SUMMARY STATEMENT

PROGRAM CONTACT:
Delmyra Turpin
240-669-5597
turpindb@niaid.nih.gov

(Privileged Communication)

Release Date: **03/28/2018**
Revised Date:

Application Number: **1 R01 AI140916-01**

Principal Investigators (Listed Alphabetically):

KLAUSNER, JEFFREY DAVID (Contact)
MEDINA-MARINO, ANDREW

Applicant Organization: UNIVERSITY OF CALIFORNIA LOS ANGELES

Review Group: **ACE**
AIDS Clinical Studies and Epidemiology Study Section
AIDS

Meeting Date: **03/13/2018**
Council: **MAY 2018**
Requested Start: **07/01/2018**

RFA/PA: **PA16-160**
PCC: **M37C**
Dual IC(s): **HD**

Project Title: **The Rea Phela 003 Health Study: Evaluating STI Screening Interventions and the Role of the Microbiome During Pregnancy**

SRG Action: **Impact Score:27 Percentile:15**

Next Steps: **Visit https://grants.nih.gov/grants/next_steps.htm**

Human Subjects: **48-At time of award, restrictions will apply**

Animal Subjects: **10-No live vertebrate animals involved for competing appl.**

Gender: **1A-Both genders, scientifically acceptable**

Minority: **1A-Minorities and non-minorities, scientifically acceptable**

Children: **1U-Both children and Adults, scientifically unacceptable**

Project Year	Direct Costs Requested	Estimated Total Cost
1	499,965	603,614
2	499,715	603,312
3	499,976	603,628
4	499,942	603,586
5	499,869	603,498
TOTAL	2,499,467	3,017,639

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1R01AI140916-01 Klausner, Jeffrey

INCLUSION OF CHILDREN PLAN UNACCEPTABLE
PROTECTION OF HUMAN SUBJECTS UNACCEPTABLE

RESUME AND SUMMARY OF DISCUSSION: In this application, the Principal Investigator proposes to establish a trial to assess the impact and cost-effectiveness of different diagnostic and screening strategies to decrease the burden of sexually transmitted infections (STIs) in pregnant women. STIs are common globally and have been associated with adverse birth outcomes. The reviewers agreed that the proposed studies are highly significant due to the impact and burden of STIs on birth outcomes in sub-Saharan Africa. The studies were deemed highly innovative as they examine the role of the microbiome on STI treatment outcomes as well as assess means to improve both cost-effectiveness and birth outcomes. Major strengths of the application were the focus on implementation to inform policy on STI testing strategies as well as cost assessment, the well-designed study, and strong investigative team. Enthusiasm was slightly dampened by the concern that syndromic management will impact STI detection since, based on the preliminary data by the investigative team, there is a high rate of asymptomatic infection. Nevertheless, the panel agreed that the proposed studies are highly significant and can potentially have a high overall impact on the management of STIs.

DESCRIPTION (provided by applicant): In 2012, WHO estimated that over 350 million cases of Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG) and Trichomonas vaginalis (TV) occurred globally. Sexually transmitted infections (STIs) during pregnancy are associated with premature rupture of membranes, preterm labor and delivery, low birth weight, congenital infections, perinatal death and mother-to-child transmission of HIV infection. STIs are common in pregnant women globally, but often go undiagnosed; recent work by our group found a 41% STI prevalence amongst HIV-infected pregnant women, of which 64% of infections were asymptomatic. Recent research suggests the vaginal microbiome may play a critical role in STI acquisition, persistence and treatment outcomes. Our pilot work has shown that diagnostic testing for CT, NG, and TV in antenatal care services for HIV-infected pregnant women in South Africa is highly acceptable and feasible; however, our work has made clear that evaluating the impact and cost effectiveness of different diagnostic screening strategies that optimally decrease the burden of STIs during pregnancy and at time-of-delivery is urgently needed. Furthermore, our findings highlight that biological factors that increase the risk for STI persistence and/or treatment failures must be further investigated. In response to the need to 1) identify cost effective screening strategies that optimally decrease the burden of STIs during pregnancy, and reduce adverse pregnancy and infant outcomes, 2) elucidate the role of the vaginal microbiome in treatment outcomes, and 3) inform STI screening and treatment guidelines in other low-middle income countries, we propose a novel, highly innovative study with the following three Aims: Aim 1: Evaluate different diagnostic screening interventions to decrease the burden of CT/NG/TV, and reduce adverse pregnancy and birth outcomes among pregnant women. Aim 2: Evaluate the cost per pregnant woman diagnostically screened and treated, cost of adverse pregnancy and birth outcomes, and cost-effectiveness per STI and DALY averted. Aim 3: Investigate the relationship between the vaginal microbiome and CT treatment failure in pregnant women. Our proposed 5-year study will enroll 1250 HIV-infected and 1250 uninfected pregnant women from three large ANC clinics in Tshwane District, South Africa. Our research team, led by established researchers, has significant expertise and experience in all aspects of the proposed study. Our multi-institutional collaborations will allow us to leverage unique implementation platforms and resources, and allow for rapid dissemination of findings to South African and global stakeholders.

PUBLIC HEALTH RELEVANCE: This effectiveness trial will increase understanding of the value and cost-effectiveness of diagnostic screening for sexually transmitted infections (STIs) among pregnant women in low and middle-income countries, to reduce adverse pregnancy and infant outcomes.

Further, results from this study will provide important data on the role of the vaginal microbiome in Chlamydia trachomatis (CT) testing outcomes and further rationale for studying the vaginal microbiome in pregnant women with CT treatment failure. Together, findings from this R01 are likely to inform changes to STI screening and treatment guidelines in low-middle income countries globally.

CRITIQUE 1

Significance: 3
Investigator(s): 2
Innovation: 3
Approach: 4
Environment: 1

Overall Impact: This application proposes to compare three different approaches to STI screening and treatment among pregnant women in SSA, evaluate the cost-effectiveness of timely STI diagnosis and treatment, and lastly examine the role of vaginal microbiome in CT treatment failure. Prevention and/or timely treatment of STI has benefits in terms of pregnancy and birth outcomes. The team has extensive experience and connection in STI research in S. Africa. If successful, the data generate could inform policy change as the current standard of care of syndromic management may be sub-optimal. However, it is unclear while this study is targeted at HIV+ and HIV- pregnant women, the outcomes should be valid regardless of HIV status.

1. Significance:

Strengths

- STI in pregnancy has negative impact on pregnancy and birth outcomes
- The burden of STI among pregnant women in SSA is high – it is a major health concern
- STI in pregnancy may have implications for HIV prevention – MTCT and sexual partner.

Weaknesses

- The significant and the benefit of the proposed work is intuitive – this application is perhaps positioned to demonstrate that it can be done
- Although, the speculation that vaginal microbiome could impair CT treatment outcome is interesting – the application lacks preliminary data in support of this aim. Persistent infection in the absence of therapy is different from treatment failure.

2. Investigator(s):

Strengths

- Dr. Klausner is leading public health and global health researcher in the field of STI – with years of experience working in S. Africa and other SSA countries.
- Co-investigators include established researchers with expertise in biostatistics, computational science with skills in microbiome sequencing and analysis, cost-effectiveness analyst, and OB-GYN.

Weaknesses

- There were a few overlapping roles

3. Innovation:

Strengths

- The propose work though not innovative by itself – the results could have positive impact on STI treatment policy
- The proposed interventions are highly likely to be cost-effective given the modest cost of STI diagnosis and therapy

Weaknesses

- None Noted

4. Approach:

Strengths

- Large prospective randomized interventions
- Study will be conduct in a region of the world with high disease burden
- Adherence rate is likely to be very high – given that the target population will return to clinic for their antenatal care
- Detail but practical state of the art POC STI diagnosis
- Incorporation of longitudinal microbiome analysis

Weaknesses

- Unclear why both HIV+ and HIV- subjects are being studies
- Given the high burden of disease – one wonders whether such a large sample size is necessary

5. Environment:

Strengths

- Outstanding environment

Weaknesses

- None Noted

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Unacceptable

- It is unclear why a DSMB is not proposed for this trial where participants are being randomized to three arms that are expected to have different outcomes

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically

- For NIH-Defined Phase III trials, Plans for valid design and analysis: Scientifically unacceptable
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans:

Acceptable

Authentication of Key Biological and/or Chemical Resources:

Not Applicable (No Relevant Resources)

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2

Significance: 2
Investigator(s): 2
Innovation: 3
Approach: 2
Environment: 2

Overall Impact: This study addresses STIs in pregnancy which are significant because they are associated with adverse birth outcomes including transmission of HIV. New point of care testing using Xpert (technology increasingly available in SSA) provides an opportunity to assess impact of moving from syndromic management to testing driven treatment. Cost effective approaches to test and treat during pregnancy are yet to be defined and if optimized will decrease the number of births exposed to STI. The study PI has expertise in the field and the study team has the expertise to successfully conduct this study. The step-wise progression from a clinical effectiveness trial to implementation science trial and simultaneously combining the collection of effectiveness and implementation relevant data is an innovative model and the plan to address the interaction between vaginal microbiome and STI treatment outcomes is novel. The approach is well articulated, feasible, and structured to successfully meet the aims of the study. The environment appears to be adequately resourced to ensure the successful completion of this study. My enthusiasm is dampened by a significant concern about the need for a standard of care arm, given data from the R21 and others that most STIs are asymptomatic and that utilization of syndromic management in pregnant women leaves a large proportion of pregnancies at risk for an adverse outcome from STI.

1. Significance:

Strengths

- This study addresses STIs in pregnancy which are significant because they are associated with adverse birth outcomes including transmission of HIV
- New point of care testing using Xpert (technology increasingly available in SSA) provides an opportunity to assess impact of moving from syndromic management to testing driven treatment
- Cost effective approaches to test and treat during pregnancy are yet to be defined and if optimized will decrease the number of births exposed to STI

Weaknesses

- There is existing evidence that syndromic management misses a significant proportion of STIs bringing in question the need for a control arm within this study.

2. Investigator(s):

Strengths

- Dr. Klausner has field experience in South Africa including having conducted research at the currently proposed sites. He also has significant expertise with rollout of STI point of care testing and with test and treat strategies
- The study team has the expertise to support the proposed research including both U.S. and SA investigators. The team includes Dr. Medina-Marino as the co-PI a molecular biologist and epidemiologist based in South Africa (history of collaboration with Dr. Klausner), a statistician, an economist, an Ob-gyn, and a microbiologist, as well as individuals with expertise in analysis of sequencing data on microbial communities, vaginal biome, and bacterial vaginosis

Weaknesses

- Klausner only has 10% support requested in the budget each year for all 5 years of the grant.

3. Innovation:

Strengths

- The step-wise progression from a clinical effectiveness trial to implementation science trial and the simultaneously combine the collection of effectiveness and implementation relevant data
- Assessment of the association between vaginal microbiome and STI treatment outcomes

Weaknesses

- ll out of test and treat strategies is not in and of its self highly novel

4. Approach:

Strengths

- In general, this is a well-designed study. The study setting, enrollment criteria, retention plans, data collection, data management, biological sampling plan, specimen transport plans and analysis plans are well articulated and are highly likely to contribute to the successful achievement of the aims of this study.

Weaknesses

- mary concern centers around the equipoise of retaining a standard of care arm given the preliminary data (as well as data from others) on the high rate of asymptomatic infection. As such the study design puts a number of deliveries at risk for STI when it is likely possible to

utilize data collected during the R21 as well as other publicly available inputs to model the costs for the standard of care arm

- kage of data to national databases can be challenging. There is no evidence that the study team has undertaken this type of linkage in the past so there are concerns about how effective they will be in doing this
- rollment table needs to be updated to include the infants since their outcomes are being assessed

5. Environment:

Strengths

- The environments at UCLA, FPD, UAB, LSU, UCT, and Anova Health appear well equipped to host the proposed research.

Weaknesses

- No discussion of space available within the two hospitals conducting deliveries to host research staff
- No documentation about how complete the medical records are the hospitals conducting delivers thus unclear how well factors related to birth outcomes and birth outcomes can be assessed by this study

Protections for Human Subjects:

Unacceptable Risks and/or Inadequate Protections

- ncerns about equipoise for the Control Arm

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Unacceptable

- Would recommend a DSMB with interim analysis of birth outcomes if the control arm would be included in the final study

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 18: Including ages <18; not justified scientifically
- s proposal actually does include individuals under 18 years of age as it is collecting data on the infant including specimens. Thus, the enrollment table needs to be updated as does the statement on children

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Applications from Foreign Organizations:

Justified

- The clinical population most at risk for HIV and perinatal transmission of HIV resides in sub-Saharan Africa.

Resource Sharing Plans:

Acceptable

Authentication of Key Biological and/or Chemical Resources:

Not Applicable (No Relevant Resources)

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3

Significance: 1
Investigator(s): 1
Innovation: 1
Approach: 2
Environment: 1

Overall Impact: This application proposes a randomized trial of three strategies for management of STIs among pregnant women in high HIV prevalence communities in South Africa. The application provides evidence for substantial burden of STIs in this population with strong prelim data showing that testing and treatment at first ANC visit did not eliminate this burden. Syndromic management, per current guidelines, is inadequate and outdated, and the availability of new point-of-care diagnostics provide an opportunity to improve clinical management, but how to most effectively utilize them for pregnant women in high HIV burden settings is unclear. This proposal aims to address this via two diagnostic testing strategies compared with syndromic management (standard of care). The investigator team is very strong, presents relevant prelim data from the study sites, and adds an interesting hypothesis about the vaginal microbiome and its effect on treatment response of chlamydia (with reasonably clear mechanistic rationale for this). The investigators propose to examine factors related to implementation alongside the trial to inform the potential adoption of new testing strategies as policy. A basic cost-effectiveness analysis of treatment strategies will also be performed and is reasonable though the description is comparatively thin in contrast to the detail provided for other components of this study, and it may be challenging to capture or estimate the disability data needed. One question is why the standard of care arm is needed given that their R21 showed it to be highly inferior (>50% greater STIs at time-of-delivery) to a testing and treatment strategy. As they already have a reference point, it would seem that focusing on multiple diagnostic strategies would be a better use of resources. Finally, it is challenging to get good efficacy estimates alongside an implementation trial as vice versa (trade-off between internal and external validity) if the implementation is designed to be reflective of the resources available at a routine ANC clinic visit. Nevertheless, the implementation

and costs are so important that there is good rationale for prioritizing this. Overall this is a promising application that could address important knowledge gaps in management of STIs.

1. Significance:

Strengths

- STIs remain a major health challenge globally and in high HIV-burden settings. They threaten adult health but also cause adverse birth outcomes
- Existing models of screening and syndromic treatment are clearly insufficient for protecting health of pregnant women and preventing these adverse outcomes at birth and in their newborns
- There is a need for a cost-effectiveness evidence base to inform policy decisions for screening and treatment of STIs
- Treatment failure for STIs including Chlamydia is a major challenge and reasons for treatment failure are poorly elucidated
- The scientific premise for altered vaginal microbiome influencing survival and host immune control of CT via indole metabolism is clearly argued
- Prelim data is strong

Weaknesses

- None Noted

2. Investigator(s):

Strengths

- Strong investigator team with expertise in clinical management of STIs, clinical epidemiology, microbiome analysis (including bioinformatics), and health economics/cost-effectiveness analysis

Weaknesses

- None identified

3. Innovation:

Strengths

- Prospective investigation of vaginal microbiome impact on CT treatment response with a priori hypotheses stated
- Collection of data on processes pertaining to reach, adoption, implementation, etc. in addition to effectiveness is a nice compliment to the RCT to provide valuable data to inform feasibility for adoption as a policy

Weaknesses

- None Noted

4. Approach:

Strengths

- Evidence of suitable participant numbers is strong

- Study design and procedures clearly described

Weaknesses

- The cost-effectiveness model was thinly described; it is unclear whether data sources for disability and life expectancy outcomes among preterm children
- For Aim 3, use of other antibiotics such as metronidazole could alter the vaginal microbiota and modify its relationship with CT treatment failure. This may of course be of interest in itself. However, it's unclear how many women will and will not be treated with metronidazole and how this will be factored into the analysis.
- The description of the randomization procedure is a bit vague; its indicated that a randomization list will be created ahead of time, before recruitment, but they will be recruiting at 3 clinics and trying to achieve balance of HIV across arms, and not clear how that will be achieved.
- The impact of HIV on vaginal microbiome and CT treatment response is unclear, and it's uncertain whether the study will be powered to investigate this.

5. Environment:

Strengths

- Environment at UCLA and UCT are excellent

Weaknesses

- Research infrastructure at ANC clinics in Tshwane not as well described, though application documents evidence of ability to successfully recruit participants for R21

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Unacceptable

- A more detailed data safety monitoring plan will be needed before the trial can be approved.

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Scientifically acceptable
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Authentication of Key Biological and/or Chemical Resources:

Not Applicable (No Relevant Resources)

Budget and Period of Support:

Recommend as Requested

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS: UNACCEPTABLE
The committee agreed that a more detailed data safety monitoring plan will be needed to monitor birth outcomes. Also, the committee was concerned about equipoise for the control arm and has requested information on inclusion of children since individuals under 18 will be included in the studies.

INCLUSION OF WOMEN PLAN: ACCEPTABLE

INCLUSION OF MINORITIES PLAN: ACCEPTABLE

INCLUSION OF CHILDREN PLAN: UNACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

Footnotes for 1 R01 AI140916-01; PI Name: Klausner, Jeffrey David

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

AIDS Clinical Studies and Epidemiology Study Section
AIDS and Related Research Integrated Review Group
CENTER FOR SCIENTIFIC REVIEW
ACE
03/13/2018 - 03/14/2018

Notice of NIH Policy to All Applicants: Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-14-073 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-073.html and NOT-OD-15-106 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-106.html, including removal of the application from immediate review.

CHAIRPERSON(S)

TIEN, PHYLLIS C, MD
PROFESSOR
DIVISION OF INFECTIOUS DISEASES
DEPARTMENT OF MEDICINE
SCHOOL OF MEDICINE
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
SAN FRANCISCO, CA 94121

MEMBERS

ANDREWS, JASON RANDOLPH, MD *
ASSISTANT PROFESSOR
DIVISION OF INFECTIOUS DISEASES
DEPARTMENT OF MEDICINE
SCHOOL OF MEDICINE
STANFORD UNIVERSITY
STANFORD, CA 94305

BAETEN, JARED, MD, PHD
PROFESSOR AND VICE CHAIR
DEPARTMENT OF GLOBAL HEALTH
PROFESSSOR, DEPARTMENT OF EPIDEMIOLOGY
SCHOOL OF PUBLIC HEALTH
UNIVERSITY OF WASHINGTON
SEATTLE, WA 98104

BOULWARE, DAVID R, MD
LOIS AND RICHARD KING DISTINGUISHED ASSOCIATE PROFESSOR
DIVISION OF INFECTIOUS DISEASES
AND INTERNATIONAL MEDICINE
DEPARTMENT OF MEDICINE
UNIVERSITY OF MINNESOTA
MINNEAPOLIS, MN 55455

CHARURAT, MANHATTAN E, PHD
PROFESSOR AND DIRECTOR
DIVISION DIRECTOR OF EPIDEMIOLOGY AND PREVENTION
INSTITUTE OF HUMAN VIROLOGY
SCHOOL OF MEDICINE
UNIVERSITY OF MARYLAND, BALTIMORE
BALTIMORE, MD 21201

COLE, STEPHEN R, PHD
PROFESSOR
DEPARTMENT OF EPIDEMIOLOGY
GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH
UNIVERSITY OF NORTH CAROLINA, CHAPEL HILL
CHAPEL HILL, NC 27599

DEHOVITZ, JACK A, MD, MPH
DISTINGUISHED SERVICE PROFESSOR
DEPARTMENT OF MEDICINE
DOWNSTATE MEDICAL CENTER
STATE UNIVERSITY OF NEW YORK
BROOKLYN, NY 11203

FITZGERALD, DANIEL W, MD
PROFESSOR
DEPARTMENT OF MEDICINE
WEILL MEDICAL COLLEGE
CORNELL UNIVERSITY
NEW YORK , NY 10021

GORBACH, PAMINA MAE, DRPH
PROFESSOR
DEPARTMENT OF EPIDEMIOLOGY
FIELDING SCHOOL OF PUBLIC HEALTH
UNIVERSITY OF CALIFORNIA, LOS ANGELES
LOS ANGELES, CA 90095-7353

GROSS, ROBERT, MD *
ASSOCIATE PROFESSOR
DEPARTMENT OF MEDICINE
PERELMAN SCHOOL OF MEDICINE
UNIVERSITY OF PENNSYLVANIA
PHILADELPHIA, PA 19104

HARTIGAN-O'CONNOR, DENNIS J, MD, PHD *
ASSOCIATE PROFESSOR
DEPARTMENT OF MEDICAL MICROBIOLOGY
AND IMMUNOLOGY
SCHOOL OF MEDICINE
UNIVERSITY OF CALIFORNIA, DAVIS
DAVIS, CA 95616

HONG, CHI-CHEN, PHD *
ASSOCIATE PROFESSOR
DIVISION OF CANCER PREV AND POPULATION SCIENCES
DEPARTMENT OF CANCER PREVENTION AND CONTROL
ROSWELL PARK CANCER INSTITUTE
BUFFALO, NY 14263

JIANG, WEI, MD *
ASSISTANT PROFESSOR
DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY
MEDICAL UNIVERSITY OF SOUTH CAROLINA
CHARLESTON, SC 29425

KANTOR, RAMI, MD
ASSOCIATE PROFESSOR
DIVISION OF INFECTIOUS DISEASES
DEPARTMENT OF MEDICINE
BROWN UNIVERSITY
PROVIDENCE, RI 02906

KWIEK, JESSE J, PHD *
ASSOCIATE PROFESSOR
DIVISION OF INFECTIOUS DISEASES
DEPARTMENT OF MICROBIOLOGY
OHIO STATE UNIVERSITY
COLUMBUS, OH 43210

LEE, HA YOUN, PHD *
ASSOCIATE PROFESSOR
DEPARTMENT OF MOLECULAR MICROBIOLOGY
AND IMMUNOLOGY
KECK SCHOOL OF MEDICINE
UNIVERSITY OF SOUTHERN CALIFORNIA
LOS ANGELES, CA 90089

MEHTA, SHRUTI H, MPH, PHD
PROFESSOR
DEPARTMENT OF EPIDEMIOLOGY
BLOOMBERG SCHOOL OF PUBLIC HEALTH
JOHNS HOPKINS UNIVERSITY
BALTIMORE, MD 21205

NAGGIE, SUSANNA, MD *
ASSOCIATE PROFESSOR
DEPARTMENT OF MEDICINE
SCHOOL OF MEDICINE
DUKE UNIVERSITY
DURHAM, NC 27705

OFOTOKUN, IGHOVWERHA, MD
PROFESSOR
DIVISION OF INFECTIOUS DISEASES
DEPARTMENT OF MEDICINE
EMORY UNIVERSITY
ATLANTA, GA 30303

PILLAI, SATISH KUMAR, PHD *
ASSOCIATE INVESTIGATOR
BLOOD SYSTEMS RESEARCH INSTITUTE
SAN FRANCISCO, CA 94118

POWIS, KATHLEEN, MD *
ASSISTANT PROFESSOR
DEPARTMENT OF PEDIATRICS
MASSACHUSETTS GENERAL HOSPITAL
BOSTON, MA 02114

RATCLIFFE, SARAH J, PHD
PROFESSOR AND VICE CHAIR FOR RESEARCH
DEPARTMENT OF PUBLIC HEALTH SCIENCES
UNIVERSITY OF VIRGINIA
CHARLOTTESVILLE, VA 22908

RIDDLER, SHARON, MD *
PROFESSOR
DIVISION OF INFECTIOUS DISEASES
DEPARTMENT OF MEDICINE
UNIVERSITY OF PITTSBURGH
PITTSBURGH, PA 15213

ROGERS, RICHARD C, PHD *
JOHN S MCILLHENNY PROFESSOR
DEPARTMENT OF AUTONOMIC NEUROSCIENCE
PENNINGTON BIOMEDICAL RESEARCH CENTER
LOUISIANA STATE UNIVERSITY
BATON ROUGE, LA 70808

RYAN, ALICE S, PHD *
SENIOR RESEARCH CAREER SCIENTIST
BALTIMORE VA MEDICAL CENTER
PROFESSOR, DIVISION OF GERIATRICS
AND GERIATRIC MEDICINE
UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE
BALTIMORE, MD 21201

SAGAR, MANISH, MD *
ASSOCIATE PROFESSOR
DIVISION OF INFECTIOUS DISEASES
SCHOOL OF MEDICINE
BOSTON UNIVERSITY
BOSTON, MA 02118

SALEMI, MARCO, PHD *
PROFESSOR
DEPARTMENT OF PATHOLOGY, IMMUNOLOGY,
AND LABORATORY MEDICINE
COLLEGE OF MEDICINE
UNIVERSITY OF FLORIDA
GAINESVILLE, FL 32610

SEKHAR, RAJAGOPAL VISWANATH, MD
ASSOCIATE PROFESSOR
DIVISION OF ENDOCRINOLOGY
DEPARTMENT OF MEDICINE
BAYLOR COLLEGE OF MEDICINE
HOUSTON, TX 77030

SHIRAMIZU, BRUCE T, MD *
PROFESSOR
DEPARTMENTS OF TROPICAL MEDICINE,
MEDICAL MICROBIOLOGY, AND PHARMACOLOGY
JOHN A BURNS SCHOOL OF MEDICINE
UNIVERSITY OF HAWAII
HONOLULU, HI 96813

TCHETGEN TCHETGEN, ERIC JOEL, PHD
LUDDY FAMILY PRESIDENT'S DISTINGUISHED PROFESSOR
DEPARTMENT OF STATISTICS
UNIVERSITY OF PENNSYLVANIA
PHILADELPHIA, PA 19104

TRAN, BINH Q, PHD *
ASSOCIATE PROFESSOR
DEPARTMENT OF BIOMEDICAL ENGINEERING
SCHOOL OF ENGINEERING
CATHOLIC UNIVERSITY OF AMERICA
WASHINGTON, DC 20064

WOOLS-KALOUSTIAN, KARA KAY, MD
PROFESSOR
DIVISION OF INFECTIOUS DISEASES
DEPARTMENT OF MEDICINE
SCHOOL OF MEDICINE
INDIANA UNIVERSITY
INDIANAPOLIS, IN 46202

XHEMALCE, BLERTA, PHD *
ASSISTANT PROFESSOR
DEPARTMENT OF MOLECULAR BIOSCIENCES
COLLEGE OF NATURAL SCIENCES
UNIVERSITY OF TEXAS AT AUSTIN
AUSTIN, TX 78712

SCIENTIFIC REVIEW OFFICER

VATAKIS, DIMITRIOS NIKOLAOS, PHD
SCIENTIFIC REVIEW OFFICER
CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

EXTRAMURAL SUPPORT ASSISTANT

STROTHERS, DIARA
EXTRAMURAL SUPPORT ASSISTANT
CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.