Luminex - ACMGF Award "Promoting Safe and Effective Genetic Testing and Services" Request for Applications

Summary

Luminex and the American College of Medical Genetics Foundation (ACMGF) have joined together to make an annual award to one ACMG member for a project aimed at promoting safe and effective genetic testing and services. The award will provide support for one applicant for up to \$100,000 for one year beginning on or before September 1, 2010. It is aimed at promoting the safe and effective integration of genetic testing and services into health care, including the development of research guidelines.

Purpose of the Award

Medical geneticists will play a crucial role in translating genetic science into medical genetic services and in defining and promoting the integration of genetics into health care. The Lumniex/ACMGF Award program will provide the award to a medical genetics professional to assist them in undertaking activities aimed at promoting safe and effective genetic testing and services.

Awards are intended to support single events or limited activities such as special meetings, national conferences, or a publication aimed at promoting the safe and effective use of genetic testing.

Project Topics

Project topics may include, but shall not be limited to:

- a. Medical genetics research
- b. Research on healthcare economics related to medical genetics
- c. Medical education and training in medical genetics
- d. Development of medical genetics standards and guidelines

Performance Period: The performance period for the award is up to twelve months. Requests for "no cost" extensions will be considered. The funding period can begin at any time between April 1, 2010 and September 1, 2010.

Eligible Entities

Applicants must have the following qualifications:

- a. Membership in the American College of Medical Genetics ("ACMG");
- b. Agreement of applicant's institution;
- c. Project not funded by another entity outside of the applicant's institution;
- d. Project to be substantially performed in the United States or Canada; and
- e. Project is executable in one year.

Eligible Costs

Funds will be distributed as an award to an individual. Grant funds may not cover construction costs, and administrative (indirect) costs are limited to ten per cent (10%).

Where to Direct Inquiries/Applications



7220 Wisconsin Avenue, Suite 300 Bethesda, MD 20814 kellis@acmg.net 301-718-2014 (phone) 301-718-9604 (fax)

Submitting an Application

* THE AWARD APPLICATION WILL NOT BE CONSIDERED COMPLETE, AND WILL NOT BE FORWARDED FOR REVIEW, UNLESS THE EXECUTED AWARD AGREEMENT IS INCLUDED. CHANGES TO THE AWARD AGREEMENT WILL NOT BE ACCEPTED.

Review Process

The ACMGF has an established committee of individuals who serve as reviewers of submitted award applications. Each individual reviewer will be asked to submit comments on each application, to provide a recommendation as to whether or not each application merits funding, and to rank the applications.

Review Criteria

The goal of this awards program is to encourage and facilitate members of ACMG to engage in activities directed toward promoting safe and effective genetic testing and services. The following review criteria will be applied, based on the nature of the proposal:

Core Review Criteria

The strengths and weaknesses of the proposed project including:

- o The importance and timeliness of the proposed project;
- o The adequacy of the scope and content of the proposed project;
- o The appropriateness of the proposed format for achieving the stated goals;
- o The adequacy of plans to disseminate the information generated by the project; and
- o Other factors deserving comment.
- The competence of the principal investigator and key personnel to organize and perform the proposed work.
- Any special attributes or deficiencies relevant to the conduct of the proposed conference.

Additional Review Criteria

- Is the proposed project clearly described?
- Will the proposed plan produce the expected outcome?
- Is the proposed product or outcome needed?
- Can the plan be executed in the time allotted?
- Do the personnel have the needed expertise?
- Are the resources adequate?
- How can the project be improved?
- Is the project likely to be effective?
- Can the proposed product be easily used?
- Can the results be easily distributed?
- Is the project likely to serve as a model for others?

Receipt and Review Schedule

Applications for this program will be considered in one round, based on the following schedule:

- Application Submission Deadline: January 29, 2010*
- Reviews and Decisions on Awards: February 15, 2010
- Award Notification: February 19, 2010
- Award Announcement: March 25, 2010 at ACMG Annual Clinical Genetics Meeting in Albuquerque, New Mexico**

^{*}In order to be considered, applications <u>must</u> be accompanied by an Award Agreement executed by both the applicant and the applicant's institution.

^{**}Awardee(s) shall be reimbursed for travel and lodging expenses to attend the award announcement at the 2010 ACMG Annual Clinical Genetics Meeting.

Application Package Lumniex – ACMGF Award

"Promoting Safe and Effective Genetic Testing and Services"

Administrative and Con	tact Informat	ion:		
Name:				
Institution:				
Department:				
Address:				
	City:		State:	Zip Code:
E-Mail Address:				
Phone:				
Fax:				
Tax Identification				
Number:				
Application Contact				
(if different):				
Title:				
Address:				
	City:	State:		Zip Code:
E-Mail Address:				
Phone:				
Fax:				
E-Mail:				
Will any special	Yes []			
assistance be provided				
to the applicant by	No []			
their institution?				
Award Type:	\$100,000 o	ne-year award.		
Has Award Agreement	Yes []	•		
been signed by				
applicant?	No []			
*Has Award	Yes []			
Agreement been				
signed by Grantee and	No []			
Institution?				
*THE AWARD APP	LICATION	WILL NOT I	BE CON	NSIDERED COMPLETE,
AND WILL NOW DO	EODIU A DD	ED EOD DEX	TEREST TI	

AND WILL NOT BE FORWARDED FOR REVIEW, UNLESS THE EXECUTED AWARD AGREEMENT IS INCLUDED. CHANGES TO THE AWARD AGREEMENT WILL NOT BE ACCEPTED.

APPLICATION STATEMENTS

All Applicants are required to agree to the following statements:

I hereby apply to the American College of Medical Genetics Foundation ("ACMGF") for consideration of my application for the Lumniex – ACMGF Award (the "Award"). I agree to disqualification from consideration, to denial of the Award, and to forfeiture and redelivery of any funds granted to me pursuant to the Award in the event that any of the statements or answers made by me in this application are false or in the event that I violate any of the rules or regulations governing the Award Program. I authorize ACMGF to make whatever inquiries and investigations it deems necessary to verify my credentials and professional standing.

I have read and agreed to the conditions set forth in the Award Agreement as evidenced by my execution of the Award Agreement which is included in this Application.

I hereby agree to hold ACMGF, the American College of Medical Genetics, Lumniex, and their respective officers, directors, members, owners, employees, and agents, harmless from any complaint, claim, or damage arising out of any action or omission by any of them in connection with this application; the application process, any award granted to me by ACMGF; the failure to grant me any award; or any demand for forfeiture or redelivery of funds issued pursuant to an award. I understand that the decision as to whether I qualify for a Lumniex – ACMGF Award rests solely and exclusively with ACMGF and that the decision of ACMGF is final.

I HAVE READ AND UNDERSTAND THESE STATEMENTS AND I INTEND TO BE LEGALLY BOUND BY THEM. Name Date Signature TO THE BEST OF MY KNOWLEDGE **Applicant Signature:** Date Signed: AND BELIEF, ALL DATA IN THIS APPLICATION ARE TRUE AND CORRECT. THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE **Applicant Organizations** Date Signed: GOVERNING BODY OF THE APPLICANT AND THE APPLICANT Representative Signature: WILL COMPLY WITH THE TERMS OF THE ATTACHED AWARD AGREEMENT IF THE ASSISTANCE IS AWARDED

If awarded, the funding period will begin on .	
	Insert requested start date

Guidelines for Application Submission

Synopsis of Proposed Project

In 500 or less words or less, please give a synopsis of the proposal.

Detailed Proposal Description

In five (5) pages or less, please describe your proposal in detail. As appropriate, please discuss exactly what will be done and when, how it will be done, what the product or results will be, and how it impacts the safe and effective translation of science into the practice of medical genetics.

Budget Proposal

Please itemize anticipated expenses and explain how the award funds will be used.

Evaluation and Dissemination

Discuss how the project will be evaluated and how the projects results will be disseminated.

Project Team

Discuss the background and qualifications of the individuals responsible for carrying out the proposed project.

Project Assurances

Applicant agrees to	comply with	the terms of the	award, including	g a progress	report at six	months
and a final report w	vithin 30 days o	of the end of the	e project period.			

Yes []	No []
**	ren and their spouses, and siblings and their spouses) e ACMGF or Lumniex, or members of the Award
Yes []	No []

Applicant agrees that there will have institutional IRB approval for any award project that includes human subjects.

Yes [] No []

LUMNIEX - ACMGF AWARD "Promoting Safe and Effective Genetic Testing and Services"

AWARD AGREEMENT

Found	_ (the dation	Award Agreement (the "Agreement") is entered into this day of, "Effective Date"), by and between the American College of Medical Genetics ("ACMGF") and, an individual ("Grantee") employed by ("Institution").
	ets direc	REAS ACMGF is sponsoring the 201 Luminex-ACMGF Award (the "Award") for cted to "Promoting Safe and Effective Genetic Testing and Services," under the terms as set forth herein; and
"	WHE " (t	REAS Grantee is submitting an application for the Award based on Grantee's project he "Project");
of the		T, THEREFORE, Grantee hereby agrees that, should Grantee be selected as a recipient, Grantee will strictly abide by the following terms and conditions of the Award:
1.	Repor	rts and Presentations
	(a)	Semi-Annual Written Updates. Grantee agrees to submit to ACMGF by, 201 a semi-annual update indicating the progress made toward completion of the Project and achievement of the purposes of the Award.
	(b)	Annual Written Reports. Grantee agrees to submit to ACMGF by, 201 an annual written report setting forth (1) the use of the Award funds granted and detailing all expenditures made from the Award funds (including travel, salaries, and supplies) and (2) progress made toward completion of the Project and achievement of the purposes of the Award.
	(c)	Annual Oral Presentation. Should ACMGF organize a presentation, Grantee agrees to make an oral report on the progress of the Project. The expenses of Grantee's participation shall be covered by the ACMGF. This presentation may be attended by individuals affiliated with ACMG, other members of the scientific community, the media, and potential donors to ACMGF. It is most likely that this presentation would occur at the annual ACMG Meetings in of 201
	(d)	<u>Final Report</u> . Grantee agrees to submit to ACMGF a Final Report upon completion of the Project. If the Project involves the creation of a written product, a copy of such written product must be submitted with the Final Report.
2.	towar Grant	tigation. If any of the reports required above indicate that Grantee is not working d achieving the purposes of the Award, ACMGF may conduct an investigation. ee understands and agrees that if ACMGF determines, in its sole discretion, that ee has not met the terms and conditions of the Award, ACMGF may halt the

disbursement of further funds and take all reasonable and appropriate steps to recover the Award funds and/or to insure the restoration of diverted funds. Grantee further understands and agrees that ACMGF may withhold any further payments until such time as it is satisfied that Grantee is meeting his/her obligations under this Agreement.

3. Use of Funds

- (a) Grantee agrees to utilize all Award funds in accordance with the purpose of the Award, "Promoting Safe and Effective Genetic Testing and Services," as determined by the Board of Directors of ACMGF.
- (b) Except as may be expressly provided herein, Grantee agrees that Award funds shall be used only for the direct support of Grantee's research and only in the manner and for the purposes indicated in the Award proposal. ACMGF grant funds may be used to pay for institutional overhead or any other indirect costs only up to a total of 10%. In addition, Grantee agrees that Award funds given by ACMGF shall not duplicate funds obtained from any other source.
- 4. <u>Institution Commitment</u>. Institution agrees that Grantee's time, facilities, and position will remain at an appropriate level to facilitate the Project.

5. <u>Assignment of Rights.</u>

- (a) If any patents arise out of or are developed as a result of the research funded by the ACMGF Award described herein, the rights to which are deemed to be the property of Grantee and/or Institution, Grantee and Institution expressly agree not to enforce their rights in any such patents against any physician or not-for-profit institution utilizing the patented property for the diagnosis or treatment of genetic diseases in patients.
- (b) If any original notes, presentations, publications, or other materials, without limitation (including any summary or description of research results) ("Materials") arise out of or are developed in connection with the research funded by the ACMGF Award described herein, the rights to which are deemed to be the property of Grantee and/or Institution, Grantee and Institution agree to (1) acknowledge in all Materials the support of the Award; (2) offer the ACMG's journal *Genetics in Medicine* first option on publication of any Materials to be published; (3) provide ACMGF with copies of the Materials; and (4) assign to ACMGF a non-exclusive, fully paid, worldwide, unrestricted license to publish and distribute the Materials following any publication thereof. ACMGF agrees that it shall not publish any previously unpublished Materials of which it receives copies or otherwise vitiate the intellectual property rights of Grantee in said Materials.
- 6. <u>Indemnification</u>. Grantee agrees to and hereby does indemnify and hold harmless Lumniex, ACMGF, ACMG, and their respective directors, officers, members, owners, employees, and agents ("Indemnitees") from any and all demands, claims, suits, and expenses, including but not limited to reasonable attorney's fees ("Claims"), which one or more of the Indemnitees may incur by reason of Grantee's negligent acts or omissions (including,

without limitation, use of third party intellectual property rights) arising out of or in connection with this Agreement. Nothing provided herein shall be construed to impute liability to any party for injuries sustained by any third party.

7. News Releases.

- (a) Grantee agrees that ACMGF may issue news releases regarding the award of the grant. Grantee also agrees to assist in the development and production of such releases as requested by ACMGF.
- (b) Grantee agrees to acknowledge ACMGF in any publication in a manner that shall be approved by ACMGF in advance.
- (c) Grantee agrees to submit to ACMGF for prior approval any and all news releases or other published statements if such news releases or published statements mention or refer to ACMGF or the Award.
- 8. <u>Permissions</u>. No party shall use the name or names of another party, or any adaptation, abbreviation, or derivative thereof, whether oral or written, without the permission of such party, except as otherwise set forth in this Agreement. Notwithstanding the foregoing, prior written permission of Grantee shall not be necessary for ACMGF to identify him/her as a grantee or in research results, summaries, or discussions the distribution of which is permitted pursuant to Section 5.
- 9. <u>Compliance with Applicable Laws</u>. Grantee warrants that, in connection with Grantee's acceptance of the Award, Grantee's work on the Project, and all investigations conducted in connection therewith, he/she shall, at all times, comply with all applicable federal, state and local laws, regulations and other requirements including, but not limited to, the following:
 - Protection of human subjects
 - Inclusion of women and minorities
 - Inclusion of children
 - Financial conflicts of interest
 - All applicable sections of the following statutes and the regulations promulgated thereunder:
 - Federal Food, Drug, and Cosmetic Act
 - Clinical Laboratory Improvement Amendments ("CLIA")
 - Health Insurance Portability and Accountability Act of 1996 ("HIPAA")

10. Termination.

(a) Either party may terminate this Agreement at any time for material breach by the other party. Within ten (10) days of such termination, Grantee shall return any unspent and uncommitted grant funds to ACMGF and provide ACMGF with a copy of all Materials prepared up to the date of termination.

- (b) Either party may terminate this Agreement upon the death or permanent disability of Grantee. Within thirty (30) days of the date of Grantee's death or permanent disability, Institution shall return any unspent and uncommitted grant funds to ACMGF and provide ACMGF with a copy of all Materials prepared up to the date of death or permanent disability.
- (c) Either party may terminate this Agreement in the event Grantee leaves the full-time employ of Institution, for any reason other than death or permanent disability, prior to completion of the Project. Within sixty (60) days of the date of such end of employment, Grantee shall return any unspent and uncommitted grant funds to ACMGF and provide ACMGF with a copy of all Materials prepared up to the date of the end of employment, unless and until ACMGF, Grantee, and Grantee's new place of employment enter into a written agreement providing for the continuation of the Project under the same conditions applicable herein or other conditions agreed to by such parties.

* * *

*Agreed to and Approved:

Grantee:	Institution:
Signature:	Signature:
Name:	Name:
Date:	Title:
	Date:
ACMG Foundation:	
Signature:	
Name:	
Title:	
Date:	

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Please direct completed applications and questions to:



Attn: Katherine Ellis 7220 Wisconsin Avenue, Suite 300 Bethesda, MD 20814 kellis@acmg.net 301-718-2014 (phone) 301-718-9604 (fax)