Subject: Re: consultation on an ethics question
From: Fred Gould <fgould@ncsu.edu>
Date: 7/18/2017 9:43 AM
To: "Thizy, Delphine C" <d.thizy@imperial.ac.uk>
CC: Rashmi L Narayana <rashmi@umotif.com>, "Fred_gould@ncsu.edu" <fred_gould@ncsu.edu>, "James, Stephanie (FNIH) [T]" <sjames@fnih.org>

Delphine,
As you may know, I'm involved in the the GBIRd group that is working on the conservation project that aims at eradicating invasive mice with gene drive approaches. Keith Hayes from CSIRO who is working with GBIRd and with Target Malaria has recently brought up the issue to GBIRd of needing to stay arm's length away from decision making in GBIRd so he can maintain neutrality.
Maybe the answer is to come up with criteria that the Target Malaria and GBIRd groups would consider as putting up a good firewall between Keith's group and both projects.
I have some concerns about the technical rigor of Keith's methodology but how does somebody within either GBIRd or Target Malaria comment of Keith's work without compromising Keith's neutrality? Do you have a third party who could be evaluating Keith's approaches?
Fred

On Jul 17, 2017, at 2:12 PM, Thizy, Delphine C <d.thizy@imperial.ac.uk> wrote:

Dear Rashmi and Fred,

I hope this mail finds you both well. I wanted to consult you on an ethics issue related to the project. We decided to put together a smaller group to consult on this and I suggested you as you have experience Fred with risk assessments and Rashmi with large scale trials. But of course if you think more people should be involved let us know.

As you may recall, each stage of our project undergoes an independent risk assessment. This is done by CSIRO, an Austrian company specialised in environmental risk assessment as well as many other things.

Recently other parts of that organisation started working and talking about the use of gene drive for conservation purpose – to fight invasive species. And so that has raised some question about a potential conflict of interest and Stephanie – from FNIH who is actually the contractor of that CSIRO study – has reached out to them to get their thoughts about this.

We thought it would be good to get your perspective on this. As you might imagine they aren't that many groups that are specialised on these issues but we want to make sure that we prevent conflict of interest and also reduce the risk of perception around a potential one.

Let me know if you need more information and more generally if the ask isn't clear

Warm regards

Delphine

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From: Keith.Hayes@data61.csiro.au [mailto:Keith.Hayes@data61.csiro.au]
Sent: Wednesday, July 12, 2017 1:52 AM
To: James, Stephanie (FNIH) [T] <sjames@fnih.org>; Paul.Debarro@csiro.au
Subject: RE: Gene drive issues

Hiya Stephanie – yeah all of these need fleshing out – at the moment they are just dot points to help structure a document for you that outlines how the risk team maintains its independence – re 5 and 8 specifically:

5. The "we" here refers to the Data61 Business Unit (which my team is part of) – this Business Unit has no vested interested in the technology – as part of the document we will need to go into further details about how the business units in CSIRO are separated

8. Yes my understanding is that the contract specifies that you own the results – we did however insert specific provisions for publications in both contracts (copied below) – the dot point is a too blunt a version of these provisions

(p) **Publications**.

i. CSIRO may seek to publish material relating to the Services or the Deliverables. CSIRO will not publish material relating to the Deliverables or any Confidential Information without first obtaining the prior written consent of Foundation, such consent not to be unreasonably withheld.

ii. Prior to submitting any material relating to the Deliverables or Confidential Information for publication, CSIRO shall forward a request in writing ("a Request") to Foundation seeking consent to publish the relevant material. The Request shall be accompanied by a copy of the proposed publication ("Proposed Publication").

iii. The Parties acknowledge and agree that it shall not be unreasonable for Foundation to withhold consent to a Request from CSIRO in order to protect any Confidential Information of a party which is disclosed in the Proposed Publication.

iv. Upon request from Foundation, Contractor will delete Foundation Confidential Information from any and all Proposed Publications.

v. Any Proposed Publication which is approved pursuant to the procedure set out above shall acknowledge the technical, scientific and other input of Foundation.

Couple of other things – on re-reading the contract I also wonder if we could make more use of this clause to ensure our independence:

Conflicts with this Contract. The Contractor represents and warrants that the Contractor is not under any pre-existing obligation in conflict or in any way inconsistent with the provisions of this Contract.

Finally I'm about 80% of the way through the male bias proposal but only about 20% of the way through the gene drive one – I think will have the former finished this week but not the later – I'll try and find time in the evenings and on the various flights to get this one knocked into shape in the next couple of weeks.

All the best

Keith

From: James, Stephanie (FNIH) [T] [mailto:sjames@fnih.org]
Sent: Wednesday, 12 July 2017 3:25 PM
To: De Barro, Paul (H&B, Dutton Park) <Paul.Debarro@csiro.au>
Cc: Hayes, Keith (Data61, Hobart) <Keith.Hayes@data61.csiro.au>
Subject: Re: Gene drive issues

Hi, both. This is useful but a few questions about points 5 and 8;
5. It was my understanding the CSIRO is likely to be pursuing its own research on genetic control strategies for other organisms and therefore will likely be perceived as an advocate of the technology.
8. This reads as if CSIRO intends to publish the results. However it was my understanding that the results belong to the customer (in this case FNIH). Please clarify.

Thanks, Stephanie

Sent from my BlackBerry 10 smartphone.

From: Paul.Debarro@csiro.au
Sent: Tuesday, July 11, 2017 11:01 PM
To: James, Stephanie (FNIH) [T]
Cc: Keith.Hayes@data61.csiro.au
Subject: Re: Gene drive issues

Hi Stephanie,

Keith and I plus our internal business support folk have discussed how best to proceed here. We think that the best way would be to develop an SOP and then append that to each contract or project document (this covers internal CSIRO work).

Here are the points that we think should be included and would appreciate your feedback. In the meantime our BD folk are reviewing and may suggest further changes which I will circulate to you.

1. We are not co-authors on any of their publications related to the importation, field trial or release of genetic control technologies – we may however be co-authors with individuals from the project team on safety-related issues for gene drives

2. Our contracts and proposals with the customer are commercial in confidence, but we require that all of our risk assessment reports and outputs are available publicly and not subject to any form of confidentiality agreement

3. We routinely involve independent domain experts (experts who are not affiliated with the project team) in formal elicitation exercises as part of our risk assessment and insist that these experts are not required to sign non-disclosure agreements

4. We routinely provide project progress reports to the funding agency and request information and data from the project team, but we are free to source information from any other source

5. We have no vested interest in development or application of genetic control technologies

6. All of risk team are on indefinite contracts so we are not reliant on external funding for their continued employment

7. External and internal customers are required to include these terms as part of the project agreement

8. The customer has the right to review documents prior to their publication and suggest changes, but they do not have the power to prevent their publication.

Regards

Paul

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From: James, Stephanie (FNIH) [T] <sjames@fnih.org>
Sent: Wednesday, 14 June 2017 11:16 PM
To: De Barro, Paul (H&B, Dutton Park)
Cc: Hayes, Keith (Data61, Hobart)
Subject: Gene drive issues

Hi, Paul. As you know, Keith Hayes and his team are working with FNIH on a second risk assessment for Target Malaria and we have plans in the works for at least two more.

Now that CSIRO is getting involved in its own efforts on gene drive, the question has arisen as to whether Keith's team can be perceived as independent while being part of an organization that is publicly advocating for the technology (http://www.abc.net.au/news/2017-06-13/should-invasive-pest-control-be-acceptable-to-the-public/8613070). There is some concern that this could become a lightning rod public perception issue.

For that reason, I would like to ask you to provide me with some documentation of CSIRO's plans to keep Keith's unit separated from any internal gene drive research activities. I know CSIRO is a huge organization, with lots of different divisions, but I think we need a better understanding of what kind of fire walls are or will be put in place – something that can withstand public scrutiny. And it is better to get this shaped up now, before it becomes an issue.

Thanks a lot!
Stephanie

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