

rDNA Committee Meeting Minutes

Date: 01/07/2015

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 for approval

2) rDNA Protocol Review

A) NIH Exempt Protocol Activity

No rDNA registrations submitted to EHS or Chair in last quarter (10/14 – 12/14).

B) Protocols for Committee Review

Protocol “Introduce β -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 Discussion:

PI desires to introduce beta-lactamase gene to enhance resistance to penicillins and allow for antibiotic selection and genetic complementation studies. Genes are to be introduced into *Chlamydia muridarum* or *C. trachomatis* either strain LGV-2 or serovar D. PI is well experienced and one of the primary investigators at the national level. Laboratory safety concerns related to work with Chlamydia have been handled well including careful attention to aerosols since infection is possible by aerosols through mucous membranes. PI noted that tetracycline resistance will not be introduced but that beta-lactam resistance will. PI & Committee concern is for introduction of penicillin resistance into the Risk Group 2 organism *Chlamydia trachomatis* serovar D. This concern is only in a small and restricted set of circumstances, but the concern is valid nonetheless.

The concern is as follows. In general, infections are self-limiting and treatments with many classes of macrolides are effective (e.g., azithromycin). Penicillin is not viewed as the drug of choice for most individuals

However, the question under lengthy discussion by the committee is the potential situation with pregnant females. The CDC guidelines state that tetracyclines, doxycycline, ofloxacin and levofloxacin are contraindicated for *Chlamydia* during pregnancy but azithromycin is safe and effective. The problem arises with pregnant women who are infected but are allergic to macrolides and thus unable to use azithromycin. The PI indicates that such individuals will be prohibited from working with *C. trachomatis* serovar D that has been modified with β -lactamases.

The committee discussed a publication arguing that amoxicillin, a penicillin family member is recommended for treatment in pregnant women and whether this impinged on the present situation. After considerable discussion, the committee evolved the following questions

Questions for PI summarized below:

Organism will have resistance to penicillin/amoxicillin.

What about resistance to other antibiotics?

Why not just use tetracycline resistance for selection instead of penicillin

PI did not properly address Q5 in registration document.

PI did not properly address Q11 in registration.

How does the PI respond to the recent publication suggesting penicillin is indicated for pregnant women.

Does this require RAC review?

Committee decision:

Registration/protocol tabled.

Committee agreed to have Chair return the registration document to PI with a request to address committee concerns & questions.

Because of the apparent urgency for application for funding the committee agreed to meet as soon as the PI response has been returned to the committee.

Committee Approval: Not at this time

3) Other Discussion Items

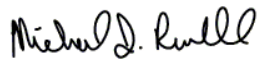
A) Reports - no rDNA problems, violations of the NIH Guidelines, nor any rDNA research-related accidents/illnesses have been discovered, identified or reported since the last meeting (time period of 10/01/2014 – 01/07/2015).

B) Membership Update – Community members have been non-participatory. Communication by EHS with CM's has indicated both members will not be participating and have requested to be removed from Committee. Need to find two new community members.

Minutes Approval

These minutes were reviewed and approved at the 10/27/2015 rDNA meeting.
3 votes in favor, 0 against, 2 abstentions.

Respectfully,



Michael J. Russell
Director
KU-EHS Dept.