# Smoking Cessation Within the Context of Lung Cancer Screening (R01)
# Pre-Application Webinar, August 4, 2015

Dr. Stephanie Land: Okay. Good afternoon. This is Stephanie Land, and on behalf of the NCI we are so delighted to be able to speak with you this afternoon about our RFA Smoking Cessation Within the Context of Lung Cancer Screening.

What we plan to do is—we will first do some very brief introductions of the NCI staff who are in the room so that you know to whom you are speaking. Michele Bloch will give a brief welcome. Jenny Twesten will provide some logistics or housekeeping information.

So while I am providing some highlights, tips, and FAQs, we will also be acknowledging and answering questions that you submit via WebEx, and in a moment Jenny is going to describe how you may do that. But my intention today is to focus on your questions, and if I don't get through all of my material, that will be fine, and if we don't get to all the questions, that's also okay, because you can reach out to any of us individually after the call. We're happy to work with you.

For those of you who can be here only on the phone and do not have access to the WebEx, we will do our best to make sure that everything is also provided orally during the call, and if there's time at the end, we will open up the phone lines so that you may ask a question directly that way, if you don't have access to the WebEx.

So let's go now to introductions. I am Stephanie Land. I'm a program director in the Tobacco Control Research Branch, and I have with me three members of the Office of Grants Administration at NCI.

We have Carol Perry, Erik Edgerton, and Jason Gill.

We also have Michele Bloch, who is the chief of the Tobacco Control Research Branch.

Let me make two more logistical comments before I turn it over to Michele. If you have any difficulty hearing us or difficulty getting onto the WebEx you may also message—well, no I'm sorry—if you're on the WebEx but you have trouble hearing, please use the chat feature, and we have people in the room who can help you.

Let me now turn it over to Michele Bloch.

Dr. Michele Bloch: Great. Thank you, Stephanie. And thank you to my OGA (Office of Grants Administration) colleagues and to Jenny Twesten from BLH for the technical development, and of course to Stephanie, who's been our lead program director on the development of this FOA, and of course to you applicants, potential applicants, who are on the call.

I'm going to say something very brief about the RFA, and then, for those who are not familiar with the Tobacco Control Research Branch, I'll say in just a moment a few things about that.

So as you know, from the RFA this work, this proposal is an outgrowth of the success of the NCI-funded National Lung Screening Trial, so that there is now broad acceptance and in fact tremendous growth in LDCT screening, and we recognize that providing smoking cessation services in this context is a new and quite different environment. And that's why we put this FOA on the street as a further opportunity to decrease lung cancer deaths in the context of screening.

Some of you are familiar with the work of the Tobacco Control Research Branch, but for those who are not, we are the primary locus of tobacco research within the National Cancer Institute. We fund a broad portfolio of research ranging from etiology and prevention to cessation and community-based and policy studies. A substantial portion of our portfolio is devoted to cessation, and we're looking very much forward to having this additional type of work within the portfolio.

So with that, I'm going to turn it back to Dr. Land and just comment that we're delighted at the level of interest in the FOA, and we look forward to answering your questions.

Dr. Stephanie Land: Okay. Thank you, Michele, and I'll now turn it to Jenny Twesten for brief housekeeping.

Jenny Twesten: Hello, everyone. We have a few housekeeping announcements to make before we dive into our presentation. First, as Stephanie mentioned before, please make sure that your phone line is muted. We will also be answering questions from the audience throughout the webinar. You may submit a question at any time. Your screen currently shows detailed instructions for how to submit questions using the chat feature. We are not able to access the raised-hand feature at this time, so please use the chat feature if you have any questions.

To submit a question using the chat feature, click on the chat at the top right side of your screen, type into the chat box, and we will receive your questions and pass them along. If you're experiencing technical difficulties or have other questions, feel free to chat them as well. We

know that some of you may not be in front of a computer. If time permits at the end of the presentation, we will unmute everyone for final questions. Unmute your line only if you have a question. This webinar is being recorded. The recording, slides, and transcript will be available on the RFA FAQ webpage one week after the webinar.

Dr. Stephanie Land: Thank you, Jenny, and I'll just add one more point to that. When you are on this WebEx and if you ask a question, we believe you have the ability to remain anonymous, and we will do our best not to state your name. We will only repeat your question and then answer it. So you should feel comfortable asking questions without revealing your name. Okay. Let's turn now back to the slides and the presentation.

So I am going to begin by restating part of what is in the RFA and then use this to mention several points that have come up in my discussions with applicants. The RFA goal is the development and testing of smoking cessation interventions and/or the development and testing of strategies for implementation of smoking cessation interventions to be delivered to current smokers who undergo low-dose computed tomography screening for lung cancer.

So the first point I will make that relates to that is that the intervention should reach the current smokers who come to the low-dose CT clinic. So I have put in boldface the word "reach" there because this is a little different from a typical research study. When one designs, say, a clinical trial of drug A versus drug B, we specify a sample size that is necessary and then attempt to accrue patients at an acceptable rate within the clinic environment. The goal is to achieve timely results and to have enough patients for statistical power.

The issues here are somewhat different. We hope that the interventions that are developed under this RFA will be accessible, feasible, of interest, motivational, and useful for most, if not, all of the current smokers who come to the low-dose CT screening clinic.

So we would like that within your research, even though we understand not everyone will want to participate in research, but you should be designing your interventions with broad reach in mind, with the attempt to capture as many of those current smokers who come in for screening as possible.

The second point related to that is—I'm repeating now—that intervention should reach the current smokers, but now I'm putting in bold who come to the low-dose CT screening clinic. So I've had a number of applicants ask about setting their intervention in, say, the primary care setting, and while you certainly can include at least part of your intervention in the

primary care setting, the goal is that you're really capturing those patients who come to the low-dose CT screening clinic, and patients if they are coming from a variety of sources and perhaps even being self-referred or coming from other specialties—they should not be missed.

Another thought here, is that we do already fund research on smoking cessation interventions delivered in the primary care center. Our goal is not to fund more research in that setting, but to fund research that's feasible for the low-dose CT screening clinic to implement. That being said, as I said before, some of the implementation—or some of the intervention can occur outside that low-dose CT screening clinic setting.

Another way to think about this is that ultimately what we would like is that essentially every patient who comes into a clinic can receive an intervention, and in the future if, say, the head of a radiology clinic is interested in providing such an intervention, we want them to be able to able to look to the outcome of this RFA to find a model that they are able to implement. If they look at our results and everything is in a primary care setting or another setting, it may not seem feasible or relevant for those screening clinics to implement.

And if there had been—it looks like there have not yet been questions coming in via the WebEx, and that's fine, and so I'll keep going.

The third point that I'd like to make is the importance of that clinic. That means that in the application, the research needs to address how patients will be recruited and intervened with in the setting of the low-dose CT screening clinic. So if you, for example, have done research in another setting—and I'm just going to say "prenatal clinic" just to throw out an example—please don't use "replace all" and substitute the word "lung cancer screening" for "prenatal," because there may be very different characteristics of the two clinic environments, and those need to be attended to in this application.

Point number four is that we ask that you provide evidence that the low-dose CT screening clinic is prepared to support the research, and in the RFA we ask for letters of support from those clinics. I'd like to expand on that a little bit and say that there may be cases where a letter of support isn't necessary or appropriate. For example, if the PI or a key personnel is the head of that clinic, then it will be obvious that the clinic is prepared to support the research.

There may also be cases where your plan is to recruit patients in a large number of low-dose CT screening clinics, and in that case you may use a scientific approach to establish that it'll be feasible for you to work in those settings. So, for example, you might take a statistical random sample

of the clinics where you hope to work and demonstrate that it is easy for you to obtain letters of support from the randomly selected clinics. The point is that you need to establish for NCI and for the scientific review panel that you will be able to work in those clinical settings.

Point number five (and now I've taken a different statement from the RFA)—the goal is to stimulate research on optimal cigarette smoking cessation approaches delivered in conjunction with low-dose CT lung cancer screening visits in a variety of low-dose CT screening settings. So now I have put in boldface the word "variety." So this goes beyond what we typically expect for research applications in terms of the environment.

Review panels evaluate whether an environment is suitable for a research project and whether the environment will be conducive to the research, but here we're going beyond that because we would also like to see that models of smoking cessation interventions are being developed in a variety of clinical settings. So, for example, we would prefer not to fund all of the R01s in comprehensive cancer centers because then the screening clinics that are in different settings won't be able to find a model that will work well for them.

So in your application please describe your clinical setting so that we can evaluate how it contributes to the variety of settings in which research is being funded. That doesn't mean that any one application needs to cover that entire waterfront of variety. It just means that the set of RFA applications as a whole need to provide as much coverage as we can achieve.

Furthermore, when you develop dissemination products from the research, we would like clinics to be able to determine which models of smoking cessation interventions will work best in their settings. So for that reason we would like you to be evaluating scientifically what aspects of the clinical setting are most salient or important to the success of the smoking cessation intervention, and then provide those data in the results so that other clinics may understand what will work for them.

Audience Question — And we have a question now from a caller and I would like to address it. The question is in reference to point number five: "Would a rural or community setting be appropriate?" And the answer is certainly yes. We would welcome applications that provide research on smoking cessation interventions that will work in rural and community settings. Absolutely. So thank you for that question.

Audience Question — Okay. Let's now go back to the RFA goal, and this time I have put in bold the words "cigarette smoking cessation approaches." I'm highlighting that because one question that's come in is about conducting ancillary research

under this RFA—for example, research that addresses or promotes the lung cancer screening itself. What we would say is that research such as promoting lung cancer screening should either be supportive of the smoking cessation intervention or be incidental and a relatively small part of the budget, because the RFA is really not intended to promote research on the promotion of lung cancer screening.

Okay. And I'm going to continue now to the next slide. So back to the sentence that I had on a slide earlier, about the RFA goal, to make point number eight. The RFA does not prescribe the types of cessation interventions that we expect you to test. So that's a scientific question that will be up to you.

We do describe in the background section of the RFA that the public health service guidelines have found evidence in favor of pharmacotherapy plus eight sessions of behavioral counseling, but that's not intended to say that we require that you use that approach. You may use whatever approach you view as most scientifically justifiable.

Okay. I'd like now to speak to a more general topic, resource sharing and dissemination, because there are aspects of the RFA that are somewhat unique in this regard. We have expectations both during the research and after the research. So during the research, and as you're writing your applications, we would like you to be thinking about common measures, both of characteristics of the individual participants in your research and their outcomes, and also characteristics of the screening setting.

This really speaks to the issue I mentioned already, which is that we would like to evaluate or to understand what characteristics of the clinical settings were conducive to the intervention's success and, to the extent those can be measured using common measures, that may facilitate pooling of data and understanding across studies in the future. And to help you work on the use of common measures and also to learn from each other during the process of the research, we will be holding annual grantee meetings. We ask you to budget for that.

And I'll also point out that the American College of Radiology has a CMS-approved registry for those who undergo lung cancer screening. There may be other registries available in the future, but the point is that the ACR has indicated a willingness to work with researchers if you would like to try to establish a linkage with the registry to reduce the burden of data collection in your study. That may be an opportunity.

After the research, we would like you to be prepared to share materials and tools. So, for example, you may have a Web-based resource or a clinic staff training protocol that you've developed. There may be brochures or

other materials, and we would like those to be made available as directly as possible to other screening clinics so that the results of your research may be implemented without additional burden on the part of clinicians.

And to do that, we also ask that you prepare to make those materials available for a longer term than the funding period of the grant. That will obviously pose a difficulty because you may not have time to continue to support the dissemination of the products after the funding period has ended.

So we have some ideas and we are happy to work with you to generate other ideas about how to prepare for that longer term dissemination. Some ideas are on our cancercontrolplanet.cancer.gov website. We have an RTIPS resource which is a place where you can put a package that then will be available to other users. You may consider partnering with a hospital system that can sustain the tools that you have developed and make them available to others. An appendix to a journal publication is another way to make materials available for the long run.

Audience Question I see a question that's come in about slides being available after the meeting. And the answer to that is yes, these slides will be available as part of the materials from this meeting, which include an audio and a transcript of the discussion.

I will say that some of my remarks are not written on the slides in part because we do have posted FAQs on our website, and to the extent I was able to answer questions and write that out using written language, I have for the most part done so, and I'm taking this opportunity to speak to issues in a way that's difficult to do on paper. And so for that reason, some of what I'm saying here isn't exactly what's written on the slide. So the audiotape and transcript will also be available.

Audience Question And let me look—there's another question on here: "Can more than one smoking cessation approach be proposed, i.e. several arms with different interventions?" Absolutely. Not only can they, but we require that the research be comparative.

Now, it may be that what you're comparing with is something relatively minimal or usual care, or it may be that you're comparing several very intensive smoking cessation interventions. But either way, you absolutely do need to have at least two arms that are being compared in the study that you propose.

Okay. So let's go to another slide, and we've just answered a couple of questions, but do feel free to keep them coming in. Let's speak now to submission, review, and selection.

A tip for new investigators is that it's a good idea to submit your application at least a week ahead of the deadline, which is October 8th, because there do tend to be little glitches that may kick your application out. In my own experience it usually had something to do with margins, and you may need time to tinker with it and resubmit before the deadline, because we cannot accept late applications. So please give yourself enough time to do that. I was told by at least one person I killed your summer, and I apologize sincerely for that.

The NCI will review applications for responsiveness before they are sent out for scientific peer review, and we will let you know individually if your application is not deemed responsive to the RFA, in which case you're still free to apply for our other funding opportunities. The peer review will be managed by NCI, who will convene a group of ad hoc reviewers, and we expect to be able to have a pre-review conference call with reviewers so that we can explain the purpose of the RFA and, really, many of the same issues that we're discussing today. After scientific review, the selection of which applications we recommend for funding, we'll also consider program priorities and, again, those priorities have been described today and are in the RFA as well.

Let's go briefly to budget. The direct costs are limited to $500,000 per year. The funding period for a given grant is up to five years, and the NCI plans to commit up to $4.5 million in fiscal year 2016 to support up to six applications.

Audience Question — One question I've received is: "May the budget include the cost of cessation medication that cannot be reimbursed from other sources?" The answer to that is yes, it may. You can't cover those costs that can be reimbursed elsewhere, but yes, you may want to expand upon the either cessation medication or behavioral interventions beyond what can be reimbursed elsewhere. Just keep in mind that the interventions should be feasible and cost-effective.

Audience Question — So let me see. There's another question that has come in. "Would having more than two arms be advantageous—i.e., baseline/minimal conservative intervention proven in other settings and a third arm as an innovative intervention?" I'm going to say maybe that's a question that we might want to discuss offline. If you'd like to comment, contact me directly, and I can consider aims with you more specifically in terms of the interventions that you might have in mind.

Okay. Let's now go to the next slide. Another point I'd like to make, because it has come up in conversations, is we mention the term "current smokers" in the RFA goal, and I was asked what is the definition of a

current smoker? I will leave that to you. We are not requiring any particular definition. So just base that on current science, and the scientific review panel may also want to evaluate the extent to which they agree with the definition that you use, and we are happy to discuss that if you like, but the RFA does not prescribe a definition.

Audience Question Okay. We also mention in our RFA goal that we are looking for smoking cessation approaches that are delivered in conjunction with low-dose CT lung cancer screening visits. And one question was, "Is it necessary that the entire intervention occur at the screening clinic?" And the answer is no, that is not necessary. Although, as I mentioned before, we certainly do want to be sure that as many of the current smokers who come into the clinic as possible receive some kind of intervention.

A general tip I'd like to provide is that we encourage you to send me your aims along with a letter of intent, or before the letter of intent, and the letter of intent is due September 8th. I'm happy to look at aims even before that and give you feedback, and also give you a sense of whether we're going to view your proposal as responsive to the RFA. My phone number and email address are not only on the slide but also in the RFA document.

I will be out of town August 21 to 28, but there are other program staff who are available to answer questions in my place, although you want to reach out to me before or after that. And Carol Perry and her staff in the Office of Grants Administration are also listed in the RFA if you have questions related to grants administration and budgets. They will be available to speak with you directly if needed.

Audience Question So there was another question that came in from the group, which is: "Will any special consideration be given to early stage investigators?" And the answer to that is we think—well, what do you think? I'm going to turn to Michele Bloch to see if you have a sense of that.

Dr. Michele Bloch: That's a really good question. I don't think we have discussed that internally, but we will, and will post it on the FAQ if we have an answer at this point.

Dr. Stephanie Land: Okay. All right. Very good question. Thank you. It's like one of those radio shows—can you stump the program staff? Okay. And I think we have addressed all the questions that have come in via WebEx and we are also at the end of my highlights.

So are there comments from anyone else in the room that you'd like to make that have not already been said? All right.

So at this time what I'd like to do is give an opportunity for those people who are only on the phone so that you may ask questions—oh, I'm sorry—one new question came in just now by WebEx.

Audience Question "What are your requirements for preliminary data?" So that's a good question, and some investigators have asked me about that, partly because some of the lung cancer screening clinics are really new and are really just coming on board and preparing to begin screening patients, and so it may be difficult for you to obtain preliminary data in that setting.

So we will caution the review panel to be somewhat aware of that limitation that may exist for certain people. We don't want to limit applications to those who are working in settings that already have an active screening practice, because we expect these screening practices to be ramping up in the immediate near term because of recommendations and reimbursement decisions that have been made recently.

So that being said, this is an R01 and the review panel will certainly expect you to have some preliminary data, preliminary evidence for the efficacy of the smoking cessation interventions, and a strong investigator team with experience that is relevant. So that's the balance that we will be expecting or looking for. So I hope that answers your question.

Okay. I think we have now addressed all of the WebEx questions that have come in, and in a moment we're going to unmute your phones on our end. However, you each may keep yourselves muted, and in fact, we ask that you do that. As much as we love your dog, we would rather not hear the dog during the call. So we're going to now unmute, and do please mute on your end. So we have unmuted, and if anyone would like to ask a question at this time, please go ahead, and remember you do not need to identify yourself unless you prefer to.

Okay. Well, it seems that we may have answered all of your questions. So at this time we will re-mute, and thank you all so much for your participation today, and more so for all of the work that you're doing in this area and for your attention to the RFA. We hope that with this RFA we can reduce the number of current smokers in our country who are vulnerable to lung cancer.

So we thank you so much for your effort in this area, and please do reach out to us with your questions as you go forward. Thank you so much.

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