

Samuel, Lee (CDC/OID/NCEZID)

From: Mayfield, Kristin (CDC/OD/OADS)
Sent: Tuesday, February 23, 2016 10:27 AM
To: Artus, Aileen A. (CDC/OID/NCEZID) (CTR)
Cc: Schafer, Ilana J. (CDC/OID/NCEZID)
Subject: RE: PR canine leptospirosis study

Yes! Sorry, I was out of town. She is fine with it not needing an IACUC protocol

From: Artus, Aileen A. (CDC/OID/NCEZID) (CTR)
Sent: Tuesday, February 23, 2016 9:20 AM
To: Mayfield, Kristin (CDC/OD/OADS) <erv4@cdc.gov>
Cc: Schafer, Ilana J. (CDC/OID/NCEZID) <wii3@cdc.gov>
Subject: RE: PR canine leptospirosis study

Hi Kristin,

Have you been able to talk to Linda about our canine leptospirosis project in Puerto Rico? You mentioned during the meeting that it is exempt but that you would talk it over with Linda.

Thanks!
Aileen

From: Mayfield, Kristin (CDC/OD/OADS)
Sent: Tuesday, February 09, 2016 7:50 AM
To: Artus, Aileen A. (CDC/OID/NCEZID) (CTR) <ygn3@cdc.gov>
Cc: Schafer, Ilana J. (CDC/OID/NCEZID) <wii3@cdc.gov>; Pimentel, Linda Capewell (CDC/OD/OADS) <gsu2@cdc.gov>; Salzer, Johanna S. (CDC/OID/NCEZID) <hio7@cdc.gov>
Subject: RE: PR canine leptospirosis study

Great, see you then

From: Artus, Aileen A. (CDC/OID/NCEZID) (CTR)
Sent: Monday, February 08, 2016 3:53 PM
To: Mayfield, Kristin (CDC/OD/OADS) <erv4@cdc.gov>
Cc: Schafer, Ilana J. (CDC/OID/NCEZID) <wii3@cdc.gov>; Pimentel, Linda Capewell (CDC/OD/OADS) <gsu2@cdc.gov>; Salzer, Johanna S. (CDC/OID/NCEZID) <hio7@cdc.gov>
Subject: RE: PR canine leptospirosis study

Thanks! We're also in cubeland but I've reserved 11101A (Bldg 24) for us at 12 PM.

Talk to you soon!

From: Mayfield, Kristin (CDC/OD/OADS)
Sent: Monday, February 08, 2016 3:08 PM
To: Artus, Aileen A. (CDC/OID/NCEZID) (CTR) <ygn3@cdc.gov>
Cc: Schafer, Ilana J. (CDC/OID/NCEZID) <wii3@cdc.gov>; Pimentel, Linda Capewell (CDC/OD/OADS) <gsu2@cdc.gov>;

Salzer, Johanna S. (CDC/OID/NCEZID) <hio7@cdc.gov>

Subject: RE: PR canine leptospirosis study

I should be able to meet at noon, I could also come to your area if anyone has an office? I am in cubeland so hard to talk to several people 😊

From: Artus, Aileen A. (CDC/OID/NCEZID) (CTR)

Sent: Monday, February 08, 2016 2:03 PM

To: Mayfield, Kristin (CDC/OD/OADS) <erv4@cdc.gov>

Cc: Schafer, Ilana J. (CDC/OID/NCEZID) <wii3@cdc.gov>; Pimentel, Linda Capewell (CDC/OD/OADS) <gsu2@cdc.gov>; Salzer, Johanna S. (CDC/OID/NCEZID) <hio7@cdc.gov>

Subject: RE: PR canine leptospirosis study

Hi Kristin,

Would it be possible to meet with you for a quick chat about our protocol on Wednesday (2/10)? If you have some time between 10am -12pm, we can come to your office.

Thanks,
Aileen

From: Mayfield, Kristin (CDC/OD/OADS)

Sent: Thursday, February 04, 2016 12:54 PM

To: Artus, Aileen A. (CDC/OID/NCEZID) (CTR) <ygn3@cdc.gov>

Cc: Schafer, Ilana J. (CDC/OID/NCEZID) <wii3@cdc.gov>; Pimentel, Linda Capewell (CDC/OD/OADS) <gsu2@cdc.gov>

Subject: RE: PR canine leptospirosis study

Unfortunately for canines there is not much of an expedited review as it has to go to full committee. Our next meeting is March 7th, if you can get it in for that meeting you should be able to get approval with a couple of weeks after (unless the committee any strong objections). I have added you to topaz and Ilana already has access (<http://topazenterprise.cdc.gov/>). You will sign in using your CDC user name and password. Just go to create original protocol and select the field study form and start filling out 😊

After you are satisfied with the form, send a PDF to an ARB veterinarian for consult, they are listed on our site under steps to protocol submission <http://intranet.cdc.gov/od/oads/osi/acupo/protocol/> there is also other helpful information there. Once the vet approves, you will need to presubmit the protocol to the branch and division designees listed in the protocol and the vet that did the consult, I am also attaching instructions for this. Once they sign off you can submit to my office for IACUC review. Let me know if you have any questions or if you would like me to come to your office for more help.

-Kristin

From: Artus, Aileen A. (CDC/OID/NCEZID) (CTR)

Sent: Thursday, February 04, 2016 12:38 PM

To: Mayfield, Kristin (CDC/OD/OADS) <erv4@cdc.gov>

Cc: Schafer, Ilana J. (CDC/OID/NCEZID) <wii3@cdc.gov>; Pimentel, Linda Capewell (CDC/OD/OADS) <gsu2@cdc.gov>

Subject: RE: PR canine leptospirosis study

Hi Linda, thanks for the timely response and for your input.

Hi Kristin,

Unfortunately, we are in a tight timeframe at the moment because the test kits for the project have already been sent to Puerto Rico and will be expiring in August, 2016. These were sent by Marta a few months ago so we are hoping to have the clinics and shelters start testing as soon as possible.

Given this, what would you suggest? Does IACUC have expedited protocol reviews? What paperwork needs to be completed? Do you have resource materials we can access to help guide us with the IACUC process?

If we did not change the protocol from what Marta had originally intended, would we be fine with proceeding forward under IACUC exemption?

If you would like to discuss further, feel free to give me a call at 404-639-3474.

Thanks,

Aileen

From: Pimentel, Linda Capewell (CDC/OD/OADS)
Sent: Thursday, February 04, 2016 12:07 PM
To: Artus, Aileen A. (CDC/OID/NCEZID) (CTR) <ygn3@cdc.gov>; Schafer, Ilana J. (CDC/OID/NCEZID) <wii3@cdc.gov>
Cc: Mayfield, Kristin (CDC/OD/OADS) <erv4@cdc.gov>
Subject: RE: PR canine leptospirosis study

Hi Aileen and Ilana,

Thanks for keeping us posted on the updates. Unfortunately, since CDC is now guiding the testing and you will have to take additional samples, you will need a protocol for this activity. Kristin Mayfield is our IACUC administrator and can assist you with setting up a protocol. Please contact her as soon as you can to get started as protocols can take approximately 3 months or longer from start to finish to get approved.

Please let Kristin or I know if you have any additional questions. We are always here to help you.

Best, Linda

Linda Capewell Pimentel, VMD, MPH, DACVPM
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Telework Fridays

From: Artus, Aileen A. (CDC/OID/NCEZID) (CTR)
Sent: Thursday, February 04, 2016 10:43 AM
To: Pimentel, Linda Capewell (CDC/OD/OADS) <gus2@cdc.gov>; Mayfield, Kristin (CDC/OD/OADS) <erv4@cdc.gov>
Cc: Schafer, Ilana J. (CDC/OID/NCEZID) <wii3@cdc.gov>
Subject: PR canine leptospirosis study

Hi Linda and Kristin,

Marta Guerra was working on setting up a project on canine leptospirosis in Puerto Rico. The project is as follows:

Dogs suspect for leptospirosis will be tested with an in-house rapid test. The leptotest for canines in this project will be used to guide treatment. There are currently no laboratories in PR that perform canine testing for leptospirosis. We will be collecting clinical information from the veterinarian, and medical and exposure history from the owners. Blood and urine for diagnostic purposes will be collected from a live dog. If the dog is euthanized, we will be collecting samples from the kidney.

Unfortunately, Marta has moved to a new position in Togo in West Africa. Ilana Schafer (copied) and myself will be taking over the project.

Based on previous emails, the study protocol was considered exempt from IACUC review since the intent is to treat the animal and use the test to guide treatment. We have been reviewing the protocol and have considered adding a recommendation to retest the dog after ~3-5 days if the initial test was negative and the dog had only been symptomatic for <4 days when sample was collected (antibodies detected by the test may have not yet developed), and if no other underlying cause of disease has been found. A retest would entail collecting additional samples from the dog. The intent is still to treat as we are testing again to ensure that it is not a false negative.

With these changes, I want to verify with you that our protocol would still fall under exempt.

Marta discussed this project with you a while ago, so if there is someone else I should reach out to regarding IACUC guidance, please let me know.

Thank you!

Aileen Artus, MPH

ORISE Fellow

Bacterial Special Pathogens Branch

Division of High-Consequence Pathogens and Pathology

Centers for Disease Control and Prevention

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Telework: Tuesday