



**Melanoma Research Foundation**  
**Request for Proposals (RFP)**  
**2023**

## **RESEARCH OVERVIEW:**

The Melanoma Research Foundation (MRF) is committed to advancing research across the spectrum of melanoma – from prevention through diagnosis, staging, treatment and survivorship. The MRF proactively partners with the NCI, Congress, the Department of Defense and other foundations to develop and collaborate on a broad agenda for melanoma research that takes full advantage of all opportunities, while also sharing challenges. Since 1998, the MRF has funded 269 innovative, high impact, basic, translational and clinical research projects. Further, in 2022, the MRF awarded over \$1,913,000 in *new* melanoma research. In 2023, the MRF will offer a CURE OM Award, Established Investigator Awards and Career Development Awards (as discussed in this RFP), as well as Medical Student Awards, Resident-Fellow Awards, Mid-Career Bridge Grants and a Pilot Translational Award (detailed in separate RFPs as noted below).

Please visit [www.melanoma.org](http://www.melanoma.org) for additional information on the MRF and to learn more about previously funded research. All questions or concerns regarding the MRF's Research Grant Program can be directed to the MRF Science Officer at [research@melanoma.org](mailto:research@melanoma.org) or by calling 800-673-1290.

## **TYPES OF AWARDS OFFERED IN 2023:**

### **Available through this award mechanism**

#### **CURE OM Options Bring Hope Award in honor of Lindsay Zubeck (CURE OM)**

This CURE OM award provides funding of **up to \$250,000 over a two-year period** (\$150,000 for year one and \$100,000 for year two) to an investigative team whose research will advance treatment for HLA-A\*02:01-negative patients with unresectable or metastatic uveal melanoma. Teams should consist of a PI and at least one co-PI, ideally from different institutions. Teams consisting of both basic scientists and clinicians are encouraged, as is the inclusion of a junior scientist.

#### **Established Investigator Awards (EIA)**

The EIAs provide funding of **up to \$100,000 per year for two years** to established melanoma researchers, or senior researchers working in closely related fields who wish to move into melanoma research.

#### **Career Development Awards (CDA)**

The CDAs provide funding of **up to \$50,000 per year for two years** to junior investigators. Researchers who are beginning a research career focused on melanoma are eligible. This year, in addition to general CDAs, the MRF will again offer the **Silverstein Family Research Grant Challenge Women in Science Award/WIS CDA**.

**Available through separate award mechanisms** (please refer to the MRF website for additional details)

### **Mid-Career Bridge Grants**

In response to a growing need in the field, the MRF has established its Mid-Career Bridge Grant to support investigators who are dedicated to melanoma research. This award will be for established researchers with pre-existing R01s, who have applied for a NIH R01 grant that was scored, but not funded. To support and sustain these investigators while they generate the data for the Response to Reviewers in the revised R01 (A1) submission, the MRF is offering bridge funding of **up to \$100,000 for one year**. Application submission deadlines are on April 14<sup>th</sup>, August 15<sup>th</sup>, or December 15<sup>th</sup>, 2023.

### **Resident/Fellow Awards**

The Resident/Fellow Awards provide funding of **up to \$10,000 for one year** to radiation oncology, dermatology, or pathology residents or fellows (either those in a two- or three-year fellowship program) in the United States with an interest in melanoma research. These awards provide opportunities and funding for residents/fellows to engage in short term clinical or laboratory-based research projects. This grant RFP will be posted in September 2023.

### **Medical Student Awards**

The Medical Student Awards provide funding of **up to \$3,000 for one year** to medical students at accredited U.S. medical schools or institutions. These awards provide opportunities and funding for medical students to engage in short clinical or laboratory-based research projects focused on better understanding the biology and treatment of melanoma. 2023 applications are currently under review.

## **SPECIFIC TOPIC PROPOSALS (STPs):**

The identification of scientific topics that address unmet clinical needs in melanoma research were identified through a series of meetings of multidisciplinary experts from the MRF's [Scientific Advisory Committee](#) and [Breakthrough Consortium Steering Committee](#). The following categories are the identified unmet needs in melanoma research selected as STPs for 2023.

### ***Prevention, Early Detection and Population Science***

Screening for melanoma is a potentially important way to reduce melanoma mortality. However, melanoma is relatively uncommon and the ratio of number of screened patients for every melanoma diagnosed would be high without better prediction of the population that should be screened. In addition, melanoma can be difficult to diagnose, lending itself to false positives and negatives during the screening process.

In order to make screening more effective and decrease mortality, better methods of melanoma diagnosis seem necessary to decrease false positives and negatives. Options might include imaging and molecular biomarkers that improve diagnostic accuracy and technologies to enhance the sensitivity and specificity of the clinical diagnosis of melanoma and/or to minimize the morbidity associated with the biopsy of benign lesions. Use of quality of life and patient-reported outcome studies to quantify the harms associated with population-based melanoma screening is an important adjunct to new research.

### ***Tumor Cell Dormancy and Metastasis***

Tumors do not progress in linear patterns but may undergo extensive dormant phases. Clinical Dormancy (the time between removing a primary tumor and relapse, especially at metastatic sites) remains one of the most critical issues surrounding durable responses in patients. The escape from clinical dormancy by melanoma and other cancer cells is likely responsible for most cancer-related deaths. Several mechanisms for dormancy have been proposed: single cell dormancy, where disseminated cells remain quiescent until triggered to proliferate by changes

within the tumor cell or in the microenvironment; pre-angiogenic dormancy, where dormant micrometastases exist as clinically undetectable lesions that eventually grow into metastatic disease in response to angiogenic signaling; and immune-related dormancy where the immune system keeps tumor cell numbers in check. Additionally, it is not known how the preferred tissue tropism of tumor cells affects their dormancy. There is a major lack of understanding of what influences and regulates tumor dormancy, how dormant cells interact with their microenvironment, and most importantly, how they escape dormancy. Basic and translational research is badly needed in this arena, which is vastly understudied and underfunded.

### ***Therapy and Resistance***

The past several years have seen approval of several new classes of agents for melanoma; however, only a minority of patients exhibit a durable response to immunotherapy or to other targeted therapies. Identification of *clinically relevant* mechanisms and related biomarkers, including genetic-, gene expression-, or protein-based, that can explain the response (or lack of) is anticipated to enable better stratification of patients to therapy, predict likelihood of response and/or accurately monitor response in the course of treatment. Addressing this STP is expected to result in defined mechanisms and related markers that could explain resistance or response of patients.

### ***Rare Melanoma Tumors***

Melanoma is now recognized as a heterogeneous disease encompassing many molecular subtypes. Identifying mechanisms underlying the development of more rare subsets of melanoma (e.g. mucosal, acral, ocular and pediatric melanoma) is expected to drive translational studies and clinical evaluations. Applicants applying to the CURE OM Options Bring Hope Award in honor of Lindsay Zubeck should select this STP.

Applicants must clearly indicate which of the categories – if any – is being addressed in their application. Applications are not required to address these STPs, although those that do might be given extra consideration. However, in all cases, the scientific merit is the most important factor underlying the selection for funding.

## **ELIGIBILITY & REQUIREMENTS:**

### **General (for all grant types)**

- Applicants must hold a PhD or MD degree or equivalent at the time of the grant submission.
- For this RFP, applicants may be the PI or co-PI on only one submitted application.
- Applicants are eligible to respond to other MRF RFPs, as long as the research proposals are significantly different.
- American citizenship is not required. However, for all grants, *with the exception of the CURE OM Options Bring Hope Award in honor of Lindsay Zubeck (see eligibility criteria below)*, the proposed research must be conducted in a non-profit research organization, a medical institution or an educational institution located in the United States.
- Applicants must show evidence of strong departmental or institutional support and commitment.
- PIs and co-PIs may not have an active research award with the MRF (please note: awards currently under no-cost extensions are not considered as active research awards).
- The use of relevant genetic models and/or human derived tumor samples is highly encouraged, but not required.
- Applicants may, but are not required to, submit applications focused on one of the STP unmet needs.

- Proposed research must comply with all applicable National Institutes of Health (NIH) animal and human welfare guidelines.
- Applicants are encouraged to discuss any eligibility questions with the MRF prior to applying.

### **CURE OM Options Bring Hope Award in honor of Lindsay Zubeck (CURE OM)**

- The proposed research must focus on advancing treatment for HLA-A\*02:01-negative patients with unresectable or metastatic uveal melanoma.
- The Principal Investigator (PI) must have a title equivalent to Associate Professor or higher at the time of the grant submission.
- PI is encouraged, although not required, to include a junior faculty member as part of the team.
- PI is encouraged to establish teams consisting of basic scientists and clinicians.
- Teams are expected to consist of a PI and at least one co-PI, ideally from different institutions.
- International scientists may be eligible to participate in this award as a co-PI or team member, but not as a PI. If an international investigator will be part of the team, the PI must include (as part of their application) confirmation that their institution is willing to subcontract with the international site.

### **Established Investigator Awards (EIAs)**

- Applicants must have a title equivalent to Associate Professor or higher at the time of the grant submission. Both tenured and non-tenured track faculty are encouraged to apply.

### **Career Development Awards (CDAs), including the WIS CDA**

- Applicants who are postdoctoral fellows must have less than 5 years of postdoctoral experience at the time the grant will be awarded and must not have previously received any major grant support (e.g. from ACS, NIH, NCI, or DoD).
- Applicants who are not postdoctoral fellows may have a title of Research Associate/Scientist, Staff Scientist, Instructor, Assistant Professor, or equivalent at the time of the grant submission. For individuals in this category, previous grant support (e.g. K08, K99, K22, etc.) is allowed.
- For the Silverstein Family Research Grant Challenge (WIS CDA), the applicant must identify as a woman.
- Applicants are required to have at least one mentor; their biosketch must be included in the application. Please note: mentors do not have to be at the applicant's own institution.

### **REVIEW PROCESS:**

The MRF's Research Grant Program emphasizes basic, translational and clinical research projects that explore innovative approaches to understanding critical problems pertaining to prevention, diagnosis, staging and treatment of melanoma. All proposals will undergo rigorous peer review, where reviewers are selected based on their expertise in diverse areas of basic, translational and clinical melanoma research. Reviewers include members of the MRF's Scientific Advisory Committee (SAC), the Breakthrough Consortium (MRFBC), the Community United for Research and Education of Ocular Melanoma (CURE OM) and the Dermatology Advisory Council (DAC) as well as members of the scientific and clinical melanoma community who are not in conflict with the application. Applications with the highest scores will be assessed by a panel of representatives from the initial review group. The top ranked grants are recommended for funding to the MRF Board of Directors. The number of grants selected for funding is determined by the MRF Board of Directors, based on available funds.

## **AWARD ADMINISTRATION AND REPORTING:**

The CURE OM Options Bring Hope Award in honor of Lindsay Zubeck will be awarded on or around **June 30<sup>th</sup>, 2023**. EIA and CDA Award decisions (including the WIS CDA) will be made on or around **August 15<sup>th</sup>, 2023**. Upon acceptance of the award, the PI and the Institution will be required to sign an award letter accepting the MRF's terms and conditions.

Awards will cover research conducted over a two-year period. Funds are distributed two times each year for a total of four payments over two years. A no-cost extension may be permitted with sufficient justification from the PI and approval from the Program Director. Requests for a no-cost extension must be made within 30 days of the award period expiration.

Interim financial and scientific progress reports are to be submitted to the MRF no later than 30 days prior to the end of the grant's first year. Final financial and scientific reports, detailing all activities during the award period, are to be submitted to the MRF within 60 days of the end of the award period (even if a no-cost extension is requested).

Acknowledgment of support from the MRF must accompany any published report using data or findings from research conducted under an award from the MRF. The intellectual property reviewed remains solely within the institution.

## **STEP-BY-STEP APPLICATION INSTRUCTIONS:**

**The MRF will accept applications from January 10<sup>th</sup> – March 1<sup>st</sup>, 2023 for the 2023 award cycle. The deadline is March 1<sup>st</sup>, 2023 at 5 pm ET.** All submissions, notifications and critiques will be completed entirely online through ProposalCENTRAL (<https://proposalcentral.altum.com/>).

**Please read the instructions carefully prior to beginning the online grant submission process.**

**NOTE:** Applications that represent resubmission of previously proposed studies, in whole or in part, may be submitted for consideration only twice; however, there is no restriction on the timing of the resubmissions. A one-page letter referencing the project title, a summary of changes to the application from the previous submission, and responses to reviewers' criticisms must be uploaded as an attachment during Step 12: Upload Attachments.

### **Step 1: Title Page**

The project title should not exceed the space provided (75 characters, including spaces).

Choose the grant program, from the list noted below, to which you are applying (and if applicable, please select the appropriate STP category). You can only select one grant program; therefore, please select the most specialized grant for which you qualify. With respect to the CDAs, all grants will be considered for the General CDA pool (if not awarded the CURE OM or WIS specialized CDAs).

- CURE OM Options Bring Hope Award in honor of Lindsay Zubeck (CURE OM) – up to \$250,000 over a two-year period
- Established Investigator Award (EIA) – up to \$200,000 over a two-year period
- Career Development Awards (CDA) – up to \$100,000 over a two-year period – this includes general melanoma CDAs and the Silverstein Family Research Grant Challenge for Women in Science (WIS CDA)

**The research period for all awards is a two-year period. The CURE OM Options Bring Hope Award in honor of Lindsay Zubeck grant period runs from July 31<sup>st</sup>, 2023 and ends on July 30<sup>th</sup>, 2025. All other award periods begin September 30<sup>th</sup>, 2023 and end September 29<sup>th</sup>, 2025.**

Please specify if this is a new application or a resubmission.

### **Step 2: Enable Other Users to Access This Proposal**

You have the option to allow other individuals access to your application. You can choose from three different levels of permission.

### **Step 3: Applicant/PI**

Profile information is pre-loaded in this section. You may update your profile information here as well.

### **Step 4: Additional Applicant/PI Information**

Additional applicant/PI information is requested in this section. All answers for this step are optional. This information will only be used for internal MRF purposes.

### **Step 5: Institution and Contacts**

Institution information and contact information can be updated and/or changed here.

### **Step 6: Key Personnel**

Key personnel, other than the applicant, who will provide support to the project will be listed here. A NIH Biosketch and Other Support Page (both active and pending) for the PI/co-PI and all Mentors will be required to be uploaded in this section. If this is a Career Development Award (CDA or WIS CDA), the PI must list their mentor in this section. The Other Support page must include information about all types of available research support (including direct costs and percent effort). Please note: with respect to the Other Support for CDA applications, there should be no funding overlap between the CDA applicant's proposed project and the mentor's funded research.

### **Step 7: Environment**

Please provide a description of your institutional environment in which the research will be conducted. Please describe how this environment will contribute to the probability of success (e.g. institutional support, physical resources including laboratory, office space and common use facilities contributing to the proposed work, etc.). For all CDA applications, including the WIS CDA grant, please also provide an overview of the institutional investment in the success of the investigator (e.g. travel, training, collegial support including the availability of organized peer groups, logistical support such as administrative management/oversight and financial support such as protected time for research with salary support) as well as a description of your career goals/objectives including any career development/training activities that will occur during the grant period.

### **Step 8: Abstracts**

#### **Scientific Abstract**

In the space provided, include a summary of the proposal that gives a brief description of the objectives, rationale, methods and expected results. The total length of the summary may not exceed 3,000 characters (including spaces) and should be written in scientific terms.

### **Lay Abstract**

In the space provided, include a brief (<3,000 characters, including spaces) summary of the proposal. The lay level abstract needs to be written so that the everyday person can understand the significance, impact and innovation of the proposed research.

### **Keywords**

Please select up to six appropriate keywords (from the list provided) that characterize the proposed research project.

*If the project is awarded, portions of the abstracts may be used in the MRF's various publications, press releases, fundraisers and educational events.*

### **Step 9: Budget Period Detail**

Awards will be made for a two-year period. Please fill out the budget information for **both years**. Please note for all grants:

- **Only direct costs are allowed.**
  - **Cost of living adjustments for personnel or non-personnel costs are not allowed.**
  - **When calculating salaries, please use actual costs – not the salary allowed by the NIH salary cap.**
  - **No more than 25% of the grant should go towards the salaries of the PI or co-PI.**
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- **CURE OM Options Bring Hope Award in honor of Lindsay Zubeck (CURE OM)**

#### **Personnel Costs**

All personnel may be named in this section. The salary and fringe benefits included in the budget is calculated based on total of salary and fringe benefits multiplied by the % effort. Salary distribution of supporting personnel is up to the discretion of the PI.

#### **Non-Personnel Costs**

All budgeted expenses such as consumable supplies, animal costs, service fees and consultant fees must be itemized. Requests for major equipment will be closely scrutinized, should be carefully justified, and should not exceed 15% of the total (two year) budget. Indirect institutional costs are not allowed. Allowable travel expenses for meetings and research purposes – including to international meetings – are capped at \$2,000 per project year.

The CURE OM Options Bring Hope Award in honor of Lindsay Zubeck will not exceed \$250,000 in total (\$150,000 the first year and \$100,000 the second year).

- **Established Investigator Awards (EIA)**

#### **Personnel Costs**

All personnel may be named in this section. The salary and fringe benefits included in the budget is calculated based on total of salary and fringe benefits multiplied by the % effort. Salary distribution of supporting personnel is up to the discretion of the PI.

### **Non-Personnel Costs**

All budgeted expenses such as consumable supplies, animal costs, service fees and consultant fees must be itemized. Requests for major equipment will be closely scrutinized, should be carefully justified, and should not exceed 15% of the total (two year) budget. Indirect institutional costs are not allowed. Allowable travel expenses for meetings and research purposes – including to international meetings – are capped at \$2,000 per project year.

Established Investigator Awards will not exceed \$100,000 per year.

- **Career Development Awards (CDA), including the Silverstein Family Research Grant Challenge for Women in Science (WIS CDA)**

### **Personnel Costs**

All personnel may be named in this section. The salary and fringe benefits included in the budget is calculated based on total of salary and fringe benefits multiplied by the % effort. Mentors should not be salaried. Salary distribution of supporting personnel is up to the discretion of the PI.

### **Non-Personnel Costs**

All budgeted expenses such as consumable supplies, animal costs, service fees and consultant fees must be itemized. Requests for major equipment will be closely scrutinized, should be carefully justified, and should not exceed 15% of the total (two year) budget. Indirect institutional costs are not allowed. Allowable travel expenses for meetings and research purposes – including to international meetings – are capped at \$2,000 per project year.

Career Development Awards will not exceed \$50,000 per year.

## **Step 10: Budget Summary**

This is a summary of the Budget Period Detail. Also, please give a brief justification for each budget item here.

## **Step 11: Organization Assurances**

Information regarding human subjects, vertebrate animals, and/or recombinant DNA will be entered here (if relevant). If an application has just been submitted, please note that as well.

## **Step 12: Upload Attachments**

All attachments must be in PDF form. Uploaded documents should fall under one of the following descriptions:

**Letter of Support** – A letter of support from your institution is required; additional letters of support are allowed. This letter should be from the department chair or other leader at the institution with direct knowledge of the applicant's value to the department and institution. A research laboratory head may write a letter of support for a postdoctoral fellow applicant; however, for all other applicants, it is anticipated that the letter of support will come from a departmental chair or other institutional leader. The letter should also mention the trajectory of the candidate in terms of leadership within the department or institution.

**Other** – If the application is a resubmission of a previously proposed study, a summary of changes to the application from the previous submission, and responses to reviewers' criticisms must be



uploaded here. This file must be limited to 1 page in length. Please note: biosketches and other support pages should be uploaded on the “Key Personnel” page.

**Research Plan** – The research plan is limited to **6 pages, Arial font, at least 11pt font with ½ inch margins**. Single line spacing is acceptable. The text of the Research Plan should contain sufficient information for the evaluation by the reviewer panel and should cover:

1. Specific Aims (if the application addresses one or more STP, please cite the topic)
2. Background, rationale and significance. Include a statement of significance of the proposed work, its clinical relevance to melanoma prevention, diagnosis and/or treatment, potential for further research and the potential for securing future funding for the project.
3. Preliminary Data: results of previous research related to the Project Title. Specify how the original research objectives have been met and include justification of support based on exceptional findings. If the original research objectives were not met or were modified, an explanation must be included.
4. Experimental design and procedures
5. References (References ARE NOT counted in the 6-page limit)

### **Step 13: Validate**

Click the 'Validate' button here to check for any missing required information or files. All missing required information will be listed on the screen. Please correct any missing information before proceeding to the next step.

### **Step 14: Signature Page(s)**

You may print the signature page(s) after you have completed all the proposal sections.

### **Step 15: Submit**

Submit your application. You will be unable to submit if you have not provided all the required information. We encourage you to submit your application as early as possible so that we can assist you with any issues that may arise. **The deadline is March 1<sup>st</sup>, 2023 at 5 pm ET.**

## **FREQUENTLY ASKED QUESTIONS:**

### **How do I apply for a grant?**

The grant application will be available ONLY during the time applications are being accepted. During that time, you can apply for a research grant online at <http://proposalcentral.altum.com/>.

### **What is the deadline?**

Applications will be accepted from January 10<sup>th</sup> – March 1<sup>st</sup>, 2023 at 5pm ET.

### **Do I need to be a U.S. citizen?**

No. However, the proposed research must be conducted in a non-profit research organization, a medical institution or an educational institution located **in** the United States. International scientists may be eligible to participate in a CURE OM Team Award as a co-PI or team member, but not as a PI. If an international investigator will be part of the team, the PI must include confirmation that their institution is willing to subcontract with the international site.

### **Am I eligible?**

Please read all eligibility requirements. Should you have questions not answered here, please contact the MRF Science Officer at [research@melanoma.org](mailto:research@melanoma.org).

### **How many grant programs are currently funded by the foundation?**

In 2023, the MRF will fund a total of 6 different grant programs: the CURE OM Options Bring Hope Award in honor of Lindsay Zubek (up to \$250,000 over a two-year period), Established Investigator Awards (up to \$200,000 over a two-year period), Career Development Awards – including a CDA for a woman in science (up to \$100,000 over a two-year period), Mid-Career Bridge Grants (up to \$100,000 over a one-year period), Resident/Fellow Awards (up to \$10,000 over a one-year period) and Medical Student Awards (up to \$3,000 over a one-year period).

### **What is the difference between the programs?**

The CURE OM Options Bring Hope Award in honor of Lindsay Zubek is for investigative teams focused on advancing treatment for HLA-A\*02:01-negative patients with unresectable or metastatic uveal melanoma. The Established Investigator Awards are designed for senior researchers. The Mid-Career Bridge Grants are for established researchers with pre-existing R01s, who have applied for a NIH R01 grant that was scored, but not funded. The Career Development Awards (including the WIS CDAs) are designed for junior researchers. The Resident/Fellow Awards are for radiation oncology, dermatology or pathology residents or medical/surgical oncology fellows (either those in a two- or three-year fellowship program) in the United States with an interest in melanoma research. The Medical Student Awards are designed for current medical students.

### **How long is the research plan section of the grant?**

The research plan is limited to 6 pages, not including references.

### **What information is included in the project plan?**

The text of the research plan should contain sufficient information for evaluation by the review panel. The plan should cover specific aims, background, rationale, significance, results of previous research directly related to the project title, experimental design and procedures and references. Please note: If the application is in response to a STP, the background section could be streamlined as the reviewers already realize the relevance/significance of the research.

### **Can an award be transferred to a new institution?**

A grant can be transferred upon approval of the MRF Science Officer. The MRF envisions that for postdoctoral fellow CDA Awardees, whom may be transitioning to independent faculty positions, this may be a common occurrence. For detailed criteria and instructions, please contact the MRF Science Officer at [research@melanoma.org](mailto:research@melanoma.org).

Term	Definition
<b>Key Personnel</b>	The PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition. Consultants also may be considered key personnel if they meet this definition.
<b>Principal Investigator (PI)</b>	This is the grantee responsible for all activity being supported by the grant. He or she is responsible and accountable to the MRF for the proper conduct of the project or activity.
<b>Other Support</b>	Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in <b>direct</b> support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts or organizational awards. Other support does not include training awards, start-up funds, prizes or gifts.
<b>Institutional Animal Care &amp; Use Committee (IACUC)</b>	Established at institutions in accordance with the PHS Policy on Humane Care and Use of Laboratory Animals with broad responsibilities to oversee and evaluate the institutions' animal programs, procedures and facilities. IACUC review and approval is required for all PHS supported activities involving live vertebrate animals prior to funding.
<b>Institutional Review Board (IRB)</b>	IRBs are set up by research institutions to ensure the protection of rights and welfare of human research subjects participating in research conducted under modifications in or disapprove research protocols based on whether human subjects are adequately protected, as required by federal regulations and local institutional policy.
<b>Clinical Trial</b>	<p>A biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four phases:</p> <ul style="list-style-type: none"> <li>• Phase I: Testing in a small group of people (e.g. 20-80) to determine and evaluate safety (e.g. determines a safe dosage range and identify side effects).</li> <li>• Phase II: Study in a larger group of people (several hundred) to determine efficacy and further evaluate safety.</li> <li>• Phase III: Study to determine efficacy in large groups of people (from several hundred to several thousands) by comparing the intervention to other standard or experimental interventions, to monitor adverse effects, and to collect information to allow safe use.</li> <li>• Phase IV: Study done after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.</li> </ul>