

rDNA Committee Meeting Minutes

Date: 01/15/2015

Time: 4pm-5pm

Location: Haworth Hall, 7040 Conference Room

Committee Members Present: Dr. Steve Benedict (Chair), Dr. Kristi Neufeld (member), Dr. Jeff Staudinger, (member), Mike Russell (Member).

Others/Guests: None

1) Approval of Minutes

None presented from 01/07/2015 meeting for approval

2) rDNA Protocol Review

A) NIH Exempt Protocol Activity

No rDNA registrations submitted to EHS or Chair in last quarter (10/14/15 – 01/14/15).

B) Protocols for Committee Review

Amendment/modification to tabled protocol.

Protocol “Introduce B-lactamase resistance gene into *C. trachomatis* serovar D.”

PI: Dr. S. Hefty.

NIH status: NIH rDNA covered (III-D-1/2).

Risk Assessment: RG2/BL2.

Committee Comments/Actions:

Committee received revised registration from PI for further review.

PI explained why tetracycline or other selective markers would not be acceptable to research.

PI adequately addressed Q5 and Q11.

Concern about females that may become pregnant but have allergies to macrolides.

PI deferred for advice about RAC review back to committee. PI did note that penicillin is known for stabilizing a persistent infection rather than curing the patient. PI also notes that use of penicillin was added to guidelines long ago and presently is under re-evaluation.

RAC Review question. Committee reviewed NIH-OBA FAQ documents on Major actions. Committee was still uncertain as to necessity for RAC review

Action: (1) Registration for Hefty protocol tabled until a decision on RAC review has been reached. (2) Committee directed EHS to confer with NIH-OBA about RAC review and provide follow-up email to committee regarding that information.

Committee Approval Status: Not at this time. Protocol tabled.

Notes added ex post facto:

i) EHS submitted email to NIH-OBA requesting consultation on 01/30/2015. Email back from NIH-OBA on 02/04/2015 indicated the following:

“The introduction of a beta-lactam resistance marker into *Chlamydia trachomatis* serovar D would be subject to Section III-A of the NIH Guidelines. Serovar D is indicated to cause urethritis, and according to CDC treatment guidelines, Amoxicillin is considered a first line treatment for pregnant women since other treatments such Doxycycline, Ofloxacin, and Levofloxacin are contraindicated in pregnancy. Additionally, there is no documented resistance to amoxicillin, and efficacy across trials is similar for azithromycin, amoxicillin, and erythromycin. With this in mind, if the principal investigator (PI) wished to proceed with this experiment it would require a review by the RAC and approval by the NIH Director. If you wish to start this process, we request that you provide us with all the information the PI would be required to submit to the IBC for a protocol review.”

ii) PI was notified on 02/04/2015 that protocol required NIH RAC review and could not be approved or initiated as submitted to rDNA Committee.

iii) EHS had a follow-up phone conversation with NIH-OBA on 02/04/2015 after receiving email. NIH-OBA indicated verbally that NIH-OBA has approved (does not require RAC review) for B-lactams resistance gene in *C.t.* serovar LGV. They indicated our PI could pursue work with *C.t.* LGV, if desired, if approved by our rDNA committee. They indicated they have not given anyone approval to pursue B-lactam resistance gene in *C.t.* Serovar D. It would have to go to/through RAC review. They indicated it would not be possible to get it to/through the RAC review scheduled for March. They indicated it would be possible to get it to the June RAC review meeting, if we (KU) do our part.

iv) PI notes that a similar proposal by an NIH scientist is under RAC review at present. PI is comfortable waiting for that decision which will set precedent for him. PI withdrew protocol at this time.

3) Other Discussion Items

A) Reports - no rDNA problems, violations of the NIH Guidelines, nor any rDNA research-related accidents/illnesses have been discovered, identified or reported since last meeting.

B) Membership Update – Potential new community member identified. Local High School biology teacher with microbiology & genetics background. EHS vetting and will confer with NIH-OBA.

Notes added ex post facto for Membership Update:

1) Unable to add LHS Biology teacher due to spouse on KU faculty which was indicated by NIH-OBA as conflict of interest.

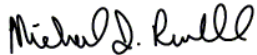
2) Identified two other potential candidates for community members. Dr. Jeff Barclay (Local Pastor) and Kevin Kennedy (Children’s Mercy Hospital – Environmental Health Center). EHS vetted through NIH-OBA that indicated acceptance. Both community members agreed to serve on committee.

Minutes Approval

These minutes were reviewed and approved at the 10/27/2015 rDNA meeting.

4 votes in favor, 0 against, 1 abstention.

Respectfully,



Michael J. Russell
Director
KU-EHS Dept