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04:17 PM

From: John Carley/DC/USEPA/US@EPA
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Cc: Kevin Sweeney/DC/USEPA/US@EPA

Subject: Gaps in Documentation of EIRB Review of the Stable Fly Study

In a preliminary review of your submitted final report for the A382 lab study with stable flies, I found several major gaps in the documentation of ethical conduct required to be submitted by the rule at 40 CFR 26.1303. I found the following specific deficiencies:

Incomplete records of EIRB reviews:

- No records of ICR submission or EIRB review of June 12 protocol and supporting documents, as required by 26.1115(a)(1)
- No notification of EIRB approval of August 21 protocol and supporting documents, as required by 26.1125(f)
- No minutes of 11/24/08 EIRB meeting at which 11/10/08 amendments were discussed, as required by 26.1115(a)(2)
- No correspondence with EIRB since 5 Feb 2008 except for 11/25 notification of approval. A complete record of all correspondence is required by 26.1115(a)(4) and 26.1125(e)

Incomplete information about EIRB members, required by 26.1115(a)(5):

- No information provided concerning members' representative capacities, experience, or anticipated contributions to IRB deliberations
- No information provided about any employment or other relationships between EIRB members and either EIRB or ICR

In addition, I noted that the version of the telephone recruiting script bearing the EIRB stamp dated 11/24/08 (pp. 182-184) is inconsistent in content with what you had submitted (pp. 167-169), and does not reflect the amendments made in the protocol version of 11/10/08. This discrepancy is not explained; it appears to be a frank error by the EIRB.

Finally, you have provided no indication or discussion of how the protocol version of 8/21 differs from the version reviewed by EPA and the HSRB, or of how the protocol version of 11/10 differs from that of 8/21. This makes review very difficult, and may result in avoidable misunderstandings.

I will defer my ethics review until you have filled the gaps in required documentation I've noted above. Please let me know when to expect a supplemental submission, and please format the

supplement consistent with PR Notice 86-5, plainly identifying it as a supplement to the primary report you've already sent in.

As a reminder of the requirements of 40 CFR 26.1303, and to help you ensure completeness of the supplement, here is what the rule requires, in the form of a checklist.

[26.1303 Requirements.doc]

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