

**Subject:** RE: Time Sensitive Response Required Non-HSR Determinations

**From:** "Wegrzyn, Renee" <renee.wegrzyn@darpa.mil>

**Date:** 5/22/2017 10:28 PM

**To:** Jason Delborne <jadelbor@ncsu.edu>

**CC:** "Parr, Lianne (contr-bto)" <lianne.parr.ctr@darpa.mil>, "Cheever, Anne (contr-bto)" <anne.cheever.ctr@darpa.mil>, Sarah Carter <carter@sciencepolicyconsulting.com>, "James V. Lavery" <james.v.lavery@emory.edu>, John Godwin <godwin@ncsu.edu>, Mahmud Farooque <Mahmud.Farooque@asu.edu>, Julie Shapiro <jshapiro@keystone.org>

Hi Jason,

Great! No questions from us in the meantime. I think we have everything we need to move forward, but it will be helpful to be able to file the IRB letter, once received.

Thanks!

Renee

-----Original Message-----

From: Jason Delborne [<mailto:jadelbor@ncsu.edu>]

Sent: Friday, May 19, 2017 7:53 AM

To: Wegrzyn, Renee <[renee.wegrzyn@darpa.mil](mailto:renee.wegrzyn@darpa.mil)>

Cc: Parr, Lianne (contr-bto) <[lianne.parr.ctr@darpa.mil](mailto:lianne.parr.ctr@darpa.mil)>; Cheever, Anne (contr-bto) <[anne.cheever.ctr@darpa.mil](mailto:anne.cheever.ctr@darpa.mil)>; Sarah Carter <[carter@sciencepolicyconsulting.com](mailto:carter@sciencepolicyconsulting.com)>; James V. Lavery <[james.v.lavery@emory.edu](mailto:james.v.lavery@emory.edu)>; John Godwin <[godwin@ncsu.edu](mailto:godwin@ncsu.edu)>; Mahmud Farooque <[Mahmud.Farooque@asu.edu](mailto:Mahmud.Farooque@asu.edu)>; Julie Shapiro <[jshapiro@keystone.org](mailto:jshapiro@keystone.org)>

Subject: Re: Time Sensitive Response Required Non-HSR Determinations

Renee,

As per our conversation yesterday, I believe we can move forward with the statement of work as-is for the engagement tasks. I sent a description to our NC State IRB one week ago, asking for their affirmation that the tasks I described would not be considered HSR, and while I have not heard back from them formally, I feel confident that we can scope the tasks in a manner to avoid HSR. This confidence comes from many conversations with NC State IRB and sponsored projects administrators, as well as communication with social scientists involved in other Safe Genes projects. As we discussed, there may be opportunities to leverage other funds to support me or my colleagues to do "research" that complements the Safe Genes supported outreach activities.

I also appreciate that you were able to reconsider the stipends to incentivize participation in the community focus groups. These nominal payments will help with recruitment and acknowledge the time spent by community members to contribute to our understanding.

I will forward a formal letter from our IRB as soon as I can secure one, but please let me know if you have any questions or concerns in the meantime.

Jason

On May 12, 2017, at 3:54 PM, Wegrzyn, Renee <[renee.wegrzyn@darpa.mil](mailto:renee.wegrzyn@darpa.mil)> wrote:

Jason,

Thanks for your response - this is much more detailed and helpful. We will work with this content to discuss with our internal legal, contracting, and fiscal teams. I will also be at the meeting next week for the Army Corps, so we can use that as an opportunity to connect.

Thanks,

Renee

-----Original Message-----

From: Jason Delborne [<mailto:jadelbor@ncsu.edu>]

Sent: Friday, May 12, 2017 1:20 PM

To: Wegrzyn, Renee <[renee.wegrzyn@darpa.mil](mailto:renee.wegrzyn@darpa.mil)>

Cc: Parr, Lianne (contr-bto) <[lianne.parr.ctr@darpa.mil](mailto:lianne.parr.ctr@darpa.mil)>; Cheever, Anne (contr-bto)

<[anne.cheever.ctr@darpa.mil](mailto:anne.cheever.ctr@darpa.mil)>; Sarah Carter <[carter@sciencepolicyconsulting.com](mailto:carter@sciencepolicyconsulting.com)>;

James V. Lavery <[james.v.lavery@emory.edu](mailto:james.v.lavery@emory.edu)>; John Godwin <[godwin@ncsu.edu](mailto:godwin@ncsu.edu)>; Mahmud

Farooque <[Mahmud.Farooque@asu.edu](mailto:Mahmud.Farooque@asu.edu)>; Julie Shapiro <[jshapiro@keystone.org](mailto:jshapiro@keystone.org)>

Subject: Re: Time Sensitive Response Required Non-HSR Determinations

Renee and all (although I don't see Shannon Kasa in this list of emails),

Your idea about the workshop makes a great deal of sense. We can certainly organize the stakeholder workshop in a manner that asks each participant to do a short talk, making them speakers eligible for travel support and free registration. This would align with our view that this workshop is about bringing diverse experts together to make strategic design decisions for the community focus groups envisioned for Phase 2. I can work on a short document with Mahmud, Julie, and John Godwin that offers these kinds of specifics for the workshop and its budget.

In my experience, the organizers of focus groups offer compensation to participants in recognition for their time and effort. Perhaps this stems from their relationship to corporate marketing studies, in which companies gather together small groups of consumers to learn about their attitudes and preferences - offering some kind of incentive since there is no "civic mission." For example, I am part of an NSF grant in "Cultivating Cultures of Ethics in STEM," and we are organizing about 15 focus groups, drawing participants from academia, NGOs, industry, and trade associations. Even though they are experts in some sense, and even though the project is aimed at broad public benefit, we provide each participant with a gift card as an incentive. We are doing the same thing in a project funded by USDA to organize focus groups of "ordinary" citizens recruited at grocery stores (gift cards to grocery stores) to discuss gene drives in agriculture. Perhaps Jim or Cinnamon could also speak to their experience with incentives for participation by community members. Again, I don't think it will be impossible to recruit community members to participate in focus groups without a stipend, but it will be more challenging. Another option is for GBIRD to seek other resources to incentivize participation in the Safe Genes focus groups, knowing that DARPA funds cannot be used for this purpose.

In terms of the topics for the focus groups (since there are no open releases planned in Safe Genes), the general vision is to create scenarios that are finalized at the stakeholder workshop that will enable the community focus groups to be meaningful to the participants and useful to a) our technical research team, b) the Safe Genes program, c) regulatory institutions that may oversee applications for field

releases, and d) the research community surrounding gene drives and other advanced biotechnologies. I'm happy to have more conversations with you at this point, but I would also say that our plan is to include DARPA in our stakeholder workshop where the specifics of the focus group scenarios and questions will be designed. And you will also have a chance to provide feedback on the draft scenarios that will come out of our landscape analysis and discussions with our technical team.

I am available all afternoon, as needed, and some parts of Monday and Tuesday. I am attending the Army Corps SynBio meeting (with Sarah Carter and others) in Boston Wed-Fri, and I have learned that we will not have access to our electronics during the meetings.

Jason

On May 11, 2017, at 10:05 PM, Wegrzyn, Renee <[renee.wegrzyn@darpa.mil](mailto:renee.wegrzyn@darpa.mil)> wrote:

Hi Jason,

I'm looping in our COR, Shannon Kasa, into the discussion so she can review the email chain so far. I'm certain we can make a path to hold a workshop, but I think what we would need next is the next level of detail in terms of what the workshop funds would be used for. For example, in my mind (and from my experience at many workshops), a workshop attendee would not be paid compensation, but someone who contributes by presenting a talk, etc, would (or at least reg fee and potentially travel, might be covered). You mention "provide the customary stipend" what does that usually entail, and have you used federal funds previously to populate a focus group with compensated community members? Based on your email, I might interpret your plan to compensate every participant. Do you mean cash? Lunch? We need more specifics, and it will be helpful to have the next level deeper discussion of the plan for meeting content and impact on the overall technical effort. At the high level the SOW is written, it is difficult to extrapolate how it all loops back into the planned technical work. It would be helpful if you could pull together a couple of slides or a document to lay out the scope of the workshop, the types of attendees anticipated, and where you would apply the funds. As part of this discussion, I'd also like to speak with you a little bit more about the topics you plan to engage with a given community since there are no open releases that are part of the Safe Genes program. Again, I think there is a path forward here, but we just don't have enough information.

Shannon - let me know when you can connect with the DARPA team to discuss. We want Jason to be able to organize a Stakeholder meeting, but also want to be compliant with rules for compensation, which there remains some confusion about. We've already discussed with our in-house HSR expert, but your experience will be helpful here as well. (Jim, you're welcome to join the call too, once we schedule)

Thanks!

Renee

-----Original Message-----

From: Jason Delborne [<mailto:jadelbor@ncsu.edu>]

Sent: Thursday, May 11, 2017 11:52 AM

To: Parr, Lianne (contr-bto) <[lianne.parr.ctr@darpa.mil](mailto:lianne.parr.ctr@darpa.mil)>; Wegrzyn, Renee <[renee.wegrzyn@darpa.mil](mailto:renee.wegrzyn@darpa.mil)>; Cheever, Anne (contr-bto) <[anne.cheever.ctr@darpa.mil](mailto:anne.cheever.ctr@darpa.mil)>; Sarah Carter <[carter@sciencepolicyconsulting.com](mailto:carter@sciencepolicyconsulting.com)>; James V. Lavery

[<james.v.lavery@emory.edu>](mailto:james.v.lavery@emory.edu)

Cc: John Godwin [<godwin@ncsu.edu>](mailto:godwin@ncsu.edu); Mahmud Farooque [<Mahmud.Farooque@asu.edu>](mailto:Mahmud.Farooque@asu.edu); Julie Shapiro [<jshapiro@keystone.org>](mailto:jshapiro@keystone.org)

Subject: Re: Time Sensitive Response Required Non-HSR Determinations

Dear Renee and DARPA team,

In reviewing your communication from yesterday regarding what activities can be supported by SafeGenes resources, we note that funds "may not be provided to participants, survey responders, workshop attendees, or other community members for their time or travel." Am I correct that this prohibits our team's ability to organize a workshop of stakeholders during Phase 1? This was envisioned by our team as a key link between our stakeholder landscape analysis and conducting focus groups in communities near potential release sites in Phase 2.

I would like to be flexible, and creative, in seeking a solution. Is it possible, for example, to envision our workshop as a gathering of experts whose travel could be supported? The outputs of the workshop would need to be adjusted somewhat, but it could still fulfill the purpose of integrating results from our landscape analysis into a plan for community focus groups.

It seems quite clear that we cannot provide the customary stipends to community members to participate in focus groups. This is quite unfortunate, as it does not communicate the respect that community members deserve when they interface with experts who wish to understand their perceptions and perspectives. And the lack of an incentive will make recruitment more difficult. But there is also precedent for community members volunteering their time to participate in stimulating discussions about emerging technologies, cutting-edge science, and conservation issues.

I have had helpful conversations with our IRB coordinator and the head of NC State's sponsored projects office. I do believe we can proceed with the three primary tasks in the engagement realm (stakeholder interviews to produce a landscape analysis, workshop, and community focus groups) without conducting HSR. As soon as we have clarity on the potential to support a workshop, I will draft an explanation of our project tasks to the head of our IRB, so that she can generate a formal letter advising us that the activities are not HSR.

Thank you,

Jason (email also reviewed with John Godwin by phone prior to sending)

On May 10, 2017, at 6:37 PM, John Godwin [<godwin@ncsu.edu>](mailto:godwin@ncsu.edu) [<mailto:godwin@ncsu.edu>](mailto:godwin@ncsu.edu) > wrote:

Hi Jason,

I haven't caught up with the emails from this afternoon that look related to this, but wanted to forward this one right away. Just based on my first read here, it looks like there are impacts on the project with the 'time and travel' part there.

John

----- Forwarded message -----

From: Parr, Lianne (contr-bto) <[lianne.parr.ctr@darpa.mil](mailto:lianne.parr.ctr@darpa.mil)>  
<<mailto:lianne.parr.ctr@darpa.mil>> >  
Date: Wed, May 10, 2017 at 3:51 PM  
Subject: Time Sensitive Response Required Non-HSR Determinations  
To: "Wegrzyn, Renee" <[renee.wegrzyn@darpa.mil](mailto:renee.wegrzyn@darpa.mil)>  
<<mailto:renee.wegrzyn@darpa.mil>> >  
Cc: "Cheever, Anne (contr-bto)" <[anne.cheever.ctr@darpa.mil](mailto:anne.cheever.ctr@darpa.mil)>  
<<mailto:anne.cheever.ctr@darpa.mil>> >, Sarah Carter  
<[carter@sciencepolicyconsulting.com](mailto:carter@sciencepolicyconsulting.com) <<mailto:carter@sciencepolicyconsulting.com>> >,  
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<[colby.stoddard.ctr@darpa.mil](mailto:colby.stoddard.ctr@darpa.mil) <<mailto:colby.stoddard.ctr@darpa.mil>> >

Dear Safe Genes teams:

Questions came to our attention regarding tasks related to community engagement in the Safe Genes projects. The BAA stated that "proposers are encouraged to consider outreach and engagement activities for community stakeholders, as appropriate, and include communications and other types of expertise in their teams, as needed." As such, several teams proposed community engagement in various ways. DARPA intends for this to continue, but needs a closer look at these tasks and associated costs to ensure that the funds are used in a way allowable by the Code of Federal Regulations and DoD policies.

We should clarify at this time that Safe Genes efforts should not include human subjects research. One of the intents of the DARPA and Safe Genes LEEDR initiatives is to encourage PIs to conduct community outreach, receive feedback regarding safety in the relevant gene editing application, and not identify specific individuals. Since the technology does not exist yet, it is not research for product testing, but this knowledge will inform the technology development related to your project in the communities that you are targeting. It is our understanding that universities conduct community outreach and should be available to advise researchers on what qualifies as non-HSR community outreach vs HSR, in close collaboration with the IRB. Specifically, any funds for community engagement may support the administration of activities including staff time, materials, supplies and facilities, but may not be provided to participants, survey responders, workshop attendees, or other community members for their time or travel.

If you intend to conduct any community outreach, DARPA asks that each prime institution submit IRB Letters of Determination stating that the protocols are not HSR for the prime and all subawardees. If there are any concerns about the tasks or costs as currently negotiated, please notify us immediately so that we can work together to modify the SOW and budget accordingly. We can schedule calls to discuss specific concerns.

Regards,  
Lianne

Lianne Parr  
Booz Allen Hamilton  
DARPA/BTO SETA Contractor

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