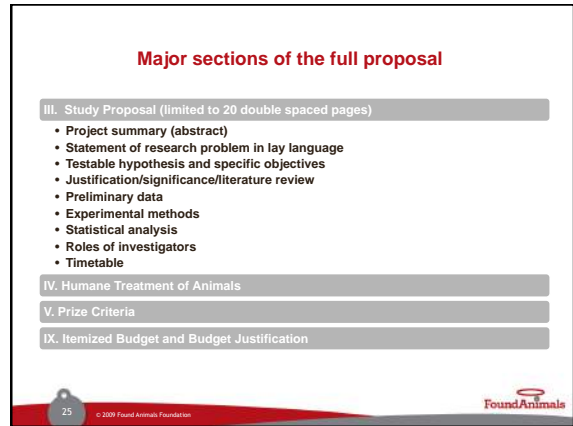
LOIs are limited to 2 pages and must be submitted through the website.

Foundation reserves the right to decline LOIs which do not conform to guidelines.

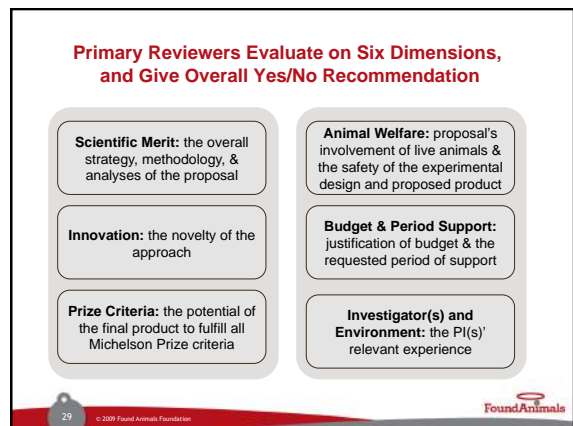
LOIs are accepted and reviewed on a rolling basis throughout the year. Found Animals aims to get back to applicants within 6-8 weeks from receipt of LOI.

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- ### Scientific Advisory Board
- Todd Alonzo, PhD, Biostatistician, USC Children's Oncology Group
 - David Brake, PhD, Founder, BioQuest Associates LLC
 - David Brent, PhD, Founder, Brent Tech
 - Scott Campbell, DVM, Founder, Banfield™ the Pet Hospital
 - Marcelo Couto, DVM, PhD, DACLAM, UCLA
 - Gary Gamerman, MS, JD, Seraphim Life Sciences
 - Thomas Graves, DVM, PhD, DACVIM, University of Illinois
 - Carl Johnson, PhD, Hereditary Disease Foundation
 - Safdar Khan, DVM, PhD, DABVT, University of Illinois & Poison Control Center
 - Michelle Kutzler, DVM, PhD, DACT, Oregon State University
 - Dennis Lawler, DVM, Ret, Nestle Purina
 - Gary Patronek, VMD, PhD, Animal Rescue League of Boston
 - Andrew Rowan, PhD, Humane Society of the United States
 - Michael Skinner, PhD, Washington State University
 - John D. Tegzes, DVM, DABVT, Western University of Health Sciences
 - David Wildt, PhD, National Zoo, Washington DC
 - Stephen Zawistowski, PhD, ASPCA, New York
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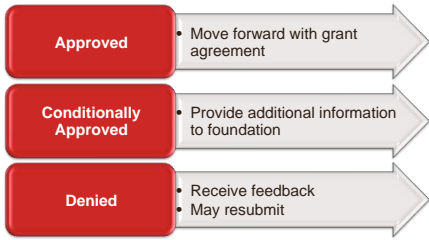
Scientific Advisory Board meeting



- One primary reviewer serves as presenter for the proposal
- Board discusses strengths, weaknesses, and suggests modifications
- Board votes to approve/ disapprove funding

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Review Outcomes



- Approved**
 - Move forward with grant agreement
- Conditionally Approved**
 - Provide additional information to foundation
- Denied**
 - Receive feedback
 - May resubmit


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Grant Contract Addresses Basic Terms and Conditions

- Must submit quarterly progress reports and a final grant report
- Must comply with animal welfare guidelines and host annual scheduled site visits and intermittent (unannounced) animal welfare visits
- Must agree that Foundation will have
 - first right of refusal to an exclusive license (with right to sublicense) to make, sell, and use product(s) in areas of interest to the Foundation
 - rights to the background intellectual property required to exercise a license on product(s) resulting from funded research
- Foundation will compensate the licensor with a royalty or comparable compensation structure if a product is approved for sale

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Tips for applicants



- Carefully review Michelson Grant requirements
- Do not include overview of pet overpopulation issue
- Title should be descriptive of the work proposed
- Stick to the page limits
- Make sure your animal use numbers are consistent
- Know what has been tried before
- Research dog & cat anatomy
- Think outside the box
- Strictly adhere to animal welfare guidelines
- Consider review criteria


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Otherwise Known As.. .



How to keep a **good** “science” proposal from being disapproved because of a **bad** “animal use” justification

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The Foundation seeks to set a high standard regarding use of animals in research




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Animal Welfare Guidelines

General Concepts:


- <http://www.foundanimals.org/index.php/About-Michelson/guidelines.html> (15 guidelines)
- Guide for Care & Use of Laboratory Animals
- Draft IACUC proposal



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Animal Welfare Guidelines


1. Use of animals shall be humane and consistent with IACUC regulations.
2. Investigators and care staff will have animal care qualifications & experience.
3. IACUC approval is required for disbursement of funding.
4. IACUC approval for archived samples must be available.
5. Informed owner consent is required for clinical trials.
6. **Unannounced site visits will be conducted to verify compliance.**
7. **Statistical evidence must be provided to justify sample size.**
8. Living conditions for research animals must be appropriate for their species.
9. **Research animals must have compassionate care, comfort, and protection from unnecessary pain.**
10. **Research animals must be appropriately socialized for their species and have appropriate environmental enrichment.**
11. **When possible, animals will be made available for adoption at the end of the study.**
12. Terminal endpoints may be acceptable if essential information can be obtained in no other way.



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Animal Welfare Guidelines

13. Michelson Grants will not fund a study that induces or allows pain or distress unless controlled by appropriate anesthetic, analgesic or tranquilizing drugs. **All invasive procedures shall require balanced anesthesia and preemptive, multimodal analgesia.**
14. Michelson Grants reserves the right to terminate a study and/or withdraw grant funding if progress is deemed unsatisfactory or if there are concerns about animal well-being.




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Animal Welfare Guidelines

"6. Found Animals will perform unannounced site visits for verification of compliance with animal welfare guidelines."

- Found Animals Foundation staff will conduct announced site visits near the end of the third quarter of each year of funding to review progress toward goals, expenditures, and animal facilities.
- An ACLAM-accredited veterinarian will conduct intermittent unannounced site visits at funded institutions to review compliance with Animal Welfare guidelines.




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Animal Welfare Guidelines

"7. Proposals must contain statistical evidence that the number of research animals proposed for use is not excessive, and yet is statistically adequate to achieve the proposed results."

- a biostatistician on the Scientific Advisory Board reviews every proposal for **sample size and appropriateness of statistical evaluation** proposed.
- the number of research animals used must be **consistent** in sections on Methods, Justification of Animal Involvement, and budgeted cost of animal acquisition.
- consider including an **algorithm** to communicate animal numbers, if use in some stages of the proposed research depends on outcomes from an earlier stage.




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Animal Welfare Guidelines

“9. Research animals must have compassionate care, comfort, and protection from unnecessary pain. All invasive procedures shall require balanced anesthesia and preemptive, multimodal analgesia.”

Provide detailed description of all animal protocols (analgesia, anesthesia, euthanasia) (drugs, routes of administration, etc).





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Animal Welfare Guidelines

“10. Research animals must be appropriately socialized for their species, and have environmental enrichment appropriate for their species.”

- Indicate whether research animal housing will be in AAALAC-accredited facilities.
- Describe environmental enrichment that will be provided.







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Animal Welfare Guidelines

“11. When possible, research animals will be made available for adoption at the study; research animals may not be reassigned to another research project at the end of the study.”

- Found Animals Foundation may assist investigators in finding adoptive homes.







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Animal Welfare Guidelines

Other:

- Justify whether breeding studies offer an advantage over gonadal histology in demonstration of sterilization.
- Consider requesting funding for “pilot” or “proof of concept” studies before requesting major funding for a project dependent on an assumption that has not yet been demonstrated.
- Consider small pilots in target species (cat, dog) rather than exhaustive studies in non-target species.





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Michelson Grants in Reproductive Biology Projects & Concepts Funded to Date

The Michelson Grants in Reproductive Biology was announced in 2008, with availability of \$50 million in competitive funding for research leading to development of a


- single dose, nonsurgical sterilant
- that is safe and effective in male and female cats and dogs
- suitable for administration in a field setting,
- with a viable pathway to regulatory approval, and
- a reasonable manufacturing process and cost



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Michelson Grants in Reproductive Biology Projects & Concepts Funded to Date

- Letters of Intent received 102
[from North America, South America, Europe, Asia, Australia]
- Letters of Intent approved to progress to proposals 35
- Proposals received 33
[from USA, Canada, UK, Australia; 7 in review process]
- Proposals approved for board review 22
[of 26; 7 in review process]
- Proposals recommended for full or partial funding 7




Michelson Grants in Reproductive Biology Projects & Concepts Funded to Date

Proposals have been received in categories of

- silencing of genes coding for proteins that are essential in the reproductive cascade,
- immunocontraception against GnRH, and
- targeted delivery of cytotoxins to pituitary or gonadal cells


The Foundation seeks more proposals in these categories and others that may bear promise



Michelson Grants in Reproductive Biology Projects & Concepts Funded to Date

Proposals Recommended for Funding **[\$3.478 million]**


- Davidson BL, Ojeda S, Disson GA: *Inducing stable infertility by RNA interference. Proof of principle studies.* University of Iowa, Oregon Health Sciences Center [\$160,000]
- Meyer RG, Meyer-Ficca M: *Targeting Poly(ADP-Ribose) metabolism for development of a nonsurgical sterilant.* University of Pennsylvania [\$577,000]
- Marrack P, Munks M, Sosinowski T: *Use of attenuated recombinant herpesviruses expressing fertility antigens, to induce infertility in cats and dogs.* National Jewish Health, Denver [\$756,000]



Michelson Grants in Reproductive Biology Projects & Concepts Funded to Date

Proposals Recommended for Funding **[\$3.478 million]**

- TBA: Targeted delivery of cytotoxin [\$206,000]
- TBA: Targeted delivery of cytotoxin [\$133,000]
- TBA: Immuno-contraception, GnRH [\$733,000]
- TBA: Targeted delivery of cytotoxin [\$913,000]



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Questions?

