

**NWX-NCI**

**Moderator: Melissa Glim**  
**February 1, 2012**  
**1:00 pm CT**

**Coordinator:** Thank you for standing by. At this time, all participants are in a listen only mode. Today's conference is being recorded, if you have any objections, please disconnect at this time.

I will now like to turn the call over to Mr. Henry Ciolino, sir you may begin.

**Henry Ciolino:** Good afternoon, welcome to the NCI Office of Cancer Centers Learning Series. My name is Henry Ciolino, I'm a program director in the Office of Cancer Centers and I'm going to moderate today's presentation. Today's topic is NCI's Cancer Clinical Investigator Team Leadership Award Program, which is directed specifically at clinical investigators at NCI designated cancer centers.

The goal of today's Webinar is to familiarize you with the award, with the new program announcement that came out Monday and perhaps help you prepare a stronger application. We are pleased to have with us today, Dr. Jennifer Hayes, a Program Director in the Coordinating Center for Clinical Trials with NCI.

She is in charge of the Clinical Investigator Team Leadership Award Program. She also oversees the Best Cancer Steering Committee. After Jennifer's presentation, we'll be joined by two current awardees, Dr. Suresh Ramalingam of the Winship Cancer Institute at Emory, who successfully competed for this award in 2010 and Dr. Brenda Weigel from the Masonic Cancer Center at the University of Minnesota, a 2011 awardee. I will have further introductory remarks about them after Jennifer's presentation.

A few housekeeping details: to see the slides that Dr. Hayes will present, you will need to have Microsoft Live Meeting installed on your computer. This will work best if you close all other applications. You will hear the audio part of the presentation by telephone at the number listed in the Webinar invitation. You cannot hear it through your computer.

You may use the question box on your screen to ask questions. We will then read them out loud. And after the seminar, complete biographies of Dr. Hayes and our two awardee presenters as well as slides of this presentation will be available on the Office of Cancer Centers Web site under News and Events Webinars, Dr. Hayes, welcome.

**Dr. Jennifer Hayes:** Thank you, Henry. So today, I'm going to present the overview of the FY12 Clinical Investigator Team Leadership Award announcement, and this was released this past Monday on January 30. And I'll go over some of the key points to the announcement and highlight some of the changes in this year's announcement.

So this is the 4th year of this award. It began in fiscal year '09 and the intent of the award remains the same. That is to recognize midlevel clinical investigators at NCI-designated cancer centers who are actively participating in cancer clinical trials and clinical research and individuals who are leaders in promoting a culture of clinical research at their institute. Additionally, the award is intended to help retain these leaders in academic clinical research careers.

So the award provides two years of funding, and that's through an administrative supplement to the Cancer Center Support Grant and that funding can be used for things such as salary and it's expected that an awardee

would devote 10 to 15% of their time and effort to the activities or projects that are associated, that they propose to carry out with the award, as well as it's expected that the sponsoring cancer center would allow that awardee to have protected time to carry out those efforts.

Additionally, new to this year's award announcement, the, some of the funds up to \$2500 per year can be used for travel and that travel can be to attend courses, seminars, meetings, conferences, and workshops and in the budget and justification that is required with the application, we would ask that the applicants include details on the proposed travel as well as information on how that travel and the intended event is relevant to the intent of this award.

And I would refer everyone to the full announcement for further details on costs that are allowable and non-allowable in this announcement. Again, I would refer everyone to the full announcement for the full eligibility criteria but some of the items that I will point out regarding eligibility would be that the nominee needs to be nominated by the cancer center director who, and that is the person who's the PI of the Cancer Center Support Grant. Each cancer center can nominate one nominee through one application.

That nominee cannot have received this award previously and cancer centers that receive the first year of this award, this past fall, are not eligible to submit an application for this upcoming year. Individuals who are nominated should be practicing in the oncology clinical setting. And I want to emphasize that not only physicians but other eligible clinical staff, such as oncology nurses or clinical psychologists, are eligible to nominate for this award if they are able to meet the evaluation criteria and eligibility criteria.

Nominees should be engaged in the conduct of NCI funded cancer clinical trials. And some changes to this year's award, the nominees not only must not currently serve but also cannot previously have served as the PI of an NIH or

KRP [Khat Research Program] Series Grant, that is, with the exception of people who have received a mentored K Award, where you were mentored by someone else. You would still be eligible to receive an application.

As well as individuals who have been leaders of the Component Research Project or a Program Project Award or co-leaders of Component Projects. The SPORE Award would not be eligible to be nominated for this award. Now, we do require a bio sketch with the application and that bio sketch should include all current, pending and past support that the nominee has received.

Now I'll discuss a few of the items that are required with the application. As in past years, the application should include a cover letter and this year in the announcement, we've also included some components of that cover letter that should be included. So in addition to naming the nominee, the cover letter should also include, briefly, the process that was used to select that nominee as well as the statement that verifies that the nominee meets all of the eligibility criteria of the award.

And this cover letter should be signed by the PI of the Cancer Center Support Grant and that would be the cancer center director. Another component of the application that has been included in past years is the narrative. This narrative should be about three to five pages and it should address the review criteria that are outlined in the announcement.

The narrative should include training, the experience and current activities of the nominees, the involvement of the nominee in NCI-funded cancer clinical trials and clinical trial-related activities. And it should also talk about the nominee's plans for career and academic clinical research.

A new component of the application this year is, and this was added in response to past awardees noting that the application was a little bit in vague in what the funds could be used for and what types of activities should be carried out under the award, is a brief, no longer than two page outline and description of the activities and projects that are proposed to be conducted under this award. This would also include a timeline for carrying this out. So, listed on the slide, and I won't go through these bullet by bullet, are examples of projects and activities that would be appropriate to carry out using this award.

Note that these are not listed in any order of relevance or preference, priority. They're just listed as some examples of projects that could be undertaken to meet the intent of this award. And an award could support multiple projects and activities as time, effort and resources allow.

So again, the description of the planned activities and projects should also include a timeline and some information on how each activity or project would help the awardee meet the intent of this award. And additional projects or activities that are not listed in the award announcement or on the slide are acceptable as well, as long as they go toward meeting the intent of the award. As in past applications we are again asking for three letters of support and those would accompany all copies of the application.

And letters, at least one of them should be an institutional support letter from an appropriate official at the institute that describes how the institute is committed to fostering the nominee's career as a clinical investigator at an academic clinical research center. That institutional support letter should reflect the extent to which the institute is willing to give dedicated and protected time to that nominee. And again, the letter should demonstrate a

commitment to allow at least 10% effort for the planned activities and projects that are proposed in the application.

Now I'll cover some of the evaluation criteria and again, the award announcement fully lists all of the evaluation criteria in much more detail. Again, these evaluation criteria, they're not weighted or listed in an order of importance, the reviewers would take into account all of the criteria and look at the full snapshot of the nominee in considering their recommendations.

So, the nominees will be evaluated on their training and experience and how it supports their potential for a leadership role in clinical oncology research and trials, the leadership experiences that the nominee has had in clinical research activities and clinical trials, evidence of the nominee's mentorship or mentoring of others who participate in clinical research activities and clinical trials, as well as the extent and breadth of participation in clinical research activities and clinical trials. So it's the nominee's experience with and role in that clinical research activities and NCI-sponsored collaborative clinical trials and the nominee's overall role in the institute or academic center's clinical research mission.

Additional criteria that will be evaluated and again, this is based on the narrative, the planned activities and projects and the other documents that are part of the application, would be activities that if the nominee, the awardee did not receive the award, would not be possible to be carried out. How the award would promote or enhance successful clinical research culture at the awardee's institute and how the awardee, the award may help retain the nominee in an academic clinical research career.

When looking at the letters of support, evaluators will be looking for the institution's commitment to support the nominee's planned activities and also

their career beyond the award period. So what they will be looking for is a clear commitment for at least 10% effort and dedicated time to carry out the activities and projects proposed in the application. Is the level of institutional commitment appropriate that, as evidenced by the letters?

And so finally, I just want to cover briefly some of the timeline associated with the award. So, for applicants who intend to apply, we are asking for a letter of intent by March 2 and the full announcement contains the contact information and address to where that letter of intent should be emailed at the Office of Cancer Centers by March 23, that is the application due date and that would include the cover letter, the application and letters of support.

An application includes a few components that I described, the narrative, the planned activities, the bio sketch, the budget and justification. And that application gets emailed in a PDF format and there're two copies, one goes to the Office of Cancer Centers and one to myself. And again, specific information of where to send that can be found in the announcement.

We anticipate notifying applicants of the outcome of the review by late summer and then awards should start no later than the end of fiscal year, which is September 30. So with that, I'll hand this back over to Henry and thank you for listening today.

**Henry Ciolino:** Well thank you very much Jennifer. What you've heard is the nuts and bolts of the program announcement. And I think it would be good if we talked to a couple of our current grantees.

So Suresh and Brenda will unmute your phones at this point? Good afternoon.

**Dr. Brenda Weigel:** Hi, I'm unmuted.

**Dr. Suresh Ramalingam:** So am I. Good afternoon.

**Henry Ciolino:** Great. So, let me do a little bit of introduction here. Suresh Ramalingam is an Associate Professor in the Department of Hematology and Medical Oncology at Emory.

He is Director of the Medical Oncology Division and Chief Thoracic Oncology at the Winship Cancer Institute at Emory. He is Board certified in Internal Medicine in oncology; his research interest is in lung cancer and other thoracic malignancies.

Dr. Brenda Weigel is an Associate Professor in the Department of Pediatrics of the University of Minnesota's Children Hospital and the Masonic Cancer Center. She is the Children's Cancer Research Fund Endow Chair in Pediatric Cancer and her research interest is in sarcoma.

So I'd like to run through the review criteria in the announcement and find out from both of you exactly how you fit the bill successfully since you both competed successfully for this award. Could you briefly discuss the formal training that you've received in oncology clinical research? Suresh, can we start with you?

**Dr. Suresh Ramalingam:** Sure. So, I was, as a fellow, since I knew that this was my primary area of interest, I had attended the Vail Clinical Research course that NCI, ASCO and AACR conduct every year and that was an outstanding experience. But I went beyond that as a junior faculty member.

I have attended a few courses on statistics related to clinical research and I think the most valuable of all is the fact of writing in LOI, writing in clinical

protocol and conducting the trial with the help of mentors. I think those all contributed to my familiarity and ability to conduct clinical trials.

**Henry Ciolino:** Okay, Brenda.

**Dr. Brenda Weigel:** So, it's somewhat similar. I also did a Master's Degree combining some pre-clinical translational research prior to medical school and continued kind of lab-based translational research throughout my training. And during my fellowship, I was fortunate enough to sort of report back to the first clinical trial that I wrote fresh out of fellowship.

And I agree, mentorship was the key for me. Parlay that into now having written and run several Phase One and upfront clinical trials for patients, pediatric patients through the NCI-funded Children's Oncology Group. That experience was invaluable and that led me to some leadership positions within the Children's Oncology Group at the strategic level for sarcoma.

But also a few years ago I was named as Vice Chair of Developmental Therapeutics, which runs all of the Phase One trials for Children's through the NCI-supported Phase One consortium for the Children's Oncology Group. So, I've had a tremendous amount of mentorship and support in learning how to do this, and I think that was the key plus formal graduate training intermixed and just continue to build on that.

**Henry Ciolino:** Okay, that actually leads me into my next question. What sort of national leadership roles have the two of you led with cooperative groups? Brenda, you just said you were involved with the Children's Oncology Groups. Suresh, do you also, are involved with cooperative groups?

**Dr. Suresh Ramalingam:** Sure, I actually was when I submitted this application for leadership award, I was a Co-Chair for the Thoracic Committee of the Eastern

Cooperative Oncology Group and I was, I'm happy to say that about six months ago I was promoted to be the new Chair of the Thoracic Committee of the Eastern Cooperative Oncology Group. And I want to second what Brenda said, the experience that I have had both from mentorship and conducting trials in the Eastern Cooperative Oncology Group have been an immense help to my career.

**Henry Ciolino:** Okay, so national leadership is an important part of these applications, of successful applications, but what about leadership at your cancer centers? What sort of leadership have you played in the clinical trials enterprise at your cancer centers? Suresh, would you like to start?

**Dr. Suresh Ramalingam:** Sure, so what, at the time we submitted the application, I had just become the Chair of the Safety Data Monitoring Committee for the cancer center. Being a member of that committee for about a year and a half or so and then I was promoted to become the Chair of the Data Safety Monitoring Committee. In addition, I also lead the Lung Cancer Research Clinical Trials Group, which includes regulatory specialists, coordinators and other faculty members interested in lung cancer research. And we use that group as a forum to conduct all clinical trials related to lung cancer. So by overseeing the aspect of every person's goal in the overall operations, I play an important role, I'm fortunate to play an important role.

So those are some of the leadership roles that I had and that I have at the institution right now.

**Henry Ciolino:** Brenda, would you like to talk about your leadership roles at Masonic?

**Dr. Brenda Weigel:** Sure and you're going to laugh because as Suresh just said, I, at the time we first submitted the application, I had served for, I hate to say it, about nine

years on the Cancer Protocol Review Committee and was, had just transitioned to leading the Data Safety Monitoring Committee for the Masonic Cancer Center.

**Henry Ciolino:** My goodness, Brenda. Did they give you some sort of award? I've never heard of anyone being on a PRC for nine years.

**Dr. Brenda Weigel:** I know, I know. My reward was becoming chair of the SMC and so and actually that played into my, I was, I started on there as a very junior faculty and actually that was a tremendous part of my education on clinical trials. Reading multiple trials and critiquing them is a great way to learn.

So I did, I took over about a year ago the Data Safety Monitoring Committee and as part of that, our cancer center is up the end of this year for our Cancer Center Core grant renewal process. And part of that with current guidelines is putting together a new Data Safety Monitoring plan, so I had the privilege of actually drafting the new plan, Data Safety Monitoring plan for our cancer center. So that's been a major project that I've undertaken on behalf of the cancer center over the last few months, which I can say thankfully, we just answered the stipulations and sent it back for, hopefully final approval.

**Henry Ciolino:** Yes, I know, it's on my desk to review right as we speak.

**Dr. Brenda Weigel:** That was a direct, that is a direct contribution from this effort and so I've been privileged in that sense. The other leadership position that I have held is at our cancer center, we had what's called Cancer Experimental Therapeutics Initiative, which is essentially our Phase One program. And I have been the associate director for that, under the leadership of Dr. Jeff Miller for the past probably year and a half or so, last 18 months.

And I have, I am within the last month, I'm transitioning off of the Data Safety Monitoring Committee to being office. So, I'm quite enmeshed within the cancer center.

**Henry Ciolino:** So, successful applications in the past have included both national leadership and institutional leadership, Data Safety Monitoring, PMC, none of these are requirements, but it shows that you are a leader in clinical trials at your institution. Suresh, you mentioned the Lung Cancer Malignancies working group, I believe. What is the breadth of the nominee's sphere of involvement in clinical trials? For example, does his or her impact cross disease sites, modalities and departments? So I imagine that sort of working group would be crossing departments and perhaps modalities?

**Dr. Suresh Ramalingam:** Yes, clearly. The working group basically includes thoracic surgeons, radiation oncologists, medical oncologists, interventional pulmonologists, and pathologists. And overall, this group supports the clinical trials activities of the program project in lung cancer that we have and they will follow vicarious leadership.

So the working group is directly responsible for carrying out the scientific goals, particularly the clinical and translational objectives of the Lung Cancer Program project. I also play a very active role in the drug development Phase One program, just like Brenda earlier mentioned. And, this again, brings together investigators from other diseases, hematologists, oncologists and even radiation oncologists who have an interest in early drug development.

So that's another forum where I have played a very active role that helps me, you know, go above and beyond what my own specialty entails and being involved and getting a knowledge about the work that other people of other departments are doing as well.

**Henry Ciolino:** I see, Brenda you're also in charge of a sarcoma working group, aren't you?

**Dr. Brenda Weigel:** Yes, and that's actually, so I'm Co-Director with Dr. Denis Clohisy of our Sarcoma, we call it Translational Working Group, here which is, our sort of disease-specific groups that are multi-disciplinary but also span our cancer [center], encompass the basic sciences as well as the clinical entities. And so what, for me, in that role, is really bridging multi-discipline, multiple programs, you know, very involved in trying to integrate our cancer etiology and molecular programs into the sarcoma program.

And it also makes, really is my, is a tremendous interspace with many of the other disciplines. The surgical disciplines for sure as well as the basic sciences and our lab medicine and pathology colleagues as well. So that's a major area where I interface is the multi-disciplinary level and is my personal clinical interest as Suresh says. You know he's really from the lung cancer perspective and meshed in that world and then both of us are in the Phase One [perspective], which is also multi-disciplinary as well.

**Henry Ciolino:** Yes, part of the review criteria discusses mentoring as important qualifying activity for this award. If you could please describe your mentoring activity at the time of the award and any changes that have happened since you went on this award. Suresh, would you start?

**Dr. Suresh Ramalingam:** Sure, I have always taken a keen role in training junior faculty and fellows in the clinical trials processes. At the time of the award, we had just put together the program for our fellows and junior faculty members. This is an eight-week course during the summer, that typically happens in August and September where every Monday evening from 5:00 to 8:00, we would sit down and have discussion and they would come up with a concept.

At the end of the eight weeks they would have a protocol written and they would have marked, IRB marks saying difficult review and it's meant to be a course lasting eight weeks that would actually familiarize people in various aspects of trials including data monitoring, data entry, I mean, just all breadth, scope of the clinical trials process.

And I think that's something I really enjoyed doing and I have also been fortunate to mentor some outstanding junior faculty members and I'm proud to say one of my mentees just secured a K23 award a few months ago from NCI.

**Henry Ciolino:** Excellent. Brenda, mentoring activities?

**Dr. Brenda Weigel:** Yes, I, similarly I would divide it somewhat for me, a little bit into local as well as national mentoring of junior faculty. At the national level, through the Children's Oncology Group Phase One Program as well as my involvement with the sub-tissue Sarcoma Committee, the whole goal there is to mentor junior faculty to lead clinical trials. And so, we actually have a system where we set up that the PI of the trial is a junior faculty or junior investigator and then they are co-led with a more senior investigator.

And that's been an incredibly rewarding experience to see some people really blossom through that process and with my role as Vice Chair of Developmental Therapeutics, that's sort of been one of my major undertakings, is to really shepherd people through that process. Locally, in April of last year, so almost a year ago, I was named the Division Director for Pediatric Oncology and through that I have had the privilege of mentoring some junior faculty. One of which is going to be leading a national clinical trial through the Children's Oncology Group at the Phase One level so I'm

very proud of her and we have put that in for a young investigator award through the NCI system, so we're waiting to hear on that.

And the other is a junior faculty member that is now leading three national cooperative clinical trials in leukemia and successfully was awarded a K12 mentored clinical translational award last summer. And so, through a collaborative arrangement with us and the Mayo Clinic and so is partnered in that process. So, we're very proud of their successes and as someone said to me, "your greatest success is the people you've mentored." And I think that's true.

**Henry Ciolino:** Great. I do want to make a point here that this award is for "mid-career clinical investigators" which is defined in the program announcement as assistant professors and associates. You're hearing from folks that have a long history in clinical research and are really quite senior even though they technically are mid-career.

So, I know that in the 2011 group, we had at least one assistant professor unsuccessfully compete. So you should not be intimidated if you're thinking of applying for the 2012 announcement. I have just a few more questions about the nuts and bolts of how the application was prepared and submitted. Each cancer center can only nominate one person for this award, so I was wondering how was the decision arrived at that you were your center's nominee for this. Suresh?

**Dr. Suresh Ramalingam:** So it's my understanding that each of the major program leaders within the cancer center were asked to nominate somebody that they thought would be a good candidate for this award and after those nominations came in, the cancer center leadership made the decision to nominate me. And once that decision was made, then I was asked to work with the administrative associate

director who was putting together the application to develop the application for this.

**Henry Ciolino:** You anticipated my next question. So the associate director for administration was sort of the lead person in preparing the application along with you? Is that correct?

**Dr. Suresh Ramalingam:** That is correct. She was primarily instrumental in telling me what other things she needed from me and, you know, she was putting together the letters and so forth.

**Henry Ciolino:** I see. Brenda, what about your case?

**Dr. Brenda Weigel:** Very similar process to Suresh. Our Clinical Research Leadership Committee considered nominations and considered potential candidates and made a recommendation to our cancer center director, as well as associate director of administration. And then I was approached by them if I would be willing, interested to participate in a trial and I was honored and thrilled. And very similarly, the associate director of administration really handled the process and I worked very closely with her to get all the necessary documents and letters, et cetera, and then the cancer center director finalized everything and submitted the application.

**Henry Ciolino:** I see. One last question for both of you, beyond the monetary value and this award carries about to 10 to 15% effort, what's, what has the award meant for you professionally? Brenda, would you start?

**Dr. Brenda Weigel:** Yes, well, it's a tremendous honor to be recognized, and by the National Cancer Institute and so I think it's a tremendous honor. It also, I think, is a tremendous recognition of the importance of clinical research within cancer

centers, so I feel that at some level it raises the recognition and particularly recognition for junior faculty considering careers in clinical translational research that it is recognized and it is recognized just being important. And that there are academic career paths that are not just the traditional R0 pathway and so I think this is a tremendous recognition of that.

I also, from my personal experience, both within the cancer center and as well as within the Department of Pediatrics, that I'm a member of, this was highlighted as a tremendous honor. And that was very gratifying but it also served as a way again of highlighting the importance of clinical research.

**Henry Ciolino:** Very much so Brenda. Great answer and I know that in preparing CCSG [Cancer Center Support Grant] applications, it's very important to highlight those clinical researchers that haven't taken the traditional R01 path, but are very involved in NCI-sponsored researches as you are and as you indicated. Suresh, could you tell us a little bit about what this award has meant for you?

**Dr. Suresh Ramalingam:** I second a lot of what Brenda said. I was excited and thrilled and wanted to receive this award. Personally, you know, as somebody who wears the badge of clinical researcher very proudly, this, you know, being one of the ultimate recognitions that exists is just something I am profoundly thankful for.

Even great was the wonderful award ceremony that the NCI had in Washington, the translational research meeting and the plaque that I received is very prominently displayed in my office. Within our own institution, there was a lot of recognition, including announcements in the newsletter, in the University newsletter, above and beyond the cancer center and also when we had the site visit for the CCSG, you know, there was a specific mention of this award to me. So, all of this make me feel, you know, that this is a tremendous

honor and like you said, in addition to the protected time and the ability to do some new projects that it brought in, being a clinical researcher to have recognition from the NCI and part of an elite group of people such as Brenda is very humbling.

**Henry Ciolino:** Well, thank you very much Dr. Weigel and Dr. Ramalingam for joining us on the call today. Jennifer, did we have any other questions we wanted to ask them?

**Dr. Jennifer Hayes:** That's good. Thank you both for your time.

**Henry Ciolino:** Thank you both, we have a few questions on the program announcements I believe. No? Okay, well, I'd like to thank everyone for joining us on this Webinar.

Before we sign off, I'd like to point out that the NCI offers a free service called the Cancer Information Service to answer questions from patients, caregivers and health providers both by phone and online. With that, I will sign off. Thank you very much for joining us.

The slides will be available on the Office of Cancer Centers Web site following the talk.

**Dr. Brenda Weigel:** Thank you.

**Dr. Suresh Ramalingam:** Thank you.

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