

R21 Project Team Example

The expertise of your team matters a lot to reviewers!

STI Screening R21 (First submission)

C.3. The Research Team. Jeffrey Klausner, MD, MPH (UCLA Co-PI): Dr. Klausner is an infectious disease epidemiologist and Professor of Medicine and Public Health in the UCLA Division of Infectious Diseases, School of Medicine and the Department of Epidemiology, School of Public Health. This study builds on more than 20 years of prior STI screening and treatment studies in San Francisco, South Africa and Peru. As Director of STD Prevention and Control Services in San Francisco, 1998-2009, Dr. Klausner began studies investigating the performance of molecular STI diagnostics, the role of self-specimen collection for STIs and the introduction and evaluation of population-based screening programs in schools, jails and adolescent clinics.³²⁻³⁹ From 2009-2011 Dr. Klausner was Branch Chief for HIV and TB at the US Centers for Disease Control and Prevention in Pretoria, South Africa, helping lead the South African PEPFAR program for PMTCT, HIV care and treatment. In that role Dr. Klausner worked directly with national, provincial and district health authorities and local South African non-governmental organizations including FPD to support the scale-up of PMTCT services nationally. He played a key role in describing the population-based provincial rates of MTCT as part of the South African national PMTCT effectiveness evaluation.^{29,40-42} Dr. Klausner is a member of the WHO STI Guidelines Committee and frequent advisor to ministries of health on HIV and STI prevention. He will have 0.20 FTE on this project, and will provide oversight of the research design, implementation, and analysis.

Andrew Medina-Marino, PhD (FPD Co-PI) is Head of FPD's Research Unit and Senior Technical Advisor for Laboratory and Disease Surveillance Systems Strengthening activities. Previously, Dr. Medina-Marino was Laboratory Branch Chief for CDC-South Africa. In this capacity, he supported and advised the South African National Institute for Communicable Diseases (NICD) National Health Laboratory Service (NHLS), South Africa's national pathology service provider, on the expansion of laboratory based surveillance programs. He also worked directly with NHLS and the National Department of Health to develop national point-of-care policy and guidelines. As a Molecular Biologist, Dr. Medina-Marino helped identify a key cell receptor that facilitates NG adherence and invasion.⁴³ Dr. Medina-Marino has worked extensively with the Tshwane District Dept. of Health and the staff at the two clinics that will serve as study sites. For this project he will provide direct oversight for the South African-based study team, including study nurses who will have direct contact with patient-participants and data managers. In his role as Co-PI he will devote 0.20 FTE and will oversee and ensure quality of all in-country study implementation efforts.

Joy Ikechi Ebonwu, MPH (Co-Investigator): Ms. Ebonwu is a STI Epidemiologist with FPD. Prior to working for FPD Ms. Ebonwu was an epidemiologist with the Centre for HIV and STIs at the National Institute for Communicable Diseases within the National Health Laboratory Service in South Africa. Ms. Ebonwu is currently assisting in the development and implementation of the first national sentinel STI etiological surveillance project. She has also worked as a laboratory supervisor at National Health Laboratory Service Mycobacteriology referral laboratory in Braamfontein, Johannesburg and has spent considerable time performing diagnostic procedures at the STI Research Laboratory at George Mukhari Hospital in Pretoria. Ms. Ebonwu is a graduate of the South African Field Epidemiology and Laboratory Training Program and has a Master of Public Health from the University of Pretoria and a Master of Medical Microbiology from the University of Witwatersrand in Johannesburg. For this project, Ms. Ebonwu will provide coordination and oversight of all specimen collection, and laboratory processing of all study specimens at both study sites.

Xiaoyan Wang, PhD (Co-Investigator): Dr. Wang is an Assistant Professor within the Statistics Core of the UCLA Department of Medicine. She has extensive experience with biostatistics in the design and analysis of large-scale cohort, cross-sectional and intervention studies. She will be responsible for all statistical analyses for this project.

James McIntyre, MBChB (Consultant): Dr. McIntyre is an OB/GYN physician-scientist and internationally-recognized expert on HIV MTCT. He is the executive director of the Anova Health Institute, and the international vice-chair of the NIH-funded International Material Paediatric and Adolescent AIDS Clinical Trials Network (IMPAACT). He regularly serves as a consultant on these issues to the WHO, UNAIDS, and UNICEF. He will provide approximately 2 hours of consultation each month for both years of this project.

Reviewer 3 said “Inclusion of an implement scientist would have strengthened the team.”

R01 Project Team Example

The evidence that your team has a substantial collaborative working history also matters a lot.

TB Stigma R01 (First submission)

Research Team: Our team has extensive expertise in epidemiology and biostatistics, HIV and TB, quantitative and qualitative approaches to stigma, TB case finding and the care cascade, measurement, health behavior, and statistical and multilevel modeling. We have deep experience conducting TB and HIV research in South Africa. **Andrew Medina-Marino, PhD**, (co-PI) is Head of Research for the Foundation for Professional Development, and has extensive research experience in TB, HIV, and STIs. He is PI on 3 recently funded NIH grants focused on STI screening (R21HD084274), TB case finding (R21EB023679), and HIV prevention (1R01MH114648), all in South Africa and with a focus on particular steps in the care cascades. He is an expert field epidemiologist and was twice deployed by *Médecins Sans Frontières* to lead their community-based case investigation and contact tracing team in Liberia during the 2014-2016 Ebola outbreak in West Africa. **Aaron Kipp, PhD**, (co-PI) is an epidemiologist and Assistant Professor at Vanderbilt University with expertise in measures of HIV and TB-related stigma, as well as other patient-reported psychosocial measures. His international research has focused on how stigma impacts access and utilization of TB and HIV treatment and retention in care. **Drs. Medina-Marino and Kipp** have collaborated for over a year to validate stigma measures in multiple South African languages and distinct socio-cultural communities, all in preparation for this proposed study. They are currently co-mentoring an MPH student and developing publications emanating from their recent work. For this study, Dr. Medina-Marino will provide administrative oversight for the grant and will be responsible for directing all in-country study implementation and data collection activities, while Dr. Kipp will oversee all aspects of study design and data analysis. They will be jointly responsible for results dissemination.

Reviewer 2 said “Brief collaborative history between the two PIs.”

This study will also benefit from key co-investigators. Specifically, **Amrita Daftary, PhD, MPH**, (co-I) is an expert in qualitative methods and conducting social and behavioral research in HIV and TB with a focus on the social determinants of TB and HIV health care seeking, particularly the role of stigma. She will be responsible for all qualitative components (Aim 4) of this study. **Kristopher Preacher, PhD**, (co-I) is a nationally-recognized quantitative psychologist specializing in highly relevant multilevel statistical methods. For this study, he will be responsible for the multilevel statistical analysis components of Aims 1 and 2. **Cari van Schalkwyk, MComm**, (co-I) is a research biostatistician at the South African Centre of Excellence in Epidemiological Modelling and Analysis (SACEMA), with expertise in biostatistical and mathematical modeling of HIV incidence and TB prevalence and transmission. She will be responsible for database development and management, and data analysis with Dr. Preacher.

TB Stigma R01 (Resubmission – 2nd Try)

Research Team: Our team has the expertise, skill and infrastructure to successfully carry out this study. **Andrew Medina-Marino, PhD**, (co-PI) is Head of Research for the Foundation for Professional Development, and is PI on 3 recently funded NIH grants focused on STI screening, TB case finding, and HIV prevention, all in South Africa. He has conducted a number of large studies funded by NIH and USAID, including a recently completed RCT of HIV prevention interventions involving 2000 adolescents over a 3-year period, for which he attained an 87% retention rate. **Aaron Kipp, PhD**, (co-PI) is an epidemiologist and Assistant Professor at Vanderbilt University with expertise in measures of HIV and TB-related stigma, as well as other patient-reported psychosocial measures. His research has focused on how stigma impacts access and utilization of TB and HIV treatment and retention in care. Other work includes previously collaborating with WHO to lead a large, multi-country, mixed-methods study of child survival in Africa. **Drs. Medina-Marino and Kipp** have collaborated for two years on validating stigma measures in multiple South African languages, presented study findings at the recent 2018 5th South African TB conference, and co-mentored an MPH student. For this study, Dr. Medina-Marino will provide administrative oversight for the grant and will be responsible for directing all in-country study implementation and data collection activities. Dr. Kipp will oversee all aspects of study design and data analysis. They will be jointly responsible for result dissemination.

This study will also benefit from expert co-investigators. Specifically, **Amrita Daftary, PhD, MPH**, is an expert in qualitative methods and social and behavioral research in HIV and TB. She is recognized for her research on TB stigma and contributions to implementation science adherence and stigma mitigation interventions with TB/HIV and MDR-TB patients in South Africa. She will be responsible for all qualitative components (Aim 3) of this study. **Kristopher Preacher, PhD**, is a nationally-recognized quantitative psychologist specializing in highly relevant multilevel statistical methods. For this study, he will be responsible for the multilevel statistical analysis components of Aims 1 and 2. **Carolyn Audet, PhD**, is an anthropologist and expert in intervention development and strategy at the Vanderbilt Institute for Global Health. Over the past 10 years she has conducted formative work and developed, piloted, and implemented partner- and community-based interventions to improve uptake of antenatal care for HIV-positive pregnant women in rural Mozambique. Dr. Audet will work with Drs. Kipp, Medina-Marino and Daftary in study years 4 and 5 to integrate study results and inform and identify potential interventions and intervention strategies.