Evaluation of the Fogarty International Center's International Research Scientist Development Award (IRSDA) Program

1999-2016

Executive Summary

By investing in outstanding early career United States (U.S.) investigators, the John E. Fogarty International Center (FIC) at the National Institutes of Health (NIH) is developing future global health researchers that will advance scientific discovery, while improving the health of populations worldwide. The *International Research Scientist Development Award* (IRSDA) program provides early career U.S. investigators the opportunity to conduct mentored research in a low- or middle- income country[1] (LMIC) to better understand the diverse health challenges and opportunities of working in low-resource settings. This support affords early career scientists the experience and skills to help launch their careers in global health research.

This report describes the results of the IRSDA program evaluation, describes select outputs of the IRSDA program in comparison to other NIH K Awardees, and documents characteristics of applicants and awardees of the IRSDA program from its start in FY1999 through FY2016 to understand the impact of program participation on awardees' careers in research and in global health.

The Program

Since 1999, the IRSDA program has supported qualified advanced postdoctoral research scientists and recently-appointed junior faculty to prepare for independent research careers in global health. Specifically, the objective of the program is to provide salary and research project support for a sustained period of mentored and protected research time with the expectation that awardees will pursue independent global health research careers, continue to collaborate with LMIC scientists, and become competitive for future research funding. Unlike most NIH K Awards, the IRSDA program has an in-country requirement that emphasizes the value of on-the-ground research experience that cannot be recreated or taught in a U.S. lab or classroom.

The IRSDA program has invested funds totaling over $34.72 million dollars since 1999. Over the course of the program's 17-year history, it has collaborated with National Institute of General Medical Sciences (NIGMS), National Cancer Institute (NCI), National Heart, Lung, and Blood Institute (NHLBI), National Institute on Minority Health and Health Disparities (NIMHD), National Institute of Environmental Health Sciences (NIEHS), National Institute on Aging (NIA), National Institute of Nursing Research (NINR), Office of the Director's Office of Dietary

[1] The World Bank. (FY2017). *World Bank Country and Lending Groups*. [Webpage]. Retrieved from https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups.

Supplements, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), Office of the Director's Office of AIDS Research, and the U.S. Department of State's Biosecurity Engagement Program.

With the support of these contributing NIH Institutes and Centers (ICs), the IRSDA program has funded 75 individuals as they engaged in international research in 33 countries across six regions of the world. Most projects (52%) were in sub-Saharan Africa (SSA), and in particular, Malawi, Kenya and South Africa.

IRSDA awardees have pursued a wide range of scientific fields, including infectious disease, non-infectious disease and the behavioral health sciences. Most projects were related to an infectious disease (64%) and, in particular, 32% had some association with HIV research. Over the last 15 years, awardees pursuing non-communicable disease or implementation science research have increased.

The Awardees

The IRSDA program ensures that U.S. early career scientists and clinicians have opportunities to engage in international research projects at a formative stage in their careers. FIC has funded a relatively gender-balanced proportion of early investigators in their mid-thirties (56% female; 44% male). The median age for the funded applicants is 36, which is consistent with the fact that the program is targeted to junior faculty, postdoctoral researchers and post-residency

clinicians. The data also show a balanced proportion of awardees with Doctors of Philosophy (PhDs) and Doctors of Medicine (MDs) (41% and 47% respectively).

Given the distribution of applicant degrees, the IRSDA program is unique from the NIH K01, which mostly attracts PhDs pursuing basic science (Appendix A). Overall, the IRSDA program appears to be attracting the types of applicants that the IRSDA Funding Opportunity Announcements (FOAs) seek to attract. IRSDA applicants tend to be early-career, varied in scientific interests (as indicated by their professional degrees) and balanced between genders.

The Alumni

The success of this program is built on the scientists who have participated in the program and the research-related careers they go on to pursue. This evaluation highlights and compares the program outcomes for four global health, K-Award cohorts (K01, K08, K23, IRSDA) in terms of scientific productivity (publications), success in obtaining subsequent NIH funding, and employment in global health. Findings from the evaluation suggest that IRSDA awardees are comparable to their counterpart NIH global health K-Awardees with respect to scientific productivity, a sustained global health research career, and success in securing future NIH funding.

Examples of Current Research of IRSDA Alumni

- A Systems Biology Approach to HIV-associated Neurocognitive Impairment: Role of Drug Abuse and Neuroinflammation (Murdoch, R01DA043241)
- Immune Responses to Vibrio cholerae infection and vaccination in Haiti (Harris, R01AI099243)
- Safety and Acceptability of Two IUDs among Cape Town HIV-positive Women (Todd, R01HD071804)
- Molecular profiling of HIV-associated lymphoma in the US and Malawi (Gopal, R21CA180815)
- Translating Molecular Diagnostics for Cervical Cancer Prevention into Practice (Paz-Soldan, R01CA190366)
- Using Behavioral Economics to Promote Exercise among Inactive Overweight Adults (Galarraga, R03CA188473)

Publications: To date, IRSDA alumni have published over 1566 peer-reviewed publications in a wide range of biomedical fields, the most common fields being infectious disease, immunology, and environmental occupational health. IRSDA scientific productivity was comparable to other NIH K awardees and most comparable to the K23 cohort.

Subsequent Funding: IRSDA awardees have been successful in obtaining subsequent NIH research funding in the role of principal investigator (PI), co-PI or multiple PI (MPI). Forty-three percent of IRSDA awardees obtained subsequent NIH funding. Of those grantees who received

additional NIH support, 80% received major research awards (R01, U01 or P01 mechanisms[2]). On average, it took an IRSDA awardee six years after their IRSDA was awarded to receive a NIH award (any funding mechanism) and an additional year (seven years) to receive a R01, U01, or P01. While IRSDA awardees were comparable to their NIH-K Awardee cohorts in terms of percentage receiving subsequent funding, IRSDA awardees took, on average, an extra year to receive their first subsequent award and two years for a subsequent R01, U01, or P01.

Global Health Pipeline: Training the next generation of researchers in global health is the core mission of the IRSDA program. The program has demonstrated important successes in this regard with over 85% of IRSDA alumni currently in a global health research career. Both the NIH K01 and K23 awardees were similar, retaining 85% and 82% respectively in global health careers. The in-country time requirement promotes regular collaborations with LMIC partners and demonstrates to the home (U.S.) institution that on-the-ground experience is integral to building global health research capacity. Many of the IRSDA awardees build lasting professional relationships with their U.S. and LMIC mentors and continue to collaborate with them later in their global health research careers. Case studies in this evaluation illustrate the long-lasting relationships fostered by IRSDA awardees and their mentors.

Through the IRSDA program, FIC has built a community of U.S. global health researchers who are committed to confronting global health challenges, who understand the realities of conducting research in resource-limited settings, and who have formed long-lasting collaborative relationships with scientists around the world.

[2] An R01 mechanism supports an investigator in his or her discrete research project. A U01 mechanism is a cooperative agreement grant between an institute or individuals in the academic field. The U01 supports a number of projects by multiple investigators in a specific research area, usually across multiple sites. A P01, in contrast, is a program project grant that involves multiple research projects (and the respective investigators) who share knowledge and resources as they strive towards a well-defined research program goal.

Contents

Introduction

The *International Research Scientist Development Award* (IRSDA) program was established by the John E. Fogarty International Center (FIC) at the National Institutes of Health (NIH) in 1999 to provide support and protected time to advanced postdoctoral United States (U.S.) researchers interested in a mentored, global health research experience at a low- or middle-income country (LMIC). Through this intensive experience, early career investigators conduct three to five years of mentored global health research under the mentorship of U.S.-based and LMIC-based mentors. Upon completion of the IRSDA grant, the individual should have gained research skills, obtained field experience in an LMIC setting, and built partnerships through their LMIC counterpart institution, all key ingredients to establishing an independent global health research career.

The IRSDA program is a NIH Career Development (K) award. There are currently 15 different career development award funding mechanisms (or "K" mechanisms) used by the NIH.[3] These mechanisms are currently being used in both parent award programs and IC-specific programs in 40 Funding Opportunity Announcements (FOAs). NIH Career Development (K) Awards generally fall within one of two categories: (1) those in which the candidate works with an established investigator in the field (mentored); and (2) those in which the candidate has reached independence as a researcher, but seeks to obtain new skills, mentor students or new investigators, or develop new curricula (independent). The IRSDA program is a *Mentored Research Scientist Career Development Award* (K01); it aims to foster an individual's path to independence through a period of mentored research and career development activities.

1.1. Program review

This report describes the results of the IRSDA program review and documents characteristics of applicants and awardees of the IRSDA program from its start in FY1999 through FY2016 to understand the impact of program participation on awardees' careers in research and in global health. After a description of the methods used to collect and analyze data on the applicants and awardees (Section 1), the report is organized into the following sections: program history, objectives and context (Section 2); characteristics of the IRSDA applicants and awardees in terms of their demographics, areas of specialties and regional focuses (Section 3); and a comparative analysis (Section 4), which compares select outputs and outcomes to other mentored NIH K Awardees in publications (Sub-Section 4.1), subsequent grant applications and

[3] The 15 different K funding mechanisms are used by parent FOAs and IC specific FOAs. The National Institutes of Health. (2017). *Research Career Development Awards.* [Webpage]. Retrieved from https://researchtraining.nih.gov/programs/career-development

awards (Sub-Section 4.2), and global health workforce (Sub-Section 4.3). The report concludes (Section 5) with a discussion of how the IRSDA program contributes to NIH's overall investment in supporting early career researchers and the unique niche the IRSDA program fills within the NIH.

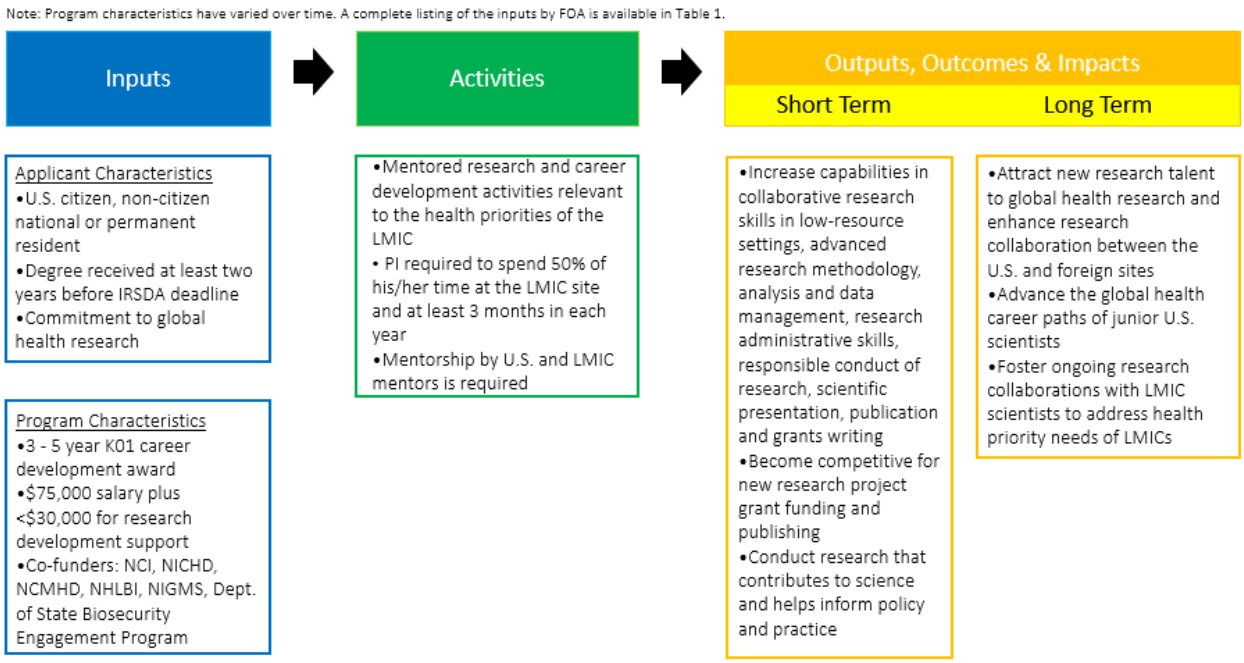
The approach to this review was broadly guided by the FIC Program Evaluation Framework.[4] All IRSDA program data were collected and summarized by FIC staff in the Division of International Science Policy, Planning, and Evaluation. All material was reviewed and approved by FIC staff and NIH community members with equity in the program.

1.2. Methods

1.2.1. Logic model

A program logic model was developed at the beginning of the IRSDA program evaluation process (Figure 1).

Figure 1: Logic Model for PAR-17-002



The model illustrates the eligibility criteria, program activities and desired outcomes and impacts of the IRSDA program as of PAR-17-002. Starting on the left of the diagram are the inputs of the program which include both the program characteristics and the applicant

[4] The Fogarty International Center. (2016 Sept). *Program Evaluation Framework* [Webpage]. Retrieved from https://www.fic.nih.gov/About/Staff/Policy-Planning-Evaluation/Pages/evaluation-framework.aspx

eligibility requirements. Applicants are eligible based on a set of guidelines including their terminal degree and citizenship status. Further information on the eligibility guidelines for applicants is detailed in Section 2.2. The IRSDA grant currently provides three to five years of support consisting of salary (up to $75,000 per year) and research development funds (up to $30,000 per year). These funds support activities that include in-country experiences at an LMIC institution, and mentored global health research that is relevant to the health priorities of the LMIC. These activities result in both short and long term outcomes. In the short term, the IRSDA program aims to increase the skills necessary for an early career investigator to successfully compete in the NIH funding environment. Long term impacts include helping develop a new talent pool of global health researchers, foster lasting collaborations between U.S. and LMIC researchers, and create a more robust career pipeline for U.S. researchers interested in global health.

1.2.2. Data sources

Descriptive information on IRSDA applications and awards, including disease, country of focus and funding, was obtained from the NIH Information for Management, Planning, Analysis, and Coordination (IMPACII) via the Query/View/Response tool. FOAs were analyzed for information about program structure and requirements, and to understand changes in the program over time. Demographic information deemed to be personally identifying (e.g., gender, terminal degree, race, date of birth, and citizenship status) was secured through the NIH's Office of Extramural Research. Publications were obtained from the National Library of Medicine (NLM) MEDLINE database, and were cross checked with Thomson and Reuters' Web of Science database or a grantee-provided University website, when available. Employment data was available through IMPACII and cross-checked with LinkedIn or a University website, when applicable.

1.2.3. Data analysis

For the demographic analysis portion of this evaluation, the IRSDA applicant pool was divided into individuals who were funded and those who were not funded. Data was further stratified to compare race, gender, terminal degree, citizenship status, and age at time of application between those who were funded and not funded.

The outcome metrics (e.g., publications, NIH grant activity) were measured among a different set of cohorts: the funded IRSDA applicants and three cohorts comprised of funded mentored NIH K Awards that focus on global health. The NIH K Awards in the cohorts were funded through the NIH parent and Institute and Center (IC)-specific FOAs for the K01, K08 and K23

mechanisms. Further details on the selection criteria, process, and methodology can be found in Section 4.

1.2.4. Limitations

There are limitations to this report. First, for analyses that aim to compare outcomes from the IRDSA program with outcomes of other funding opportunities, it is important to note that while the other funding opportunities serve as a comparison, the programs groups are not uniformly equivalent. Specifically, while the IRSDA program uses a K01 mechanism, which by NIH's standard emphasizes basic research, by comparison to other K01 mechanisms, the IRSDA program funds a larger proportion of MDs and clinical researchers (e.g., MD/PhDs) (Figure 6) than the other programs, which predominantly fund PhDs. It is worth noting that individuals with MDs may follow different research career paths compared to those with PhDs, or dual MD/PhD, and therefore may not be comparable. The analyses presented herein sought to minimize this limitation by using three comparison groups: K01, K08 and K23. However, it is important to note the differences between the IRSDA program and these mechanisms (Appendix A).

Second, this review looks at three quantitative measures of impact: publications, subsequent grants, and current employment. However, there are other important measures of scientific success that are not quantifiable including, for example, impacting policy change or mentoring the future generation of scientists. To get at some of the less quantifiable impacts, the review captures qualitative evidence using case studies of the IRSDA program on grantee career paths, institutional capacity, and research networks. However, results may be limited by the lack of additional qualitative data.

Thirdly, as a measure of success in a research career, the evaluation examined subsequent funding from NIH. Nonetheless, it is possible that grantees may have secured funding from an alternate source. In addition, for this metric, the analyses do not control for time since the end of grantees awards. This may result in a bias where older awards show greater success in receiving subsequent funding given that they will have had more time since their award to successfully compete.

Lastly, given that the demographic section contains sensitive information, any group with less than eleven individuals with data was not analyzed to protect the privacy and identity of the individuals. Since the IRSDA program is small, further disaggregation of applicants for trend analysis (either by FY or FOA) was not possible due to confidentiality requirements.

Program background and management

The overall goal of the NIH Career Development (K) programs is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address biomedical, behavioral, and clinical research needs. The objective of the IRSDA program is to prepare qualified advanced postdoctoral research scientists and recently-appointed junior faculty for independent research careers that will have a significant impact on the health-related research needs of LMICs. Field experience in LMICs is critical for building a career in global health and for establishing robust partnerships. However, for junior scientists, finding the time to gain this field experience can be difficult as they need to balance administrative duties, apply for grants, and fulfill teaching requirements. The IRSDA program addresses this challenge and offers early-career U.S. scientists an opportunity to conduct global health research under protected time.

1.3. Origins and evolution of the IRSDA program

The framework for the IRSDA program was seeded in 1975 when the Senior International Fellowship (SIF)[5] program began offering established faculty members in the U.S. an opportunity to travel abroad to increase the exchange of ideas and research between U.S. and foreign scholars, to contribute to on-going research at foreign institutions and to improve the research competitiveness of U.S. medical institutions.[6] However, over the next two decades, it became clear that spending long periods of time away from a senior scientist's home university was problematic given responsibilities such as lab research, mentoring, teaching and grant writing. FIC adapted the SIF program to focus on young investigators who had more flexibility to spend time away from their universities. This was the start of the IRSDA program.

The first IRSDA FOA was issued in March of 1999 as RFA-TW-99-004.[7] Since then there have been nine subsequent IRSDA FOAs (RFA-TW-00-005, PAR-01-025, PAR-02-041, PAR-04-058, PAR-07-014, PAR-10-066, PAR-13-072, PAR-15-291 and PAR-17-002) under the supervision and management of six different FIC Program Officers (POs).

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[5] Coralie Farlee. The Fogarty International Center. (1986). *Evaluation of the Senior International Fellowship (SIF) Program*. (Contract No. NO1-TW-3-2109). Brookline, Massachusetts: Policy Analysis Inc.

[6] The National Institutes of Health. (1974, October 18). *NIH Guide for Grants and Contracts* (Volume 3, Notice 16). Retrieved from https://grants.nih.gov/grants/guide/historical/1974_10_18_Vol_03_No_16.pdf

[7] The Fogarty International Center. (2016). *International Research Scientist Development Awards for U.S. Postdoctoral Scientists* [Funding Opportunity Announcement]. Retrieved from https://grants.nih.gov/grants/guide/rfa-files/RFA-TW-99-004.html

1.4. Objectives

Since its inception, the IRSDA program has supported U.S. postdoctoral biomedical, epidemiological, clinical, social and behavioral scientists who are in the formative stages of their careers to conduct mentored research in LMICs. The objective of the program is to provide salary and research project support for a sustained period of mentored and protected research time with the expectation that awardees will launch independent global health research careers, continue to collaborate with LMIC scientists, and become competitive for future research funding.

Benjamin Chi, MD, MSc
A Training Program in International Women's Health (2005- 2009)

Dr. Benjamin Chi's career in global health began in 1999 when, as a medical student, he worked for two months at the Chris Hani-Baragwanath Hospital (Johannesburg, South Africa). It was in this setting that Chi realized how increased coverage of even the simplest interventions could dramatically reduce disease burden. During his obstetrics and gynaecology residency, Chi returned to sub-Saharan Africa – this time to Lusaka, Zambia – to further cultivate these career interests. He worked with Drs. Jeffrey Stringer, Moses Sinkala, and Robert Goldenberg on an assessment of provider attitudes towards and clinical practices for HIV-infected women. This became a foundation for future collaboration; all three scientists – alongside Dr. Sten Vermund – would later serve as mentors for his IRSDA award.

In 2003, Chi joined the University of Alabama at Birmingham as a research fellow and moved to Zambia full-time. His original fellowship provided salary through project budgets; however, in his first year, he applied for, and was awarded his IRSDA. The IRSDA program had an important impact on his early career. Scientifically, it provided support to investigate the effectiveness of single-dose tenofovir-emtricitabine for reducing antiretroviral drug resistance associated with intrapartum nevirapine[1], a regimen commonly used at the time to prevent mother-to-child HIV transmission. It also provided resources for his further professional development, including support for Masters-level studies in epidemiology and opportunities to network with other scientists in HIV and maternal health.

Perhaps most importantly, the IRSDA program provided Chi with dedicated and extended time abroad. While his field presence ensured the successful completion of his clinical trial, it also positioned him in Zambia at a historic time in the AIDS response. Beginning in 2004, HIV care and treatment services expanded rapidly countrywide with support from the U.S. President's Emergency Plan for AIDS Relief. Chi played an important role in establishing observational HIV cohorts in the city of Lusaka. The service platforms were leveraged in clinical trial recruitment, including later studies for the National Institute of Allergy and Infectious Diseases (NIAID)-supported International Maternal Pediatric Adolescent AIDS Clinical Trials Group. The extended time in Zambia fostered longstanding partnerships with local Zambian scientists, clinicians, and policy makers – many of whom are now leaders at the University of Zambia and the Zambian Ministry of Health. The experience at the intersection of program implementation and clinical research advanced Chi's interests in HIV implementation science, a trajectory of his research that continues to this day. Finally, Chi continues the central legacy of the IRSDA program by mentoring young investigators in global health research, supported by the FIC and other ICs within the NIH.

[1] Chi, B.H., et al. (2009 Nov). Intrapartum tenofovir and emtricitabine reduces low-concentration drug resistance selected by single-dose nevirapine for perinatal HIV prevention. *AIDS Research Human Retroviruses.* 25(11), 1099-106

The initial FOA in 1999 articulated four goals of the program[8]:

- Attract new research talent and enhance the multi-disciplinary synergy among the research collaborators at the U.S. and foreign sites;
- Leverage existing research and training support for developing country scientists and U.S. scientists committed to international research;
- Support the coalescence of the critical, sustainable components necessary to move developing country institutions with significant potential to new levels of research excellence;
- Stimulate a more effective translation of evidence-based research into practical public health actions.

Since then, the objectives have been streamlined and the overall expectation of the IRSDA program is "that through [a] sustained period of research career development, awardees will launch independent global health research careers, continue to collaborate with LMIC scientists on research that addresses the health needs of their countries and become competitive for new research project grants (e.g., R01) funding".[9]

The overarching goal of the IRSDA program is to support the development of a cadre of young scientists who can independently and productively pursue global health research careers, and who have strong field experience and collaborative networks with LMIC scientists that can ultimately foster more efficient and effective global health research. While the structure of the program has remained relatively consistent, there have been some changes in the in-country time requirements and salary support for the award, as shown in Table 1.

Table 1: Requirements by Funding Opportunity Announcement (FOA)

FOA	Time Requirement in LMIC	Salary Support	Research Support	Length of Award
RFA-TW-99-004	2 years in the first 3 years	$50,000/year	< $20,000 /year	3 years (with option of 2 year competitive renewal)
RFA-TW-00-005	2 years in the first 3 years	$50,000/year	< $20,000 /year	3 years (with option of 2 year competitive renewal)
PAR-01-025	>24 months and for lengths of > 3 months per stay	$75,000 per 12 months		36 funded months over 3-5 years

[8] Ibid.

[9] The Fogarty International Center. (2016). *International Research Scientist Development Award (IRSDA) (K01)* [Funding Opportunity Announcement]. Retrieved from http://grants.nih.gov/grants/guide/pa-files/PAR-17-002.html

FOA	Time Requirement in LMIC	Salary Support	Research Support	Length of Award
PAR-02-041	24 months of the total grant period and at least four months/year	< $75,000/year	< $20,000 /year	< 4 years (with option of 3 year competitive renewal)
PAR-04-058 PAR-07-014	>50% of the total grant period and at least three months/year	< $75,000/year	< $20,000 /year	3-4 years (with option of 3 year competitive renewal)
PAR-10-066	>50% of the total grant period	Salary consistent with institution structure	< $30,000 /year	3-5 years
PAR-13-072 PAR-15-291	>50% of the total grant period and at least three months/year	< $75,000/year	< $30,000 /year	3-5 years
PAR-17-002	>50% of a grantee's cumulative effort over the total project and at least three months/year	< $75,000/year	< $30,000 /year	3-5 years

Unlike the other NIH K01 FOAs, the IRSDA program is unique in its requirement that grantees spend most of their three to five years of protected research time at a LMIC site. Specifically, candidates must commit a minimum of nine person-months (75% of full-time professional effort) to conducting the proposed research and career development activities, and they are required to spend at least 50% of the award period and at least three months in each year of the award in the designated LMIC. The remaining effort can be divided among teaching,

Jeffrey M. Bethony, PhD
Host Genetic Correlates of Helminthic Coinfection (2000 –2006)

Jeffrey Bethony's IRSDA mentors helped foster his early career development in tropical medicine and immunology. The relationships with these mentors have continued post-IRSDA and Bethony often collaborates with his former mentors, evidence of the strong relationship that was built during his IRSDA experience.

Both his U.S. mentor (Dr. Peter Hotez, formerly of George Washington University) and LMIC mentor (Dr. Rodrigo Correa-Oliveira of the Brazilian Ministry of Health) allowed and encouraged Bethony to stay for long periods of time in the field, to build relationships in Brazil and to apply for future funding opportunities. Being in the field provided immediate access to the endemic Brazilian areas with schistosomiasis and hookworm which were paramount for the research of Bethony. Also crucial was the ability to utilize Correa-Oliveria's laboratory, knowledge and field infrastructure in-country, thereby focusing the IRSDA funds and attention on developing a sound project.

During his third year of IRSDA funding, Bethony was asked by Dr. Peter Hotez (his U.S. mentor) to join the Human Hookworm Vaccine Initiative, Department of Microbiology and Tropical Medicine at George Washington University. The work paid off because Hotez and Bethony were awarded a $22 Million grant from the Bill and Melinda Gates Foundation for the clinical development of a hookworm vaccine Phase 1a Clinical Trial.[1]

Since the IRSDA program in 2000, Bethony has been PI or co-PI in over 14 research projects of which almost half (six projects) included one of his IRSDA mentors. For Jeffrey Bethony, the IRSDA mentors have remained important colleagues and collaborators throughout his career.

[1] Hotez, P.J., et al. (2013 April). The Human Hookworm Vaccine. *Vaccine.* 31(Suppl 2), B227-B232.

administrative, or clinical activities, as appropriate to the candidate's career development. Over the past 15 years, the annual salary for IRSDA grantees has been $75,000, although the research budget has increased from $20,000 to $30,000.

Eligibility criteria for applicants require that an individual (1) be a U.S. citizen, non-citizen national or lawfully admitted for permanent residence (consistent with requirements of the K01 mechanism); (2) hold a research or health-professional doctoral degree; (3) not be a past or present recipient of a major independent research award from any funding entity; (4) have a full-time appointment at a higher education institution; and, (5) designate both a LMIC and a U.S. mentor committed to the career development of the individual.

Mentorship is a critical element of the IRSDA program. Unlike the other NIH mentored career development awards, where only one mentor (traditionally from a U.S. institution) is required, the IRSDA program requires two mentors; one each from a U.S. and a LMIC institution. The purpose of this requirement is to help foster sustained collaborations between U.S. and LMIC institutions – a necessity in global health. Not only does this requirement generate useful scientific information and promote collaboration between investigators and institutions with shared interests but it increases the likelihood of research being implemented into policy or practice at the local level. IRSDA mentors should be active investigators in a relevant research field to the IRSDA grantee and should have the mentoring skills necessary to supervise the career development and research experience of the awardee. At the end of each funding period, the grantee submits a progress report which must include statements from both U.S. and LMIC mentors providing their assessments of the candidate's progress.

1.5. Niche within research community

One aim of this evaluation was to understand whether the IRSDA program fills a unique niche in the research community and for global health. To help understand this, similar programs were identified with a focus on supporting early career U.S. scientists conducting research in LMICs both within and outside of NIH. Programs of interest outside of NIH were selected based on suggestions from directed internet searches and prior knowledge of FIC personnel and include:

- Doris Duke Clinical Scientist Development Awards: This award supports early-career physician-scientist faculty in pursuing independent research careers. Started in 1998, the program has awarded 270 Awards totaling over $100 Million for physician-scientists to conduct clinical research under protected, mentored time. Each awardee receives up to $495,000, over 3 years ($150,000 direct cost and $15,000 indirect costs per year). Eligibility includes a U.S. medical license; however, U.S. citizenship is not required.

Source: http://www.ddcf.org/what-we-fund/medical-research/goals-and-strategies/encourage-and-develop-clinical-research-careers/clinical-scientist-development-award/

- Howard Hughes Medical Institute's International (HHMI) Early Career Scientists: Since 2012, HHMI has supported approximately 28 foreign scientists in 12 countries (China, Portugal, Spain, Argentina, Brazil, Chile, Hungary, India, Italy, South Africa, Poland, and South Korea). Scientists are trained in the U.S. and have led their own laboratories for a period less than seven years. Awardees receive $650,000 over five years (averaging $130,000 annually) to conduct global health research. Source: http://www.hhmi.org/programs/biomedical-research/international-programs

- HHMI International Research Scholars: Announced in March 2016, HHMI along with the Bill & Melinda Gates Foundation, Wellcome Trust, and the Calouste Gulbenkian Foundation, established an international program aimed at early career researchers who have demonstrated talent within a biomedical research field. Eligible scientists are trained in either the U.S. or United Kingdom for at least one year, are not from a G7 country[10] and have run their own laboratories for less than seven years. Selected individuals receive funding for five years totally $650,000 (averaging $130,000 annually). Source: https://www.hhmi.org/programs/biomedical-research/international-research-scholars

- Human Frontier Science's Young Investigators' Grant: This grant goes to a team of international researchers (including U.S. investigators), all whom are within the first five years of obtaining their own laboratory. The emphasis of these grants is cross-collaboration across countries and disciplines to address a problem in the life sciences. The 2016 awardees, on average, received $110,000-125,000 of annual support for three years.[11] Source: http://www.hfsp.org/funding/research-grants

- National Science Foundation's (NSF) International Research Fellowship Program (IRFP): Although this program is no longer being funded directly, IRFP brought U.S. scientists and engineers in the early stages of their careers to international settings. The goal was to create a collaborative research opportunity, thereby furthering research capacity and

[10] G7 countries are Canada, France, Germany, Italy, Japan, United Kingdom and United States
[11] Human Frontier Science Program. (2016). *The 2016 HFSP Research Grants support discovery life sciences research* [Press release]. Retrieved from http://www.hfsp.org/sites/www.hfsp.org/files/HFSP%202016%20Research%20Grants.pdf

fostering international collaborations among scientists, technologists and engineers abroad. Source: http://www.nsf.gov/funding/pgm_summ.jsp?pims_id=5179

This review of the landscape of early career research opportunities outside of the NIH, suggests that the IRSDA program fulfills a unique niche. Other programs appear to provide more limited opportunities due to their eligibility criteria. Although the NSF program appears similar to the IRSDA program, it does not focus specifically on LMICs; furthermore, the program stopped funding awards in 2012. Howard Hughes provides two offerings to early career scientists though one of its programs is not available for U.S. citizens and the other program is not global health specific. Doris Duke's program does not specifically target global health-research, and it requires an MD degree. The Human Frontier Science's Young Investigator Grant promotes international teams, but only in basic research. Among programs funding early career health scientists, the FIC's IRSDA program appears to offer a mandatory focus on LMICs combined with a unique flexibility that others do not – the opportunity to conduct both basic and clinical research spanning a wide range of biomedical fields in LMIC settings around the world.

Margaret Kosek, MD
Epidemiology of Shigellosis in the Peruvian Amazon (2001-2008)

The IRSDA program was the beginning of a fruitful relationship between FIC and Margaret Kosek. Since 2008, she and other Johns Hopkins University researchers became involved with the Malnutrition & Enteric Infections: Consequences for Child Health and Development Program (MAL-ED), a multi-year, multi-site project funded by the Bill and Melinda Gates Foundation and led by the Fogarty International Center. The overall goal of MAL-ED is to investigate the interactions among exposure, infection, and disease associated with enteric pathogens, diet and nutritional status, and, socio-economic status in relation to resulting impacts on gut physiology, immune function, vaccine response, physical growth, and cognitive development.[1]

Kosek and her colleagues work in the Peruvian site; Peru is one of eight countries in which MAL-ED is conducting research. The Iquitos Satellite Laboratory, where the research is being done, was established in 2002 by Robert Gilman, Kosek and Pablo Yori. These same individuals have been peers and mentors of Kosek since her IRSDA experience.

[1]MAL-ED Network Investigators. (2014 Nov). The MAL-ED study: a multinational and multidisciplinary approach to understand the relationship between enteric pathogens, malnutrition, gut physiology, physical growth, cognitive development, and immune responses in infants and children up to 2 years of age in resource-poor environments. Clinical Infectious Disease. 59(Suppl 4), S193-206.

In assessing whether the IRSDA program fills a unique niche within NIH, we reviewed multiple mentored career development award programs which all share a common goal of enhancing the career trajectory and research knowledge of the individual investigators. The IRSDA

program is the only current NIH career development program[12] directed solely at supporting careers in global health across diseases and fields by sending early career U.S. investigators to LMICs. The IRSDA program is similar to other K01 awards in that it seeks to foster research independence through a period of protected mentored research and career development activities. However, FIC's IRSDA program is unique in its requirements that grantees spend a certain percentage of cumulative effort conducting research in a LMIC and be mentored by both U.S. and LMIC scientists. Although other NIH career development opportunities do not prohibit global health research, FIC's significant in-country requirement supports critical in-country research experience for its awardees and is intended to help foster sustained collaborations and research capacity in global health.

1.6. Funding and partners

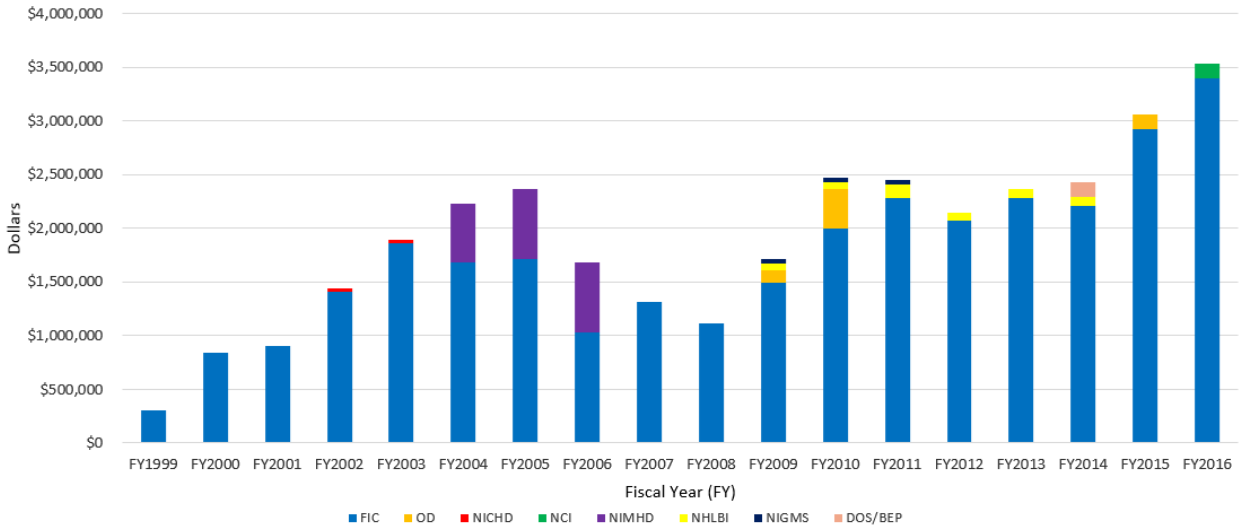
Over its 17-year history (1999-2016), the IRSDA program has been supported with funds totaling over $34.72 million dollars. As shown in Figure 2, funding for the program steadily increased between FY1999 and FY2005, starting at $301,505. Funding then dipped between FY2005 and FY2008, although funds were still over $1M each year. Beginning in FY2009, the funding level has continued to increase.

Since participants of the IRSDA program are not confined to a specific research focus or disease, the program offers an opportunity to partner with other ICs within the NIH. In most cases, partnerships occur through co-funding; an IC will contribute funds to the FIC administered IRSDA award most often when the research aligns with the priorities of the IC. In other instances, ICs have confirmed their commitment to the IRSDA program by signing on to the IRSDA FOA. The IRSDA program has collaborated with National Institute of General Medical Sciences (NIGMS), National Cancer Institute (NCI), National Heart, Lung, and Blood Institute (NHLBI), National Institute on Minority Health and Health Disparities (NIMHD), National Institute of Environmental Health Sciences (NIEHS), National Institute on Aging (NIA), National Institute of Nursing Research (NINR), Office of the Director's Office of Dietary Supplements, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), Office of the Director's Office of AIDS Research, and the U.S. Department of State's Biosecurity

[12] In FY2014 NIMH issued a K01 FOA (RFA-MH-14-120) that would fund early career investigators in global mental health. Three K01 awards focusing on mental health in LMICs have been funded through this program. However, since the 2015 FOA (RFA-MH-15-700), there has been no recompetition of this program. The program was like the IRSDA program in that there was an in-country requirement at an LMIC (four months annually) beginning the second year of the grant. The FOA encouraged, but did not require, LMIC mentors.

Engagement Program. IRSDA partners have contributed a total of $3.4 Million (10%) between FY1999 and FY2016, as shown in Figure 2.

Figure 2: Funding for the IRSDA Program by Partner, FY1999-2016[13]



Although the program has involved several partners over the years, as of FY2016, the only NIH IC signed on to the FOA as a participating partner is the NCI. NCI is currently supporting an awardee conducting breast cancer research in Nigeria.

Applications, awards and demographics

The following section describes the total applicant pool and the characteristics of those who were successful in obtaining IRSDA funding versus those who were not, to understand factors associated with successful applications.

1.7. Application success rates

For the purposes of this evaluation, the "award rate" is defined as the number of awards funded divided by applications reviewed, including resubmissions. [14] The "award rate" describes the chance of an individual application being funded.

Applications were considered on both a council year (CY), which refers to the year in which a group of applications submitted to the same receipt date are reviewed by FIC's Advisory Board;

[13] FY2009 and FY2010 include ARRA funding in the FIC total count.

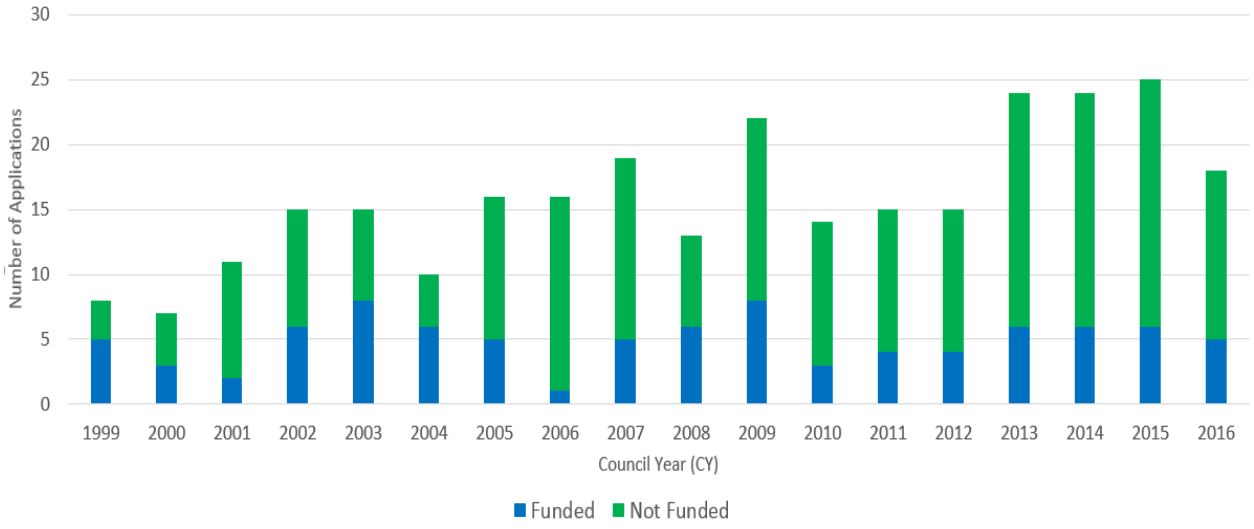
[14] Rockey, S. (2015, June 29). *What are the Chances of Getting Funded?* [Web blog post]. Retrieved from https://nexus.od.nih.gov/all/2015/06/29/what-are-the-chances-of-getting-funded/

and funding opportunity basis and were included if the application was peer reviewed and either scored or unscored in peer review by an Integrated Review Group.[15]

From FY1999 to FY2016, 90 awards were funded from a total of 214 unique applications by 202 individuals. Of these 90 funded awards, 75 were new awards (Type 1) and the remaining 15 were renewals (Type 2). Fifty of the 75 new awards (66%) were awarded on the first submission. Twenty-three individuals (31%) submitted a second application before being funded, and two individuals (3%) submitted more than two applications or amendments before securing an award. Of the 127 individuals who never received any funding, 25 (20%) submitted two unsuccessful applications and three (2%) submitted three unsuccessful applications.

As shown in Figure 3 and Table 2, the number of applications, grants funded, and overall award rates have varied over time. The number of applications has generally increased from the first couple of years of the IRSDA program, when there were fewer than a dozen applications per FOA. The peak in response to an IRSDA FOA was PAR-13-072 with 73 applications over three years (FY2013-FY2016).

Figure 3: Award Counts and Rates by Council Year (CY), CY1999-2016



[15] Those with an application status of "Withdrawn" were excluded. Those applications with a status of "Pending" or "Administratively Withdrawn by IC" were included as unfunded.

Table 2: Award Counts and Rates by FOA, FY1999-2016

RFA/PAR	# of Receipt Dates	No. of Applications Reviewed and Deemed Eligible	No. Applications Awarded	Award Rate
RFA-TW-99-004	1	9	5	56%
RFA-TW-00-005	1	6	3	50%
PAR-01-025	1	11	2	18%
PAR-02-041	2	30	15	50%
PAR-04-058	3	42	12	29%
PAR-07-014	3	54	19	35%
PAR-10-066	3	44	11	25%
PAR-13-072	3	73	18	25%
PAR-15-291	1	18	5	28%
TOTAL	18	287	90	35%

When aggregated by FOAs, the average award rate is 35%. As seen in Figure 3, given the variance over the years the award rate drops to 33% when averaged by CY.

Ann M. DiGirolamo, PhD, MPH
Effects of Caregiving on Child Malnutrition (2000-2007)

Ann DiGirolamo was always interested in psychology, but she didn't discover her passion for global health until she spent time in Latin America. While completing a Masters of Public Health (MPH), she worked on a Guatemalan dataset examining children's cognitive development, and she traveled to Costa Rica and Nicaragua to improve her Spanish language skills. Following her degree, a fellowship at the CDC allowed DiGirolamo to further involve herself in research projects working in low resource settings. Opportunities in rural Alaska and in Pakistan both provided fieldwork and programmatic experiences that exposed her to issues that were important to a budding researcher working in resource limited environments.

After her CDC fellowship, DiGirolamo applied to and was awarded an IRSDA. The goals of her IRSDA award combined her background in Child Health Psychology and global public health to address the psychosocial factors influencing child malnutrition, growth and development in Mexico. She credits the IRSDA program with providing an opportunity that allowed protected time to work directly in Mexico, immerse herself in the culture, learn the local populations' needs, and develop important collaborative relationships.

Her experience during her IRSDA, working on maternal depression and child development in Mexico, confirmed her desire to pursue a career in international health research. At the end of her IRSDA funding, she was awarded a NIH R01 to conduct a randomized controlled trial examining the effects of zinc supplementation on mental health and school performance in school-age Guatemalan children.[1] She is now an Associate Research Professor in the School of Social Work and Director of the Center of Excellence for Children's Behavioral Health in the Georgia Health Policy Center at Georgia State University, as well as an adjunct faculty member at Rollins School of Public Health at Emory University. DiGirolamo provides expertise in research and policy related to child and adolescent behavioral health, and continues working with resource limited communities in Latin America and other low-income countries.

[1]DiGirolamo AM, Ramirez-Zea M, Wang M, Flores-Ayala R, Martorell R, Neufeld LM, Ramakrishnan U, Sellen D, Black MM, Stein AD. Randomized trial of the effect of zinc supplementation on the mental health of school-age children in Guatemala. Am J Clin Nutr. 2010 Nov;92(5):1241-50.

1.7.1. Unfunded applicants applying to other K awards

Several of the individuals who applied to the IRSDA program but were not funded went on to apply to other NIH Career Development (K) Awards through other ICs. Grant data was extracted using IMPACII and data was analyzed based on characteristics such as funding success and administering IC.

Of the 127 unfunded individuals, 24 (19%) subsequently applied to other K programs following their unsuccessful IRSDA application. Of those, 11 individuals (9%) were successful in obtaining other K awards. A total of fourteen K awards were funded to the 11 individuals who were former, unsuccessful applicants of the IRSDA program. Two individuals were successful in securing more than one type of K award (different mentored and non-mentored/independent K awards) over their careers.[16] The most common mechanism was the K23, with over half of the awards (n=7, 50%) funded through this mechanism. The National Institute of Allergy and Infectious Diseases (NIAID) provided support for most of these subsequent awards (n=6; 43%).

1.8. Demographic characteristics of applicants and awardees

This sections describes the demographic characteristics of IRSDA applicants and awardees. Demographic information was obtained through the Office of the Director's Office of Extramural Research at the NIH. Data was voluntarily self-reported at the time of application by the individuals.[17] In accordance to Health and Human Services (HHS) policy, FIC suppressed any fields with less than 11 people reporting.

1.8.1. Sex, race, ethnicity, and citizenship

Of the 75 individuals who were funded, 44% (n=33) were male and 56% (n=42) were female. This is nearly identical for

Daniel Fitzgerald, MD
HIV Host Resistance Factors (1999-2005)

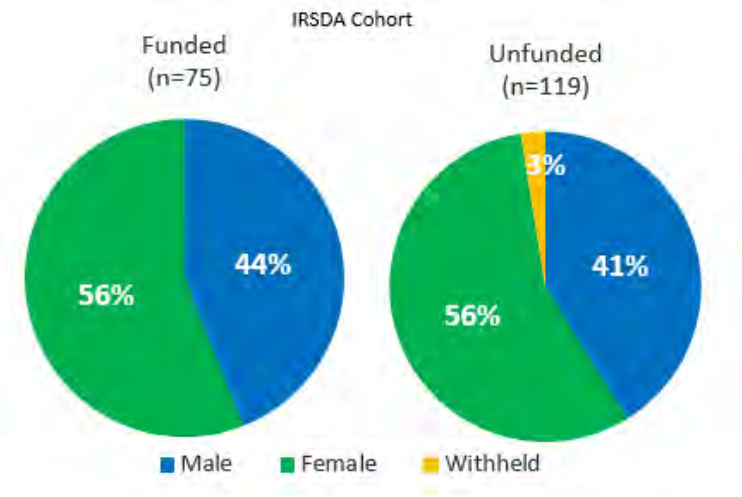
Daniel Fitzgerald is currently Professor of Medicine, Microbiology and Immunology and co-Director of Weill Cornell's Center for Global Health. He conducts NIAID supported research in HIV and tuberculosis and mentors medical students and young physician scientist as they conduct mentored research in Haiti and Tanzania.

Fitzgerald has been a recipient of NIH awards through FIC, NIAID and NCI, and has also received support from President's Emergency Plan for AIDS Relief (PEFPAR), BioMerieux Foundation, Mulago Foundation, the U.S. CDC and the Bill and Melinda Gates Foundation. Recently he helped establish and serves as Director for the Global Health Research Fellowship, which trains clinician-scientists for global health research careers in Brazil, India, Tanzania and Haiti. This program is supporting Weill-Cornell post-residency graduates of medicine to study in LMICs for three-years as they gain the skills to design and conduct patient-oriented research that will make them competitive researchers. These individuals are on a path to become the next generation of global health leaders and perhaps future applicants to the IRSDA program.

[16] One unfunded IRSDA applicant went on to receive three NIAID Ks (K02, K23 and K24) during her career. Another unfunded IRSDA applicant was awarded two NIEHS Ks (K01 and K02) after unsuccessfully applying to IRSDA.
[17] The category of Unknown/Other/No Code was used for individuals who did not report demographic information.

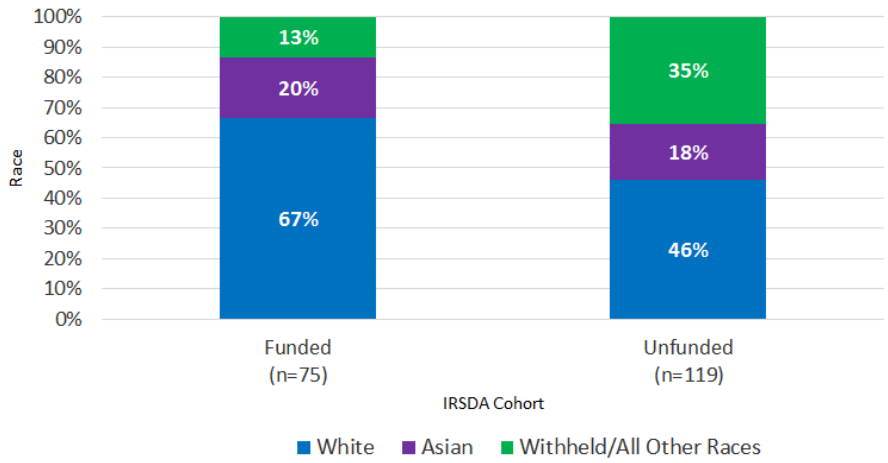
the unfunded individuals (41% male, 56% female and 3% unknown or withheld). Because the IRSDA program requires a large time commitment in-country and is geared towards early career professionals, there have been concerns expressed that female applicants would be deterred from applying because of childbearing/rearing priorities. However, the data show women are being funded similarly to men, suggesting that the IRSDA requirements are not deterring female applicants.

Figure 4: Gender of Funded and Unfunded Applicants, FY1999-2016



The review also examined race/ethnicity of IRSDA applicants and awardees. The majority of funded and unfunded IRSDA applicants identified themselves as White (67% and 46% respectively) (Figure 5). A similar percentage in both applicant pools identified themselves as Asian (20% funded and 18% unfunded). Due to the HHS policy requiring suppression of groups smaller than 11 in order to protect the privacy of small identifiable groups, the "Withheld/All Other Races" category for funded applicants includes African American/Black individuals.

Figure 5: Race of Funded and Unfunded Applicants, FY1999-FY2016



FIC was also interested in whether applicants to the IRSDA program had existing ties to LMICs where they proposed to conduct their research. FIC's initial interest in citizenship status was to ascertain how many applicants were permanent residents, and to understand who and where individuals held dual citizenships. While citizenship alone is not indicative of any association to a country, it provides one measure that may indicate a prior connection to a LMIC. However, the information requested upon application is not as detailed as FIC had anticipated as citizenship is categorized into only three status levels: (1) Non-U.S. Citizen not residing in the U.S. (2) Permanent Resident of U.S. and (3) U.S. Citizen or non-citizen national.[18] Sixty-six of the 75 (88%) funded applicants identified as a U.S. Citizen or non-citizen national. Seventy-one of the 119 unfunded applicants[19] (60%) were U.S. Citizen or noncitizen national and 16 (13%) were Permanent Residents.

1.8.2. Degree distribution

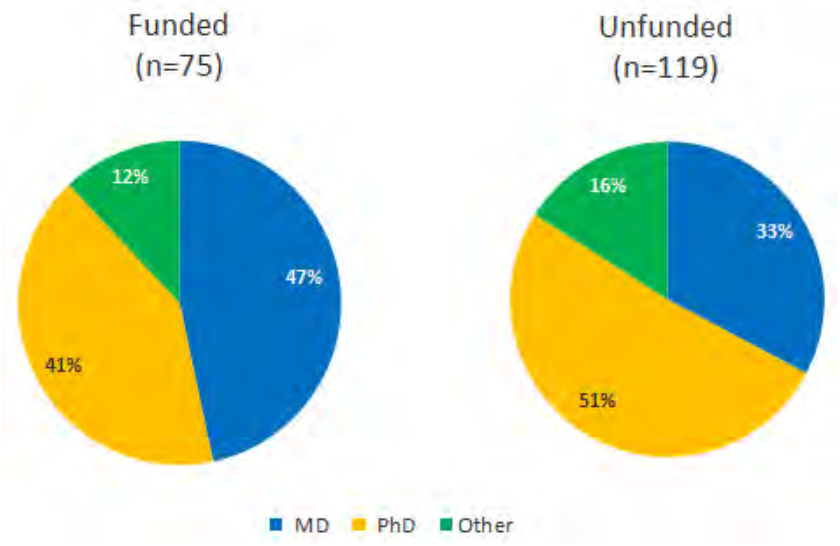
This section describes the terminal degrees of IRSDA applicants and awardees at the time of application submission. Of note, the IRSDA program uniquely gives individuals with a doctoral-level degree opportunities in both clinical and non-clinical global health research through the K01 mechanism. In contrast, the NIH K01 mechanism primarily focuses on the non-clinical sciences.

[18] As defined by the Immigration and Nationality Act, 8 USC 1452(b), non-citizen nationals are individuals of the United States who owe permanent allegiance to the U.S. but are not citizens. Only individuals born in an outlying possession of the U.S. (i.e. American Samoa or Swains Island) or born to a parent who is a non-citizen national can be identified as a non-citizen national.

[19] The number of unfunded applicants is lower (n=119) than the number reported in the Award Rate section (n=127). The Office of the Director's Office of Extramural Research data were pulled before the end of FY16 and do not include any of the Pending awards.

As shown in Figure 6, successful (funded) applicants were fairly evenly distributed between MDs and PhDs (47% MD and 41% PhD), whereas 51% of the unfunded applicants were PhDs. Given the terminal degrees reported by the pool of applicants, the IRSDA program is successfully attracting those interested in both basic and clinical research.

Figure 6: Terminal Degrees for Funded and Unfunded IRSDA Applicants



1.8.3. Applicant age and year since terminal degree

The IRSDA program aims to support early career scientists. While there are no age requirements for the program, evidence suggests that the program is funding age-appropriate early career scientists, consistent with the purpose of the NIH Career Development (K) programs. Age was computed as the difference between the FY of the application and the FY of the individual's birth date. For those with multiple applications, the age of the applicant at the time of the first successful IRSDA award or last unsuccessful application was used. Twenty-eight individuals (10 funded and 18 unfunded) were not included in the age analysis as their date of birth data was not available.

The median age of funded individuals at the time of their IRSDA award is 36 years. For the applicants who were not funded, the median age was 38 years (Table 3). When disaggregated by gender, the average age for applicants was slightly higher for both males and females who were unfunded, as compared to their counterparts who were funded. The youngest and oldest funded individuals were 29 and 45 years old at the time of their application, respectively.

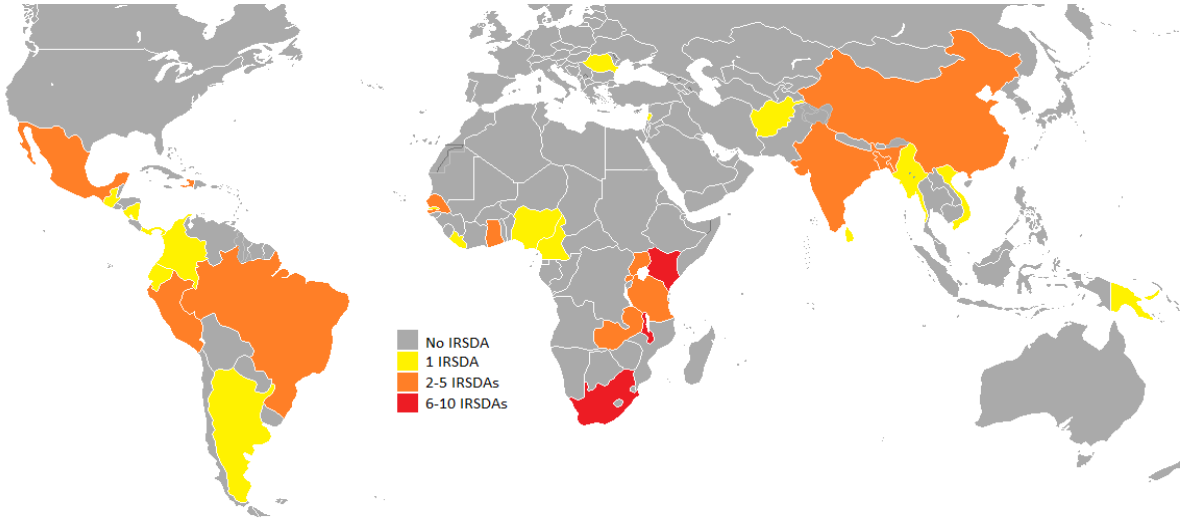
Table 3: Age of Funded and Unfunded Applicants at time of Application, FY1999-2016

	Ave. Age for Funded Applicant	Ave. Age for Unfunded Applicant
Female	35	39
Male	37	38
All Sexes	36	38

1.9. Program snapshot by region

The IRSDA program has funded early career investigators to conduct research in 33 different LMICs. For the purposes of this report, countries were classified per World Bank Regional categories[20]: Africa, including only sub-Saharan African (SSA) countries; East Asia and the Pacific; Europe and Central Asia; Latin America and the Caribbean; Middle East and North Africa; and South Asia. Thirty-nine of the funded projects (52%) were conducted in SSA followed by Latin America with 19 projects (25%).[21] The Middle East and North Africa region, as well as the European region were underrepresented, as each only had one project (in Lebanon and Romania, respectively). Figure 7 and Table 4 illustrate the geographic distribution of research conducted by IRSDA awardees.[22] The three countries with the most IRSDA research were in sub-Saharan Africa: Malawi (n=7) Kenya (n=7) and South Africa (n=6). Bangladesh, India and Mexico then followed with five projects each.

Figure 7: Geographic Distribution of IRSDA Awardees' Research Focus, FY1999-2016 (n=75)



[20] The World Bank. (FY2017). *World Bank Country and Lending Groups*. [Webpage]. Retrieved from https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups.

[21] Two projects were counted twice in the country/regional analysis due to their unique circumstances. One project changed countries/regions at the time of the renewal award. The other project conducted research in two different countries and regions.

[22] One project conducted research in two countries within the same region. As such, regional totals are not congruent with country totals.

Table 4: Country and Region of IRSDA Awardees' Research, FY1999-2016

Middle East & N. Africa	**Total n=1**
Lebanon	1
South Asia	**Total n=12**
Afghanistan	1
Bangladesh	5
India	5
Sri Lanka	1
Latin America	**Total n=19**
Argentina	1
Brazil	2
Colombia	1
Ecuador	1
Guatemala	1
Haiti	2
Mexico	5
Nicaragua	1
Panama	1
Peru	4
Europe	**Total n=1**
Romania	1
SSA	**Total n= 39**
Cameroon	1
Gambia	1
Ghana	2
Kenya	7
Liberia	1
Malawi	7
Nigeria	1
Rwanda	2
Senegal	2
South Africa	6
Tanzania	3
Uganda	3
Zambia	4
East Asia & Pacific	**Total n= 5**
China	2
Myanmar	1
Papua New Guinea	1
Vietnam	1

1.10. Distribution by scientific area of focus

Research supported by the IRSDA program has focused on numerous scientific areas. Applicants can propose research in any discipline that addresses a global health research area

of scientific relevance to the LMIC. For the purposes of this report, awards were coded into a scientific area of focus based on key areas important to FIC as determined by its most recent Strategic Plan.[23] Coding was done using a mixed approach of manual classification and text mining. For those applications received after FY2008, the Research, Condition, and Disease Categorization (RCDC)[24] coding system was used to initially classify applications, followed by a manual process of reading the title and abstract. For applications received prior to FY2008, abstracts and titles were read and subsequently coded.

Awards were binned into five categories: HIV, Infectious Disease other than HIV (ID, non-HIV), Non-Communicable Disease (NCD), Implementation Science (IS) and Other.[25] Although some applications could be classified into more than one category, multiple bins were applied conservatively.[26] As shown in Figure 8, the majority of research projects (n=58, 64%) are related to an infectious disease area. Thirty-one projects (34%) focused on an infectious, non-HIV

Elizabeth M. Stringer, MD
Career Development Award in International Women's Health (2001-2006)

Elizabeth Stringer is an obstetrician-gynecologist who obtained an IRSDA award from FIC after completing a fellowship in global women's health in Zambia. During the period of her support (2001 – 2006), one in four pregnant women in Lusaka were infected with HIV[1] and it was unclear whether the intrauterine contraceptive device (IUD) was effective or safe in HIV+ women. Stringer's IRSDA research – a randomized trial of IUD in postpartum HIV-infected women – demonstrated safety of the method in this population and now provides key evidence for the WHO's contraceptive recommendations.

During her IRSDA support, Stringer was also involved in implementing a large program to prevent mother-to-child HIV transmission in Lusaka, and later in the roll-out of antiretroviral (ARV) therapy in pregnancy. Upon demonstrating the feasibility of such a program, she and her team could secure larger funding through PEPFAR that would go on to support over 250,000 patients on ARVs.

Today, Stringer and the Global Women's Health Division at University of North Carolina Chapel Hill continue to conduct crucial research in women's health and HIV. The group now has active projects in Zambia, Malawi, South Africa, and Nicaragua, and has supported several other junior investigators in obtaining FIC and NIAID/NIH career development support.

[1] Stringer EM, Sinkala M, Kumwenda R, Chapman V, Mwale A, Vermund SH, Goldenberg RL, Stringer JS. Personal risk perception, HIV knowledge and risk avoidance behavior, and their relationships to actual HIV serostatus in an urban African obstetric population. J Acquir Immune Defic Syndr. 2004 Jan 1;35(1):60-6.

[23] The Fogarty International Center. (2014, April). Strategic Plan of the Fogarty International Center at NIH. [Webpage]. Retrieved from https://www.fic.nih.gov/about/pages/strategic-plan.aspx.
[24] The National Institutes of Health. (2012, May 16). *The Research, Condition, and Disease Categorization Process*. [Webpage]. Retrieved from https://report.nih.gov/rcdc/ Note: Since RCDC began in FY2008, data using this categorization process is only available from FY2008 onward.
[25] Other included topics on health services, economic analysis, air pollution, violence, and nutrition.
[26] Multiple binning was used to capture co-morbidity research projects. The use of "Other" would be chosen in conjunction with another category only if the topical areas appear in the title.

disease and 29 projects (32%) focused on HIV.[27]

The number of IRSDA grants focusing on NCDs has been steadily increasing over the past 15 years (Figure 9). The first three FOAs awarded no applications that focused on NCDs. However, starting in FY2002, two NCD-focused awards were made, followed by another award in FY2003. Under PAR-10-066, five of the 11 awards made (45%) were NCD related and the subsequent FOA had a similar percentage of awards focusing on NCDs (44%).

Figure 8: Disease Area for Awarded IRSDA Grants (n=90)

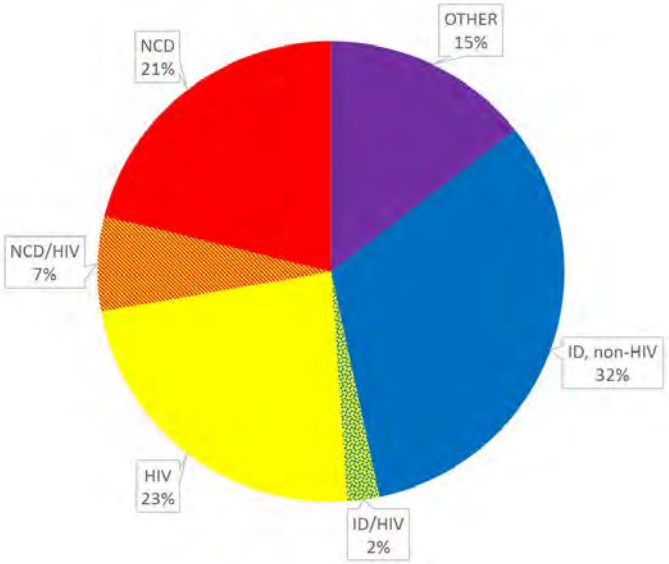
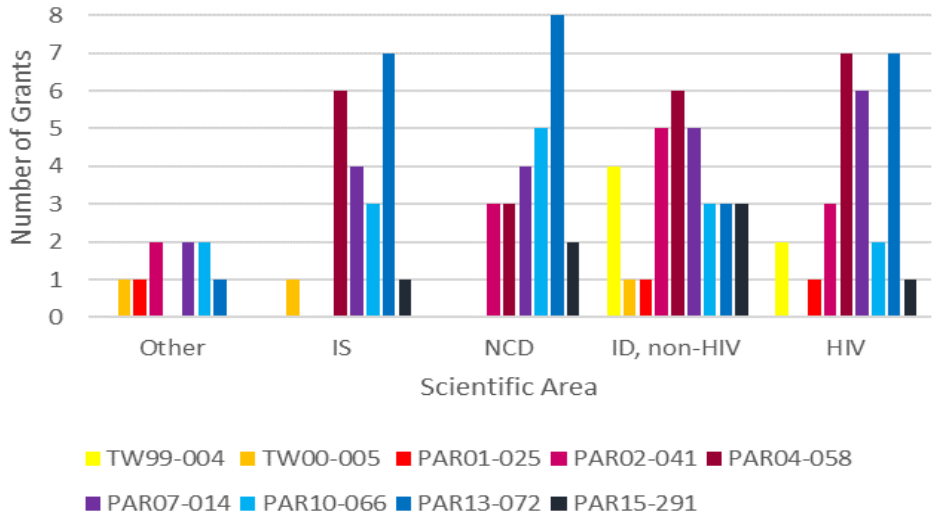


Figure 9: Scientific Area for Awarded IRSDA Grants by FOA (n=90)



[27] Eight projects dealt with co-morbidity meaning HIV and a non-HIV infectious disease (e.g., tuberculosis) or NCD (e.g., mental health).

The number of IRSDA grants focusing on implementation science (IS) has also grown; over the course of the entire IRSDA program, 22 projects have focused on IS. In 2000 there was one award focusing on IS. By 2004 several awards focused on IS (n=6 for PAR-04-058). Nine (41%) of the 22 IS projects were HIV-related. Interestingly, the same amount (n=9, 41%) of IS awards were also focused on NCD related issues.[28]

Program results

The IRSDA program has resulted in increased capacity in global health research. In this section, we review the outcomes of the program in terms of publications, subsequent NIH funding and employment. These outcomes were selected as indicators to measure whether an individual has successfully transitioned into an independent research career and, more specifically, within a field related to global health.

We compared four cohorts (Section 1.2.3). The IRSDA cohort includes any individual funded between FOA RFA-TW-99-004 through PAR-13-072.[29] The IRSDA cohort was compared to three NIH K cohorts (K01, K08, K23) funded through the NIH parent and Institute and Center (IC)-specific FOAs. Each of the comparison mentored NIH K Awards share characteristics with the IRSDA program. For example, while the IRSDA program uses the K01 mechanism, it encourages clinical and patient-oriented research (attributes within the K08 and K23 programs, respectively). Appendix A provides a further description of the differences between the various K mechanisms.

To generate cohorts of individuals engaged in global health research within the mentored NIH K Award cohorts, all funded, competing K01, K08 and K23 abstracts from FY1999 through 2016 were exported from IMPACII. For awards funded after 2013, data from IMPACII's Foreign Award and Component Tracking System (FACTS) were used to obtain country level information. For grants prior to 2013, titles and abstracts were searched and read using a list of LMIC country terms using the World Bank classification system.[30] Additional variations of keywords for "developing country," "global health," and "LMIC" were also searched.

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[28] Two of the IS awarded IRSDA grants were related to both HIV and NCD and are counted in each category. One grant focused on the treatment of HIV-associated cognitive impairment, another on integrating mental health in HIV clinics and the last on hypertension in HIV-Infected individuals.

[29] IRSDA grantees funded between FOA RFA-TW-99-004 through PAR-13-072 had start dates ranging from FY1999 to FY2016. Five projects funded under PAR-15-291 were excluded from the Program Results section, as they were too recently awarded at the time of the analysis.

[30] The World Bank. (FY2017). *World Bank Country and Lending Groups*. [Webpage]. Retrieved from https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups.

The size of each mentored NIH K Award cohort was capped at 70 individuals, a similar size to the IRSDA cohort. Individididuals included in the cohort were selected to best match with the start fiscal year (FY) of the IRSDA cohort. Individuals were matched with the IRSDA cohort based on the region of focus and biomedical field focus.

Outcome data on subsequent NIH grants, publications and employment were obtained for all individuals in all four cohorts.

- **Subsequent Grant:** For each awardee, subsequent grants were captured beginning in the fiscal year after their K award was first funded through FY2016. An award was included in the analysis if it was funded[31] and the grantee was listed as a Principal Investigator (PI), Multiple PI (MPI) or Co-Investigator. The "time until the award" analysis was calculated from the start date (in FYs) of the K Award until their first subsequent NIH award was funded.

- **Publications:** To better understand whether IRSDA trainees stay in a research career, publication analysis was conducted using the sample of individuals who completed their K awards. Publications were extracted from PubMed MEDLINE starting from the end date of the K award through July 2016. Name matching of a K awardee to author name was based on names, first and last name plus middle initial (if available). Some academic institutions provide links or references to their employees' publications. In these instances, the academic website list was crossed checked with a MEDLINE query to ensure the list was up-to-date.

  Publications were then analyzed using the bibliometric tool, iCite. iCite is a NIH-developed, bibliometrics tool.[32] The tool calculates a relative citation rate (RCR) that provides a metric to understand how influential an article, or portfolio of articles, is in a respective field of research. The RCR is the numbers of citations per year received by an article normalized by year and field.

- **Employment**: Employment information was collected on individuals who have completed their K awards as of July 2016. Using a Google search and prior knowledge of

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Note: Since 1999, certain countries have since moved income levels. Those that are now high income countries (HIC) were LMIC in the early 2000s. As such, we included those in our sample as LMIC.

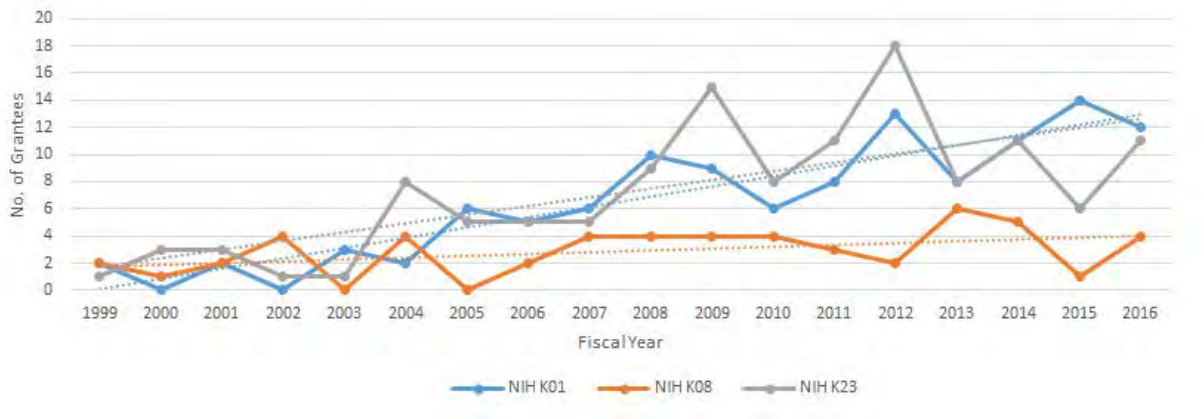
[31] Grants with a status of "pending" or "to be paid" were excluded.

[32] Hutchinson, B.I., Yuan, X., Anderson, J.M., Santangelo, G.M. (2016 Sept 6). Relative Citation Ratio (RCR): A New Metric That Uses Citation Rates to Measure Influence at the Article Level. *PLOS Biology. Volume 14*(9). Retrieved from http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002541

their current institution, from IMPACII, individuals were matched online and information on current career status (e.g., job location, title, sector, disease area) was extracted and analyzed.

As shown in Figure 10, the number of individuals funded in global health for each of the mentored NIH K Awards (K01, K08 and K23) has grown (Figure 10). The dotted lines represent linear trendlines, a best-fit straight line that is used to demonstrate a steady rate of increase in the growth of K awards for each cohort. The K01 and K23 awards have increased the most as indicated by their linear trendlines having a larger slope than the K08 awards.

Figure 10: Count of non-FIC, NIH Grantees in Global Health by K Mechanism, FY1999-2016



For the outcome analysis, a subset of the individuals in Figure 10 were selected. Table 5 provides the sample size for each of the cohorts. Given that the publication and employment analysis did not include active (i.e. current) awardees, the sample size is lower.

Table 5: Sample size for IRSDA and Mentored NIH K Award Cohorts in each Analysis

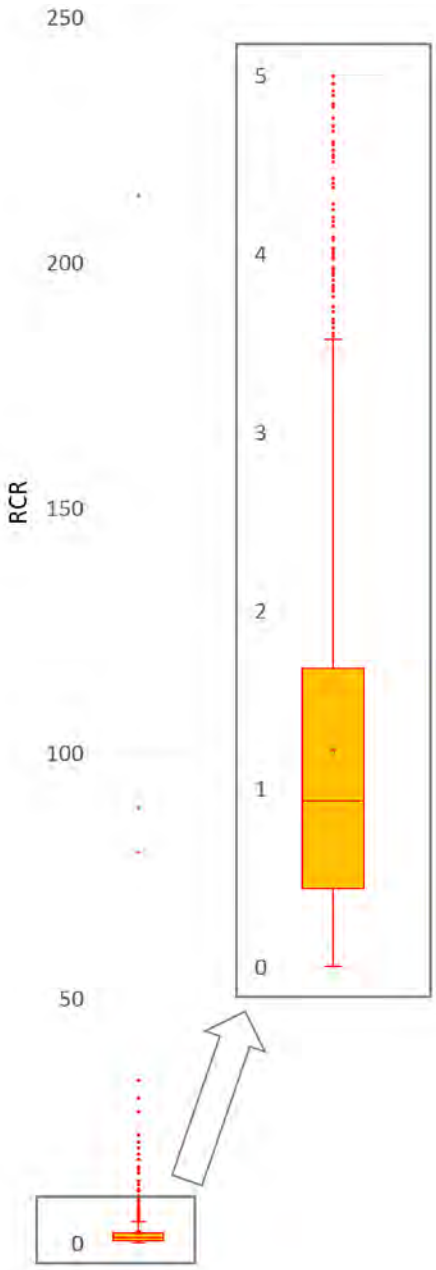
Cohort	Sample Size in Subsequent Grant Analysis	Sample Size in Publication Analysis	Sample Size in Employment Analysis
IRSDA	70	46	46
NIH K01	69	47	47
NIH K08	52	35	35
NIH K23	68	50	50

1.11. Publication analysis

Publication analysis is one approach to measure research productivity and help quantify scientific contributions within a given field. Publications represent a contribution in scholarly discourse and the number of times a publication is cited offers one metric that can measure the

impact the publication has within the scientific field. This section will outline the specific, quantitative contributions of IRSDA awardees by examining numbers of publications, citations, and scientific focus areas as compared to the K01, K08, and K23 NIH global health K Awardees.

Figure 11: RCR Range and Distribution for IRSDA Publications



1.11.1. Counts and citations

IRSDA recipients published a total of 1566 publications as of July 2016; the average individual publishing 37 publications since the time of his or her IRSDA award. Of those 1566 publications, 1510 were available for analysis in iCite (Table 6), as described in Section 1.2.3. On average, articles published by IRSDA awardee are cited four times a year (MEAN=3.96). One IRSDA grantee has a 2011 global-health related publication in the New England Journal of Medicine (NEJM) that has been cited 2,798 times.[33]

While the citation count per year for the IRSDA program is 3.96 (MEAN), this does not take into consideration that older publications accumulate more citations or certain fields of research are more heavily cited. The relative citation rate (RCR) offers a numerical representation of scientific influence of an article

[33] Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, Hakim JG, et al. (2011). Prevention of HIV-1 infection with early antiretroviral therapy. *New England Journal of Medicine*. 365(6), 493-505.

based off the citations per year normalized by field and year.[34] Once research field and time are normalized for the articles, a similar RCR appears for the IRSDA program and comparison cohorts (MEDIAN RCR=1.0). Given outliers like the NEJM article, the median offers an important indicator of the influence of the papers within the IRSDA cohort (Figure 11). The median (MEDIAN=1.0) shows very little variation between the four cohorts, suggesting awardees' publications have received the same number of citations per year as the median NIH-funded paper. Overall, this suggests that the cohorts have contributed equivalently to the scientific evidence in global health.

Overall, the IRSDA program appears comparable to their counterpart mentored NIH K Awardees with respect to scientific productivity. In particular, the IRSDA program and the K23 are very similar in total number of articles published (IRSDA=1510, K23=1574), the average number of articles published per year (IRSDA=116, K23=121), the average citations per year (IRSDA=3.9, K23=4.1) and the average RCR (IRSDA=2.1, K23=2.4).

Table 6: iCite Publication Outcomes by K Program

	Total Pubs	Pubs per Year	Cites/Year				RCR			
			MAX	MEAN	SEM	MED	MAX	MEAN	SEM	MED
IRSDA	1510	116	466	3.96	0.39	1.6	214	2.1	0.2	1.01
NIH K01	825	55	59	2.5	0.2	1.0	25	1.7	0.1	1.01
NIH K08	808	54	148	3.6	0.3	1.6	82	2.1	0.2	1.03
NIH K23	1574	121	599	4.1	0.5	1.7	256	2.4	0.3	1.08

1.11.2. Scientific Topics

The research focus of awardees post-funding provides an indication of whether the grantee has stayed in the same research field as their IRSDA grant and, of more interest, in a field relevant to global health research. When applying to the IRSDA program, applicants must demonstrate that the disease studied is of local relevance to the LMIC. As illustrated in Figure 8, most IRSDA grantees were conducting research in infectious diseases during their FIC funding period. By analyzing the publications published post-IRSDA for a subset of these grantees, it appears they have conducted research on a broad range of scientific topics, from preventing occupational injuries, to identifying barriers in HIV transmission, to developing hookworm vaccines. Table 7 illustrates these articles with a heat map created using the Web of Science Categories. Each row contains visual and numerical representations of that cohort's publication topics in comparison to the IRSDA cohort. The ten categories with the most IRSDA publications are ranked from 1 to

[34] An RCR of 1.0 has received the same number of citations per year as the median NIH-funded paper in the same field.

10 from dark red to light pink, with 1 representing the highest number of publications. These same categories are then ranked and color-coordinated in relation to IRSDA for each of the mentored NIH K Award cohorts. As shown, Infectious Disease and Immunology were the subjects of the most common publications for all four cohorts. Also interesting, the NIH K08 and K23 cohorts share similar top 10 categories to the IRSDA publications (evident from the visual shading from dark red to light pink). However, the NIH K01 only shares 5 (50%) of the top 10 categories; the other categories are either lower in ranking or not even in the top 25 (e.g., parasitology).

Table 7: Publication Web of Science Categories by Ranking by K Program

Web of Science Categories	IRSDA (n=1331)	NIH K01 (n=722)	NIH K08 (n=716)	NIH K23 (n=1411)
INFECTIOUS DISEASES	1	2	1	1
IMMUNOLOGY	2	3	2	2
PUBLIC ENVIRONMENTAL OCCUPATIONAL HEALTH	3	1	5	3
TROPICAL MEDICINE	4	19	3	8
MICROBIOLOGY	5	8	4	4
MULTIDISCIPLINARY SCIENCES	6	6	6	5
PARASITOLOGY	7	N/A	7	12
MEDICINE GENERAL INTERNAL	8	10	9	9
VIROLOGY	9	14	10	7
PEDIATRICS	10	11	11	6

1.12. Subsequent NIH grant support

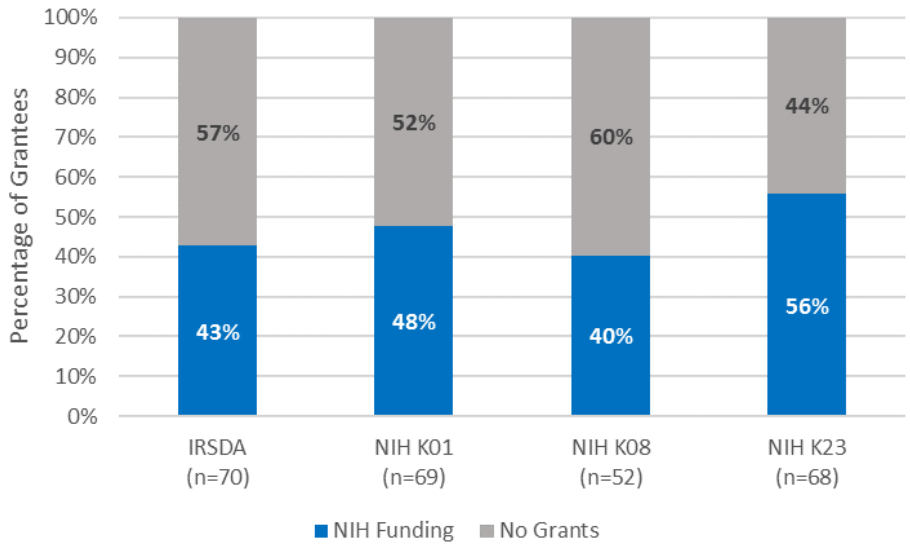
A key objective of any mentored K award mechanism is to prepare early career investigators for a successful independent research career. For many within the biomedical research community, a key indicator of success is a researcher's ability to obtain subsequent independent research funding. The NIH's large research project grant (RPG) funding mechanisms, such as the R01, U01 or P01, are often seen an indicator of scientific independence. However, in the global health research arena, other smaller RPG mechanisms (e.g., R03, R21) and training mechanisms (e.g., D43, R24) can be as influential in building a researcher's career and collaborations in the field. As such, this evaluation looks at a variety of mechanisms, both RPGs and non-RPGs[35], for individuals who have a PI, MPI or co-investigator role on a grant.

[35] RPG awards that were included: DP1, DP2, R01, R03, R15, R21, R34, R41, R44, R56, RC2, P01, P20, U01, U19. Non-RPG awards that were included: D43, G08, K01, K02, K24, M01, P30, R24, R25, T32, T37, U2C, UM1, U54. Loan repayment grants were excluded (i.e. L mechanisms).

1.12.1. By mechanism

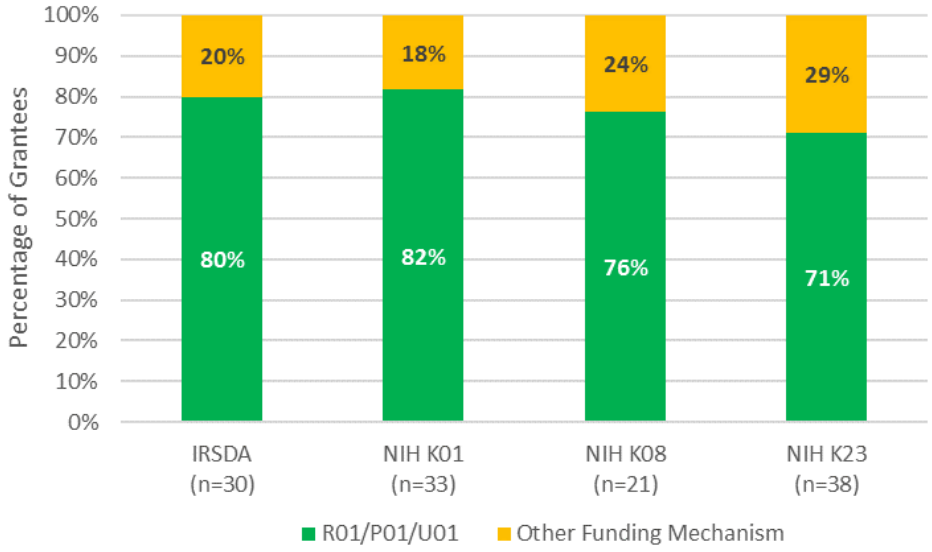
As seen in Figure 12, IRSDA grantees appear comparable to the other three cohorts with respect to their success in competing for subsequent funding starting the FY after their K award was first funded through FY2016. Thirty of the 70 IRSDA grantees in this analysis (43%) went on to receive subsequent NIH funding. Of those 30, 24 (80%) were named as a PI, co-PI or MPI with a funded R01, U01 or P01 (Figure 13). Fifty-seven percent of IRSDA awardees never received subsequent funding (n=40). Overall it appears the NIH K23 perform slightly better than the other cohorts, as a larger percentage of awardees (56%) received subsequent funding and, of those receiving subsequent funding, more (n=27; 82%) received a R01, U01 or P01 mechanism. In addition, the average NIH K23 awardee received three awards since his or her K was awarded, compared to the NIH K01, NIH K08 and IRSDA that averaged two awards (data not shown).

Figure 12: Attainment of Subsequent NIH Funding



While Figure 12 illustrates the percentage of individuals able to obtain funding, it does not provide any further information on the type of mechanisms those individuals receive. As seen in Figure 13, in all K cohorts, around 70-80% of the awardees who successfully competed for subsequent NIH funding received R01/P01/U01 awards. Overall, the majority of IRSDA participants that received subsequent funding in each cohort were successful in obtaining a R01/U01/P01 mechanism.

Figure 13: Funding by Mechanism for those Who Attained Subsequent NIH Grants



It is noteworthy that several K awardees included in this analysis successfully competed for subsequent funding from FIC. Nine IRSDA awardees have received FIC awards after their IRSDA K01 (data not shown). Several NIH K23 awardees in this analysis also went on to receive FIC funding; seven of the NIH K23 awardees are or have been FIC grantees, including two that are very prolific in the FIC and global health community.

Thomas Gaziano, MD
Cost-effective prevention of cardiovascular disease (2004-2012)

The research supported during Thomas Gaziano's IRSDA grant became a stepping stone for future modeling research that is benefitting both the U.S. and LMICs. As an IRSDA grantee, Gaziano focused on developing and evaluating a cost-effective screening tool to assess cardiovascular disease (CVD) risk without the use of laboratory testing.[1] Gaziano tested the validity of a low-cost model that required no blood testing of cholesterol in LMIC populations. The results showed an inexpensive way to accurately predict CVD risk based on age, gender and other factors in South Africa and India. The model's strength was tested beyond these two countries when the Disease Control Priorities Project used it to assess the cost-effectiveness of various CVD interventions across six World Bank regions.

A year before completing the IRSDA program, Gaziano and his U.S. mentor, Milton Weinstein, were awarded a R01 by NHLBI to develop a model that could estimate the health and economic consequences of CVD screening, treatment and prevention in the U.S. and South Africa.[2] Creating a successful model that can predict future disease burdens in both developing and developed settings will allow policy makers to make appropriate policy decisions regarding the prevention, assessment and treatment for CVD.

[1] Gaziano T.A., Opie L.H., & Weinstein M.C. (2006 Aug). Cardiovascular disease prevention with a multidrug regimen in the developing world: a cost-effectiveness analysis. *Lancet*. 368(9536), 679-86.

[2] Pandya A., Sy S., Cho S., Weinstein M.C., & Gaziano T.A. (2015 July 14) Cost-effectiveness of 10-Year Risk Thresholds for Initiation of Statin Therapy for Primary Prevention of Cardiovascular Disease. *JAMA*. 314(2), 142-150.

While 9 IRSDA awardees included in this analysis went on to secure other FIC support, 21 IRSDA awardees were successful in obtaining research support from other ICs, demonstrating that the program has been successful in integrating its awardees into the portfolios of other ICs. These 21 individuals have become competitive scientists supported by other IC's opportunities.

1.12.2. Time until next grant

While Figure 12 shows that 43% of the IRSDA awardees received subsequent NIH funding, it does not provide any further details on the awardee's career progression. An analysis was conducted to determine how long it takes individuals to receive subsequent NIH funding.

As shown in Table 8, it takes IRSDA awardees longer to receive subsequent funding than the other K cohorts. On average, an individual from the mentored NIH K Award cohorts receives his or her first subsequent award[36] 4.7 years after the K was awarded; for the IRSDA individual it takes, on average, 6.0 years. A similar pattern emerges when looking at the time until the first R01/U01/P01: the mentored NIH K Award cohorts average approximately 5 years for all three K cohorts, while the IRSDA cohort, on average, takes 7 years to obtain an R01/U01/P01.

Table 8: Time (in years) Until Subsequent Award, by Mechanism

	IRSDA	NIH K01	NIH K08	NIH K23
Average Time Until First Award	6.0	4.8	4.7	4.7
Average Time Until First R01/U01/P01	7.0	5.0	5.0	5.2

1.13. Global health workforce

In-country collaborations and on-the-ground in-country experience are critical to building independent and long-standing careers in global health research. To better understand retention in global health research, the current employment of awardees in the IRSDA program and mentored NIH K Award cohorts were analyzed. Only individuals whose K awards ended as of July 2016 were included in this part of the analysis.

Of the 46 IRSDA awardees who completed their award at the time this evaluation began, 39 (85%) are currently in a position related to global health. For the NIH K01 and K23 awardees in this cohort, retention in global health is similar; 85% and 82%, respectively, of the awardees have maintained a career related to global health. Sixty-six percent of the NIH K08 cohort have maintained a global health focus in their work.

[36] Time until funding is measured as FY between the first funding FY of the K01 to the first funding FY of the subsequent funding mechanism.

As illustrated in Figure 14, the majority of IRSDA awardees (67%) are conducting either HIV or non-HIV infectious disease research. The majority of the research currently being conducted by IRSDA alumni is focused in the sub-Saharan Africa region (51%) as illustrated in Figure 15.[37]

Figure 14: Current Research Focus of IRSDA Alumni Who are Still Engaged in Global Health Research (n=39)

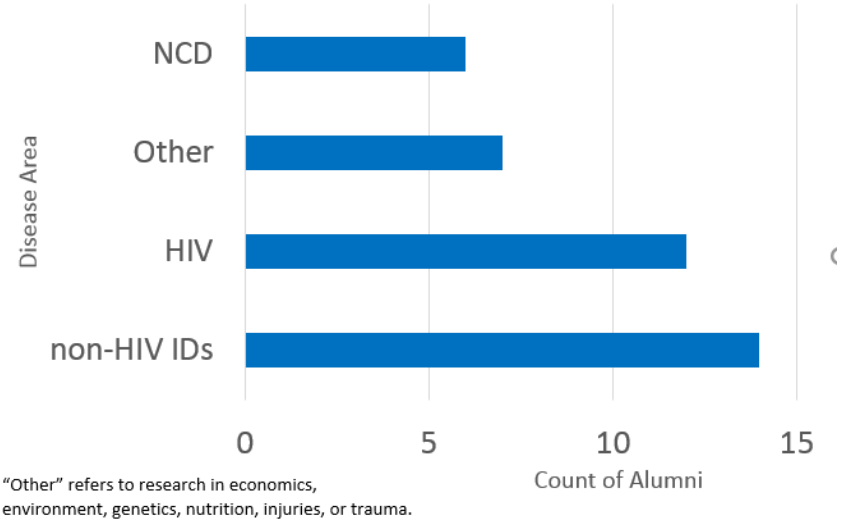
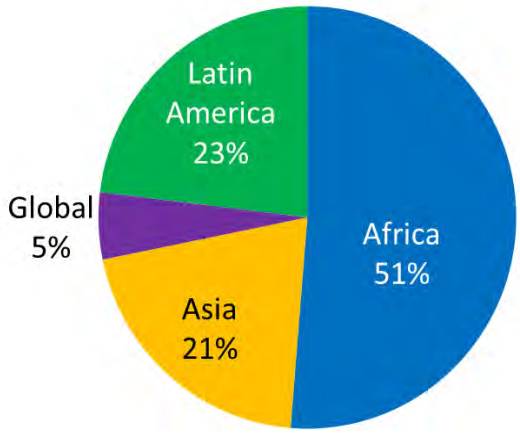


Figure 15: Current Geographical Focus of IRSDA Alumni Who are Still Engaged in Global Health Research (n=39)



[37] An individual working in multiple regions is counted in these regions as a percentage. For example, someone working across three regions, is marked as spending 33% of his time in each region. Global refers to those individuals where the work is not focal to a region but rather generalizable to LMICs or "developing countries."

Joseph David Tucker, MD, PhD
Syphilis social epidemiology in the People's Republic of China (2010-2014)

Photo Credit: Joseph Tucker

Joseph David Tucker has spent the majority of his career focusing on sexual health research in China, and in particular, syphilis. His IRSDA award, which was partially funded by the NIH Office of AIDS Research, allowed Tucker to create the Plum Blossom Project. The Plum Blossom Program, also supported by the World Health Organization, evaluated a routine HIV/syphilis testing program[1] and examined how communities could be involved in testing programs.[2] This work provided evidence that informed China's first ever national syphilis plan.[3] With the resurgence of syphilis in China, the Chinese Ministry of Health created a ten-year National Syphilis Control and Prevention Plan (2010-2020) to reconfigure syphilis screening practices.

Dr. Tucker's research led to publications in the *New England Journal of Medicine*[2] and *The Lancet Infectious Diseases*.[4] In addition, by the final year of his IRSDA award, he had received two NIH R01 grants as PI (1R01AI114310, 1R01A108366) and a D43 training grant as PI (1D43TW009532). He joined the faculty at the University of North Carolina as a tenure-track Assistant Professor in 2012. Building on the findings of his IRSDA award, he also started a research project called SESH (Social Entrepreneurship for Sexual Health, www.seshglobal.org) which uses social entrepreneurship principles to promote sexual health in China.

1. Tucker JD, Yang LG, Yang B, et al. (2011). A twin response to twin epidemics: integrated HIV/syphilis testing at STI clinics in South China. *Journal of Acquired Immune Deficiency Syndromes*. 57(5): e106-11.
2. Tucker JD, Chen XS, Peeling RW. (2010). Syphilis and social upheaval in China. *New England Journal of Medicine*. 362(18): 1658-61.
3. Tucker JD, Cohen MS. (2011). China's syphilis epidemic: epidemiology, proximate determinants of spread, and control responses. *Current Opinions in Infectious Disease*. 24(1): 50-5.
4. Tucker JD, Bu J, Brown LB, Yin YP, Chen XS, Cohen MS. (2010). Accelerating worldwide syphilis screening through rapid testing: a systematic review. *Lancet Infectious Diseases*. 10(6): 381-6.

Conclusions

The FIC IRSDA program has successfully developed a cadre of productive, independent global health researchers. As demonstrated in this review, the IRSDA grantees are advancing the global health research agenda in over 33 countries in an array of biomedical and behavioral science fields.

1.14. IRSDA program's niche

The IRSDA program plays an important role in the overall NIH investment in supporting early career scientists in that it provides an opportunity for early career investigators to immerse themselves in global health research. The program supplements already robust mentored Career Development (K) programs at the NIH by offering a targeted global health focus. The steady increase of global health-related grants awarded through the mentored NIH K

mechanisms (K01, K08, K23) over the past 15 years (Figure 10), suggests there is a significant interest in global health research among early career academics. Indeed, the IRSDA program has seen a growth in applications since inception (Figure 3). And even with the increase in awards supporting global health research through other NIH K mechanisms, the IRSDA program has received a steady flow of over 25 applications per year over the past three years, numbers that have only been achieved one other time (2006).

Given the landscape of funding opportunities for early career scientists at the NIH and through other funders (Section 2.3) it appears that those applying to the IRSDA program are looking for the unique experience offered by the IRSDA program – conducting global health research in an LMIC setting under the mentorship of both a U.S. and LMIC mentor. While some potential applicants may find the in-country time and dual mentorship requirements burdensome, the growth in applications suggests that some applicants find benefits in these requirements. From informal discussions with both applicants and awardees, the significant in-country requirement of the IRSDA program provides individuals leverage with their departments and institutions in negotiating significant time away from their home institutions. Although there are other NIH K mechanisms that allow the recipient to spend time at a foreign site, without the explicit requirement stated in the FOA, recipients may find it difficult to devote the time needed at these sites given other obligations at the home institution.

The IRSDA program has received some support from ICs in the past, either by co-funding awards or participating in FOAs; however, there has not been as much support in recent years with the notable exception of NCI, which has been formally partnering on the program since FY2016 and fully funding a FY2016 award. This may be because the Parent K01 FOA, which includes many ICs, allows foreign components and because many ICs have IC-specific FOAs that allow global health. Six of the ICs, that currently or formerly supported the IRSDA program, have IC-specific K01s. For example, NCI, the current IRSDA funding partner, has a K01. Given the number of institutes that have their own IC-specific K01 FOAs, it may be inferred that the IRSDA program is not fulfilling a programmatic gap for these ICs; instead, the IRSDA program provides another opportunity for these ICs to expand their portfolio globally.

The IRSDA program has a truly global reach. While some NIH global health programs target specific regions (e.g., Medical Education Partnership Initiative and Human Heredity and Health in Africa), the IRSDA program has historically supported researchers working in any LMIC. The program aims to build research careers. Restricting the program to particular regions or scientific topics would limit FIC's opportunities to support rising stars in other areas. That said, a key feature of the program is its ability to foster robust international research collaborations. If

FIC identifies needs to seed collaborations in poorly represented areas, NIH Guide Notices could be issued to encourage projects in those scientific fields or geographic regions. It is also important to note that although FIC's scientifically and geographically diverse K awards have historically been all managed by one program officer, management has recently shifted so that awards are now assigned to the FIC PO with the most relevant portfolio. The goal of this change is to better integrate awardees with existing relevant programs and networks at FIC and across the NIH.

Building a robust global health workforce that can function across cultures and borders to solve today's health problems requires accomplished independent researchers around the world. By providing protected time to conduct mentored research in LMICs, the IRSDA program has been successful in launching the independent research careers of U.S. citizens or permanent residents (like almost all NIH Career Development (K) Awards). Until recently, the NIH did not offer such opportunities for LMIC investigators. In 2016 FIC awarded the first *Emerging Global Leader Awards*, using the new K43 funding mechanism, to individuals from LMICs working at LMIC institutions. Modeled on the successful approach of the IRSDA program, the *Emerging Global Leader Award* provides support for salary, a mentored research project and career development activities. Several NIH components are partnering with FIC on this new program, including NCI, National Human Genome Research Institute, National Institute of Dental and Craniofacial Research, NIEHS, National Institute of Mental Health (NIMH), National Institute of Neurological Disorders and Stroke, and the Office of Research on Women's Health (ORWH). In the inaugural year (2016) of the program, FIC issued seven awards and received co-funding from ORWH, Office of Behavioral and Social Sciences Research and NIMH. The level of interest reflected in this long list of partners indicates that the *Emerging Global Leader Award* program is filling a gap across the NIH by supporting LMIC investigators.

The *Emerging Global Leader Program* complements the IRSDA program and other FIC-supported programs that target earlier points in the career pipeline for both U.S. and LMIC investigators. Together, these two mentored career development programs offered by FIC seek to strengthen the global health research community by developing independent researchers, enhancing the research capacity of LMIC institutions, and fostering long-term international research collaborations.

Acronyms

ARV= Antiretroviral
CY= Council Year
CVD= Cardiovascular Disease
FACTS= Foreign Award and Component Tracking System
FOA= Funding Opportunity Announcement
FIC= Fogarty International Center
FY= Fiscal Year
HIC= High Income Country
HIV= Human Immunodeficiency Virus
HHMI= Howard Hughes Medical Institute
HHS= Health and Human Services
IC= NIH Institutes/Centers
ID= Infectious Disease
IMPACII= NIH Information for Management, Planning, Analysis, and Coordination
IRFP= International Research Fellowship Program
IRSDA= International Research Scientist Development Award
IUD= Intrauterine Contraceptive Device
LMIC= Low- or Middle- Income Country
MAL-ED= Malnutrition & Enteric Infections: Consequences for Child Health & Development Program
MD= Doctor of Medicine
MPI= Multiple Principle Investigator
NCI= National Cancer Institute
NEJM= *New England Journal of Medicine*
NHLBI= National Heart, Lung, and Blood Institute
NIA= National Institute on Aging
NIAID= National Institute of Allergy and Infectious Diseases
NICHD= *Eunice Kennedy Shriver* National Institute of Child Health and Human Development
NIEHS= National Institute of Environmental Health Sciences
NIGMS= National Institute of General Medical Sciences
NIH= National Institutes of Health
NIMHD= National Institute on Minority Health and Health Disparities
NINR= National Institute of Nursing Research
NLM= National Library of Medicine
NSF= National Science Foundation
ORWH= Office of Research on Women's Health
PEFPAR= The U.S. President's Emergency Plan for AIDS Relief
PhD= Doctor of Philosophy
PI= Principal Investigator

PO= Program Officer
RCDC= Research, Condition, and Disease Categorization
RCR= Relative Citation Rate
RPG= Research Project Grant
SIF= Senior International Fellowship
SSA= Sub-Saharan Africa
U.S.= United States

Appendices

Appendix A: Comparison and Description of K Mechanisms

	MENTORED RESEARCH SCIENTIST DEVELOPMENT AWARD (K01)	MENTORED CLINICAL SCIENTIST DEVELOPMENT AWARD (K08)	MENTORED PATIENT ORIENTED RESEARCH CAREER DEVELOPMENT AWARD (K23)
PURPOSE	The K01 mechanism provides candidates with "protected time" to develop an independent research career in the biomedical, behavioral or clinical sciences. The K01 requires three to five years of commitment under the guidance of an experienced mentor. The expectation is that through this sustained period of mentorship and research development and training, awardees will launch independent research careers.	The K08 program supports didactic study and mentored research for individuals with clinical doctoral degrees. Awardees are afforded "protected time" and an intensive, mentored research career development experience in biomedical or behavioral research, including translational research. This mechanism can be used by individuals interested in clinical research, but not patient-oriented research (that is reserved for the K23).	The K23 mechanism supports scientists working in patient oriented research (POR) areas as they develop an independent research career. POR is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator directly interacts with human subjects. This mechanism is appropriate with individuals who are interested in the patient-oriented research side of biomedical research.
TARGET DEGREE	Research or health professional doctorate	Clinical doctorate	Health professional doctorate
AWARD DURATION	3-5 years	3-5 years	3-5 years
NIH PARENT FOA	PA-16-190	PA-16-191	PA-16-198

Appendix B: IRSDA Awardees and Projects by FY (n=75)

Awardee Name	Grant Number	Project Title	FYs of Project	Country of Focus
Kathryn Deriemer	K01TW000001	Molecular vs Conventional Assessment of TB Transmission	1999-2005	Mexico
Daniel Fitzgerald	K01TW000002	HIV Host Resistance Factors // Informed Consent in Developing Country Research (Renewal)	1999-2005	Haiti
Nathan Wolfe	K01TW000003	The Emergence of HIV Genetic Diversity in Cameroon // Retrovirus Emergence among Hunters in Central Africa (Renewal)	1999-2007	Cameroon
Matthew Dorsey	K01TW000007	Clinical and Molecular Studies of Drug-Resistant Malaria	1999-2006	Uganda
Jeffrey Bethony	K01TW000009	Host Genetic Correlates of Helminthic Coinfection	2000-2006	Brazil
Ann Digirolamo	K01TW000013	Effects of Caregiving on Child Malnutrition	2000-2007	Mexico
James Kublin	K01TW000014	Impact of Ts Prophylaxis on Antifolate Resistant Malaria	2000-2002	Malawi
Donnie McGrath	K01TW000016	Cost-Effectiveness Analysis of Micronutrient Supplementation	2000-2004	South Africa
Elizabeth Stringer	K01TW005708	Career Development Award in International Women's Health	2001-2007	Zambia
Jin Shin	K01TW005716	Family-Centered Early Intervention Program for Children	2002-2005	Vietnam
Margaret Kosek	K01TW005717	Epidemiology of Shigellosis in the Peruvian Amazon	2001-2008	Peru

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Lia C. H. Fernald	K01TW006077	The Effect of Mexican Anti-Poverty Program on Stress	2002-2005	Mexico
Barbara Lohman Payne	K01TW006080	CTL responses in HIV-1 infected infants	2002-2007	Kenya
Bouke C. De Jong	K01TW006083	Mycobacterial Determinants of Cavitation & Transmission // Genomic and immunological comparisons of M africanum and M tuberculosis (Renewal)	2002-2010	Gambia
Sarah Barber	K01TW006084	The Mediating Influence of Care Quality on Health	2003-2007	Mexico
Dharambir Sanghera	K01TW006087	Indo-US Collaboration in Genomic Studies on Diabetes	2002-2011	India
Li-Wei Chao	K01TW006658	Economic Analysis of Funerals in South Africa & Malawi	2003-2008	South Africa, Malawi
Erica Lynn Dueger	K01TW006659	Rapid Sampling for Resistant S. Pneumonaie in Guatemala	2003-2008	Guatemala
Benjamin Chi	K01TW006670	A Training Program in International Women's Health	2004-2010	Zambia
Mina Hosseinipour	K01TW006677	Effect of Parasitic Infection of HIV Diseases in Malawi	2003-2007	Malawi
Nalini Tarakeshwar	K01TW007136	Religion, Culture, and HIV Secondary Prevention in India	2004-2007	India
Thomas Gaziano	K01TW007141	Cost-effective prevention of cardiovascular disease // Cost-effective prevention of cardiovascular disease in developing countries (Renewal)	2004-2013	India, South Africa

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Serena Koenig	K01TW007142	Health Outcomes/Cost of Early vs Delayed ART in Haiti // Cost-effectiveness of Early vs. Delayed Antiretroviral Therapy in Haiti (Renewal)	2004-2012	Haiti, Georgia
Regina Larocque	K01TW007144	Host-pathogen interaction in Vibrio cholerae infection // Identification of human gene polymorphisms related to Vibrio cholerae infection (Renewal)	2009-2011	Bangladesh
Heena Brahmbhatt	K01TW007403	Morbidity/Mortality and Disability in Children Study	2005-2010	Uganda
Theresa Ochoa	K01TW007405	Role of virulence heterogeneity in acute and persistent EPEC diarrhea	2006-2010	Peru
Catherine Todd	K01TW007408	Blood-borne infection screening in an Afghan antenatal population	2005-2010	Afghanistan
Jason Harris	K01TW007409	The role of TcpA in cholera immunity and vaccination // T-cell immune responses to Vibrio cholerae infection (Renewal)	2005-2013	Bangladesh
William Carr	K01TW007793	AIDS-Restrictive Innate Immune Mechanisms	2007-2012	South Africa
Marcy Balunas	K01TW008002	Tropical Disease Drug Discovery from Marine Cyanobacteria in Panama	2009-2012	Panama
David Martin Murdoch	K01TW008005	The Role of Immune Reconstitution Inflammatory Syndrome (IRIS) in Pulmonary Tuber	2008-2012	South Africa

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Gita Sinha	K01TW008006	Utilization of Decentralized HIV Clinical Services in Rural Maharashtra, India	2008-2011	India
Omar Galarraga	K01TW008016	Conditional Cash Transfers to Prevent Sexually Transmitted Infections in Mexico	2008-2012	Mexico
Andres Villaveces	K01TW008194	Pedestrian Injuries and the Built Environment in Colombia	2009-2013	Colombia
Karen Huyck	K01TW008199	Hairdressers Health Study	2009-2010	Brazil
Joseph David Tucker	K01TW008200	Syphilis social epidemiology in the Peoples Republic of China	2010-2014	China
Sylvia Irene Becker-Dreps	K01TW008401	Preliminary Effectiveness Analysis of Universal Rotavirus Immunization, Nicaragua	2009-2013	Nicaragua
Robert Choi	K01TW008406	The role of HIV-1 neutralizing mucosal IgA and lgG and genital shedding of HIV-1	2010-2013	Kenya
Gerald Bloomfield	K01TW008407	Risk Factors for Atherosclerosis among Patients with Heart Failure in Kenya	2011-2015	Kenya
Phillip Taddei	K01TW008409	Radiotherapy outcomes for children in developing versus developed countries	2010-2015	Lebanon
Valerie Harder	K01TW008410	Evidence-based mental health assessment and treatment for HIV prevention in Kenya	2010-2014	Kenya
Valerie Andrea Paz-Soldan	K01TW008414	Examining Human Behavior in Dengue Prevention Efforts in Iquitos, Peru	2010-2015	Peru

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Jody Rae Lori	K01TW008763	New Avenues to Increase the Use of Skilled Birth Attendants in Ghana	2011-2017	Ghana
Ana-Claire Meyer	K01TW008764	Treatment of HIV-Associated Cognitive Impairment	2011-2017	Kenya
Matthew Harrison Bonds	K01TW008773	The economic impacts of community-based integrated health care systems in rural Rwanda	2010-2016	Rwanda
Lisa Reimer	K01TW008778	Malaria transmission potential of the Anopheles punctutatus species complex	2011-2013	Papua New Guinea
Angela Bayer	K01TW009206	Structural Behavioral HIV Prevention for Male Sex Workers in Peru	2012-2017	Peru
Adam Carl Levine	K01TW009208	Assessment of Dehydration in Children with Diarrhea in Resource-Limited Settings	2012-2018	Bangladesh, Rwanda
Karen Jacobson	K01TW009213	Geospatial clustering and molecular and social epidemiology of drug resistant TB	2013-2017	South Africa
Rajesh Vedanthan	K01TW009218	Nurse Management of Hypertension in Rural Western Kenya	2011-2017	Kenya
Jay Paul Graham	K01TW009484	A Study of Enteropathogenic Bacteria Transmitted from Animals to Humans	2014-2018	Ecuador
Jonathan Charles Samuel	K01TW009486	Best Management of Sigmoid Volvulus: a Prospective Randomized Trial	2012-2014	Malawi

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Satish Gopal	K01TW009488	Developing a clinical cohort of histopathologically characterized lymphoma	2012-2017	Malawi
Maria Hyoun Kim	K01TW009644	Improving prevention of mother-to-child HIV transmission outcomes in Malawi	2013-2018	Malawi
Miriam George	K01TW009648	Testing a refugee family dynamics model: A study with Sri Lankan Tamils	2013-2018	Sri Lanka
Cristian Ioan Meghea	K01TW009654	Family Smoking Cessation in Romania Using Pregnancy as a Window of Opportunity	2015-2020	Romania
Jennifer Tang	K01TW009657	Evaluation of the immunologic and genital tract changes among Malawian women	2013-2017	Malawi
Tamora Callands	K01TW009660	Promoting Mental and Sexual Health Among Young Pregnant Women in Liberia	2013-2018	Liberia
Ameeta Shivdas Kalokhe	K01TW009664	Primary prevention of intimate partner violence in India	2013-2018	India
Angela Arenas	K01TW009981	Use of the goat model to test human Brucella vaccines in Argentina	2014-2019	Argentina
Dorothy Dow	K01TW009985	Integrating Mental Health into a HIV Clinic to Improve Outcomes in Tanzanian Youth	2015-2020	Tanzania
Carrie Waterman	K01TW009987	Reducing the burden of chronic inflammation through dietary integration of Moringa oleifera	2015-2020	Kenya

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Eric Douglass Mccollum	K01TW009988	Pulse oximetry for childhood pneumonia in rural Bangladesh	2014-2019	Bangladesh
Evelyn Hsieh	K01TW009995	Risk for Bone Loss Among Individuals with HIV in a Resource-Limited Environment	2015-2020	China
Khandaker Talat Islam	K01TW009996	Effect of Cook Stove Exposure on Adverse Pregnancy Outcomes and Infant ALRI	2015-2020	Bangladesh
Michael Jeffrey Vinikoor	K01TW009998	Impact of antiretroviral therapy on liver fibrosis in Zambian HIV/HBV patients	2015-2018	Zambia
Catherine Staton	K01TW010000	Addressing High Risk Alcohol Use Amongst Injury Patients in an Emergency Department in Tanzania	2015-2019	Tanzania
Joshua Rhein	K01TW010268	Improving Outcomes of HIV-Associated Cryptococcosis in Resource-Limited Settings	2016-2021	Uganda
Tomi Akinyemiju	K01TW010271	Metabolic Syndrome and Epigenetic Markers of Breast Cancer in Nigerian Women	2016-2021	Nigeria
Michael Emmanuel Herce	K01TW010272	Understanding Longitudinal Clinical Outcomes and Post-release Retention in Care among HIV-infected Prisoners in Lusaka, Zambia	2015-2019	Zambia
Tierra Smiley Evans	K01TW010279	Epidemiology of zoonotic viruses in forest communities in a key biodiversity area of rural Myanmar	2016-2021	Burma (Myanmar)

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Robert Peck	K01TW010281	Hypertension in HIV-Infected Tanzanians: Time Course and Pathogenesis	2015-2020	Tanzania
Adel Driss	K01TW010282	Role of MicroRNAs in malaria and sickle cell severity	2016-2021	Ghana
Jon Andrew Dykens	K01TW010494	Reducing barriers and sustaining utilization of a cervical cancer screening program in rural Senegal	2016-2021	Senegal
Amy Bei	K01TW010496	Employing genetic and genomic surveillance to reveal mechanisms of malaria parasite persistence	2016-2021	Senegal

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