

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

From: Jason Delborne <jadelbor@ncsu.edu>

Date: 5/11/2017 11:52 AM

To: "Parr, Lianne (contr-bto)" <lianne.parr.ctr@darpa.mil>, "Wegrzyn, Renee"

<renee.wegrzyn@darpa.mil>, "Cheever, Anne (contr-bto)" <anne.cheever.ctr@darpa.mil>, Sarah Carter <carter@sciencepolicyconsulting.com>, "James V. Lavery" <james.v.lavery@emory.edu>

CC: John Godwin <godwin@ncsu.edu>, Mahmud Farooque <Mahmud.Farooque@asu.edu>, Julie Shapiro <jshapiro@keystone.org>

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> 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>

Date: Wed, May 10, 2017 at 3:51 PM

Subject: Time Sensitive Response Required Non-HSR Determinations

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

Cc: "Cheever, Anne (contr-bto)" <anne.cheever.ctr@darpa.mil>, Sarah Carter <carter@sciencepolicyconsulting.com>, "Jenkins, Amy (contr-bto)" <amy.jenkins.ctr@darpa.mil>, "Lee, Andrew [USA]" <Lee_Andrew@bah.com>, "Stoddard, Colby (contr-bto)" <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

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