

## **Outline**

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### **1. Career Development Program Summary: Abstract and Overview**

The Wilmer Institute, Johns Hopkins is recognized as a premier ophthalmic clinical, research, and teaching center in the United States, having trained more clinician-scientists through the K award mechanisms than any other institution (K08, K11, K12, and K23). Our mentored scholars have an unsurpassed record of subsequent and ongoing NIH R01 funding and most of them maintain full-time faculty teaching and research roles as leaders of multidisciplinary teams. Wilmer's 135 full time faculty members are first in awarded federal vision research dollars (\$19M direct costs, fiscal 2014). The K12 program at Wilmer was the first to be funded by NEI and the first to be awarded a second 5 year funding period. We now request a renewal of 5 years, based on the high rate at which our clinician—scientist scholars have transitioned from K12 to K08/K23 status and their subsequent successful competition for grant funding. Of those whose K awards were completed at Wilmer more than 2 years ago, 19 of 29 (66%) have achieved NIH funding as Principal Investigators of R series grants, substantially exceeding the recent published success rate of 13%<sup>1</sup> for K awardees (see Track Record of Wilmer Awardees, p. 7). One past scholar is Dean of an Optometry College and 3 were selected as Chairpersons of Departments of Ophthalmology, while 72% are full-time faculty members of medical or optometry schools.

As demonstrated by these outcomes, we are successfully generating clinician—scientists for the vision research community through multidisciplinary research training programs that add new approaches to the understanding of the epidemiology, pathogenesis, and treatment of visual disorders. Each scholar's program has a multiperson, integrated faculty mentor group, exemplifying the diversity of expertise available among our research faculty in the Johns Hopkins School of Medicine and Bloomberg

School of Public Health. Research areas of study (detailed below) have included all of the ocular disease areas that represent high priorities for the National Plan of the National Eye Institute, including ocular genetics, molecular biology, therapeutics, bioengineering, computer-based methodology, and behavioral/quality of life effects produced by clinical conditions. Several past scholars have attained masters and doctoral degrees during their mentored training.

Editorials that decry the difficulties encountered by clinician-scientists in the present research environment have documented the increasingly smaller proportion who successfully compete for federal research support<sup>2,3,4,5,6</sup>. Wilmer has shown that this trend can be reversed at institutions with active recruitment, diverse faculty mentor skills, detailed attention to scholar training programs, and departmental financial support early in the career of the clinician—scientist.

We propose to continue support of one new K12 scholar per year, with each scholar spending an initial 1-2 years under the K12 mechanism, then making a transition to an individual K08 or K23. They are appointed Assistant Professor with commensurate salary and benefits. Each multidisciplinary research training experience includes didactic instruction appropriate to the area being studied, research experience with a mentor team, and an environment that nurtures the requisite skills in human research ethics and methodology, along with practical skills in achieving funding and collaboration with appropriate peers.

## **2. Program Evaluation: Track Record of Past and Present Awardees**

For 20 years, the Wilmer Institute has carried out clinician-scientist training under NIH-funded K awards supplemented by private funds, foundation support, and departmental funding. The track record of these programs illustrates our successful faculty commitment to this process, as exemplified in the following Table. Our clinician—scientist (K award) program trained 30 persons from 1987 to 2014. In addition, 3 persons are presently engaged in individual K awards, and 1 has a K award through our K12 grant.

The Wilmer K12 Program Chair and Committee regularly review the effectiveness of the program through the twice yearly review of each active candidate in personal interviews, with written comments and recommendations to mentees and mentors. Furthermore, the Committee evaluates the program by assessing:

- a. the number of potential scholars who contact us and are counseled:
  - During 2014-15, 10 individuals contacted the PI and began the process of constructing a program. Four of these made full K applications for the available position on the K12 and all 4 submitted either K08 or K23 individual proposals to NIH. We have 4 applicants waiting for slots on the renewal period of this grant.
- b. the quality of training exemplified in these reports
  - An example of the training plan for K12/now K08 scholar Ian Pitha is attached (Appendix 1: K program for Ian Pitha.pdf)
- c. the output of peer-reviewed publications as these appear in later years of K training
  - The peer-reviewed publications of Wilmer Scholars is included (Appendix 2 Recent Publications of Wilmer K Scholars.pdf)

- d. the successful transition from the K12 to K08/K23 programs:
  - Of the last 5 K12 appointed scholars, 3 have made the transition to K08 and the other two have pending K08/K23 applications.
- e. the successful acquisition of peer-reviewed research funding—particularly NIH grants
  - 20 of 30 scholars have achieved funding through at least one NIH R series grant or federal contract as principal investigator (see Track Record table below)
- f. the successful entry into full-time academic positions as clinician—scientists
  - Of 30 scholars, 26 have entered and remained in faculty positions within vision research institutions or Federal agencies (see Track Record Table below)
- g. the responses of past trainees to a questionnaire about the Wilmer K12 program
  - The responses from 11 present and past scholars show substantial benefit from the program, along with suggested improvements (Appendix 3 Questionnaire Responses by K Scholars.pdf).

**Track Record of Past Wilmer K11, K12, K08 and K23 Awardees, 1987 to Present**

**This listing includes those whose programs were entirely on the K12, those who began on the K12 and transitioned to a K08/K23, and those whose initial award was K08, K11, or K23**

<b>Name</b>	<b>K award type</b>	<b>K training years</b>	<b>Present Position</b>
Richard Semba MD PhD Grants: R01 HD32247; R01AI41956; R01 DA15022; R03 NR09478, among others since	K11 EY 00286	1987-92	Professor, Johns Hopkins
Jonathan Javitt MD	K11 EY 00285	1987-92	Faculty, Johns Hopkins
Charles Weitz MD PhD Grants: R01 MH059943; R03 EY013824; R01 NS043491	K11 EY 00289	1988-93	Assoc Professor, Harvard
Don Zack MD PhD Grants: R01EY009769; R01EY013357; R21EY017155; U10EY010364, presently 2 R's	K11 EY 00297	1988-93	Professor, Johns Hopkins
Stuart McKinnon MD PhD Grants: R01EY016516	K08 EY 00361	1996-2001	Assoc Prof, Duke University
David Friedman MD PhD Grants: R01EY013460	K23 EY 00358	1996-2001	Professor, Johns Hopkins
Shannath Merbs MD PhD Grants: R01EY09769, R01EY020406, R01EY023188	K08 EY 00378	1996-2001	Professor, Johns Hopkins
Patrick Tong MD PhD Grants: R03EY13744	K08 EY 00362	1997-2002	private practice
Elia Duh MD PhD Grants: R03EY014136, R01EY018138	K08 EY 00398	1998-2003	Assoc Prof, Johns Hopkins
John Kempen MD PhD Grants: R01EY014943, R01FD003910	K23 EY 00386	1998-2003	Professor, U Pennsylvania

Nathan Congdon MD	K23 EY 00388	1998-2003	Chinese Univ. Hong Kong
Grants: R01AG018730			
Mark Walker MD	K08 EY 00400	1998-2003	former Asst Prof, J. Hopkins
Grants: RO1 HD040289			
Kang Zhang MD PhD	K08 EY 00401	1998-2003	Professor, UC San Diego
Grants:R01EY014428, R01EY014448, R01EY024134, R01CA184097, R01EY018660, R01EY021374			
Ronald Farkas MD PhD	K08 EY 00416	2000-2005	Staff Scientist, F.D.A.
Peter Gehlbach MD PhD	K08 EY 13420	2001-2006	Assoc Prof, Johns Hopkins
Grants: R01 EY007969, R01EY021540			
Quan Nguyen MD PhD	K23 EY 13552	2001-2006	Chair Ophth, U of Nebraska
Grants: R01EY017577-01			
John Kerrison MD	K08 EY 13946	2002-2005	private practice
Elizabeth Bradley MD PhD	K23 013844	2002-2007	Asst Professor, Mayo Clinic
Neal Adams MD PhD	K12 then K08 015191	2002-2007	Chair, Ophthal, Texas Tech
Jennifer Thorne MD PhD	K23 013707-05	2002-2007	Professor, Johns Hopkins
Grants: RO1EY014943, U10EY014655, U10EY08052			
Roy Chuck MD PhD	K08 000412	2002-2007	Chair, Ophth, Albert Einstein
Howard Ying MD PhD	K12 Wilmer	2004—2008	Assoc Prof, Johns Hopkins
Grants: R01EY019347			
Albert Jun MD PhD	K08 015523	2005-2009	Professor, Johns Hopkins
Grants: R01EY019874			
Michael Boland MD PhD	K12 Wilmer	2005—2009	Assoc Prof, Johns Hopkins
Grants: AHRQ, Contract 290-2007-10061			
Jennifer Sung MD PhD	K12 Wilmer	2006—2010	private practice
Lydia Giardano OD	K12 Wilmer	2006—2008	private practice
Pradeep Ramulu MD PhD	K12 Wilmer then K23	2007—2011	Assoc Prof, Johns Hopkins
Grants: R01EY022976			
Ava (Kiser) Bittner OD	K23 018356	2008-2012	Asst Prof, Nova SE Univ
Grants: R44EY018990, R21EY023720			

Lori Grover OD PhD	K23 017615	2008-2012	Dean, Penna College Optometry
Gillian Shaw DVM PhD	K12 Wilmer	2011—2014	continued training, U. Wisc

**K programs still ongoing**

Akrit Sodhi MD PhD	K12 Wilmer now K08	2009—present	Asst Prof, Johns Hopkins
Derek Welsbie MD PhD	K12 Wilmer now K08 Grants: R21EY022769	2010—present	Asst Prof, Johns Hopkins
Kati Ebrahimi MD	K12 Wilmer	2013—present	Res Assoc, Johns Hopkins
Ian Pitha MD PhD	K12 Wilmer now K08	2014--present	Asst Prof, Johns Hopkins
Alan Eghrari MD PhD	K12 Wilmer	2014—present	Asst Prof, Johns Hopkins

**3. Recruitment of Scholars**

a. **Problems faced by potential scholars:** Many potential candidates have no real information about this career path and come from institutions where there are no mentors who exemplify the clinician-scientist role to which they aspire. Furthermore, while they have a general idea of the research topic that might best suit their training needs, they do not know the specific areas of research of each senior faculty—potential mentor. Those who have only modest exposure to past research are not certain that their choice of such a program will be in their interest. The application process—a first NIH-type format—seems daunting. To overcome these roadblocks, we use a variety of methods to identify, inform, and recruit candidates. Our program benefits from our reputation as a successful training institution. We have a faculty with a broad range of experience as clinician—scientists. The K12 program provides to each potential applicant a comprehensive view of all training possible here. Examples of past K applications are provided to the potential scholar to show how the process works.

b. **The initial interaction with scholars:** The biggest barrier to attracting candidates continues to be the lack of visibility of clinician—scientist training programs at the clinical training programs nationally. While there are a few Departments of Ophthalmology with past K training records, most have none. Thus, there are no mentors to provide a forward view of this career path. As a result, the potential candidates often view the role of clinician—scientist as either impossibly taxing in terms of their capability, or, they are simply unaware of how the K program can make this a possible career for them. Many are worried that the requirement of 75% or more time for research training will cause an erosion of their clinical skills. In our first interaction with every possible candidate, we deal immediately with these issues and point out how past successful (now senior) faculty have dealt with them.

c. **Advertising the K program:** To make our program known, we have used every available means.

- We have partnered with the other K12 programs in having posters at ARVO. We have used national advertisements in journals and research organization job sites.
- We have purchased advertisements aimed at all major clinical training programs in ophthalmology, optometry, and visual sciences and in national journals with a broad audience, as well as major journals related to visual science and clinical ophthalmology. Past advertisements were placed in American Journal of Ophthalmology, Ophthalmology, Archives of Ophthalmology, and Investigative Ophthalmology and Visual Science, and the ARVO jobs listing.
- The Web Site of the Wilmer Institute draws frequent inquiries to our program, and the K program is featured on its home page prominently, with videos from past K awardees ([http://www.hopkinsmedicine.org/wilmer/glaucoma\\_center\\_excellence/training\\_gce.html](http://www.hopkinsmedicine.org/wilmer/glaucoma_center_excellence/training_gce.html) and [http://www.hopkinsmedicine.org/wilmer/education/clinical\\_scientist1.html](http://www.hopkinsmedicine.org/wilmer/education/clinical_scientist1.html)).
- A description and application materials were made available for electronic application from the Wilmer Institute website. <http://www.hopkinsmedicine.org/wilmer/education/residency/training/ClinicianScientistTrainingProgramWebPage.pdf>
- Each of the faculty members of the K12 Committee includes reference to clinician--scientist training in national lectures, especially at institutions that have a higher proportion of minorities.
- Dr. Quigley instituted a special interest group meeting that is now held annually at ARVO to provide information to potential clinician-scientists. He has attended that session to give information on the K program and on Wilmer's program each year.
- An editorial was written for Ophthalmology Times on availability and need for clinician—scientist training
- An email was sent to every resident in Ophthalmology in the United States through their Chairpersons pointing to the availability of the K program in general and Wilmer's program specifically.

**d. The personal telephone call from the P.I.:** All inquiries for the K program are directly to the P.I. Harry Quigley, who arranges a telephone or Skype call or an interview in person. Dr. Quigley has 30 years' experience as PI of training grants, including a T32 training grant and 11 years as head of the K12 Wilmer program since its inception. By having Dr. Quigley serve as a centralized departmental person for contact, the scholars know the key person to call to begin a daunting process. Furthermore, this telephone call allows the candidates to learn quickly the overview of the program, its breadth, how they can begin the process of identifying a subject for training, research methods that they wish to learn, and how to contact faculty who could serve as potential mentors. In some cases, these initial contacts with faculty by the candidate are not fruitful, and other faculty members are suggested as possible mentors by the PI or K12 committee. In other cases, the candidate is referred to a different institution that has a K12 program with more appropriate faculty mentors for the needs of that candidate. We have found that the initial barrier of learning how to start a K program is a major reason that fewer than the desired number of candidates begins the process. Written material (or the web site address) is sent to each inquiring candidate on how to apply for our program. We have had an increasing number of annual applications (4 applications for the single position open in our July 1, 2014 slot). In addition to those

from whom we receive full K applications, we discuss the program at length and plan potential programs with many more candidates. Each of these inquiring candidates is linked to one or more of the K12 mentor faculty, choosing them as appropriate for the project topic selected by the candidate.

As can be seen from the prior candidates whom we have accepted for K training, we have had MD, MD—PhD, OD, OD—PhD, and DVM degree holders. Every candidate had some prior research experience, either in clinical or laboratory work, or both. Those with a PhD naturally had undergone more formal and extended training in a specific lab for their doctoral work. Both those candidates who have applied for a position (but were not accepted), and those who were accepted, were interviewed with regard to their personal intention to make research a life-long activity. Recommendations in written form and by telephone/in person are conducted with senior faculty members who have previously interacted with each candidate to determine their capability as evidence so far and their potential for long-term research.

**e. Selecting a lead mentor and mentor group:** Each potential applicant is given stepwise instruction in generating a training mentor group and a program of their interest, with hands-on assistance in the writing of a full K award proposal that must be submitted to the K12 committee for the competition. Personal interaction with the mentor group ahead of application gives the best chance for selection. Mentor groups consisting of faculty outside the ophthalmology department are often favored in our K12, as they add intellectual content both to the scholar's program and to Wilmer's portfolio of research areas. This diversity of mentors produces programs consisting of basic science at the cutting edge and translational value. The committee prefers to meet in person with potential applicants, either by their traveling to Baltimore, or by meeting at national research meetings.

**f. Writing the K12 proposal application:** Each scholar applying for our K12 must submit to us a full K08 or K23 application, ready for submission as an individual proposal. A candidate goes through the steps of finding a potential mentor group, identifies training areas needed, lists courses to be taken in the didactic portion of training, and writes the full application. This allows candidates to determine their level of interest and to ascertain the availability of courses, programs, research projects, and collaborative mentors. Simultaneously, these preliminary interactions allow faculty to assess the likelihood that the candidate will be an appropriate match for training. The committee members read each application and provide a written statement on strengths and weaknesses of the training plan, including the following elements: 1) evaluation of candidate as a potential clinician—scientist; 2) appropriateness of subject matter for training; 3) strength and diversity of mentor group to provide training; 4) facilities and equipment availability; 5) importance of subject area to vision research; 6) likelihood of funding later as an individual K08 or K23. Based on these criteria, an overall score is given 1 (best) through 10 and the scores of the voting committee members are averaged to award available positions. The review process and suggestions made are incorporated into each candidate's K08 or K23 application. Thus, whether they are selected for the K12 or not, they each submit an individual K proposal to the CSR/NIH. It is our opinion that the pre-review by the committee has led to a high rate of funding for these individual K awards, as our experienced committee has served on CSR study sections reviewing these proposals and have extensive experience in mentoring K awardees.

**g. Plan to enhance diversity:** We have specifically targeted advertisement of the K program to institutions serving identified minorities and women. Of the 12 scholars appointed to our K12 program, 4 have been women. We make it clear in every conversation and advertisement that there is an Institutional Commitment to Diversity in our training programs and that underrepresented minorities, women and the disabled are actively encouraged to apply. Johns Hopkins University School of Medicine requires all faculty to participate in a course on diversity. Dr. Quigley has spoken at the National Medical Association meeting, describing the availability of training to the largely African-American, young audience. Through Daniel Laroche, MD, an officer of the National Medical Association, we offered specific ideas about the identification of candidates in training who are African-American to apply to our program. This illustrates our attention to diversity at the K12 program. Of the 8 members of the K12 committee, 4 are women, one of whom is African-American.

During the 12 months from July, 2013 to January, 2015, we had 25 inquiries about the K12 program, each handled personally by Dr. Quigley. Of those, Dr. Quigley had personal interviews by telephone, Skype, or in person with 12 persons, 6 of whom were female and 2 of whom were African-American. One African-American female candidate submitted a K12 application, which, while not receiving the funded K12 slot, has been submitted as a K23. In her case, Dr. Quigley and other members of the K committee worked with the candidate to improve the K application.

#### **4. Available Training Plans and How They Are Selected**

**a. Mentors and Training Plan Areas:** Each candidate scholar is provided with the many opportunities available at Wilmer for their training summarized here. We have more than 20 faculty who have been part of a past mentor team. The K12 committee description gives their past mentorship experience. Most mentor teams add faculty members from outside the Department of Ophthalmology. Each mentor team has a lead mentor, or occasionally a pair of leads, with one more clinically oriented and one more laboratory oriented. Candidates with minimal past research experience will most often have a staged program, heavy on course work and methodological skill development in the early years. Those with some past research experience will move more quickly into the mentored experimental work in their program. Mentors in our program all have had specific past NIH R level grant funding and therefore are helpful mentors in the actual process of grant writing, beginning with the writing of the K application itself. Our mentor group has diversity, including two African Americans and a Hispanic American.

The facilitated inclusion of new faculty and a wider mentor group is a particular strength of our K12. While faculty members who have mentored a past K awardee understand the application process and the mentoring relationship, we found that we could involve a wider range of faculty members in mentor groups, including particularly those from departments outside Ophthalmology, to achieve the fullest training experiences. All of our present K12 mentees have at least one non-Ophthalmology faculty member mentor. By observing which mentor groups have been successful (or not), our

committee makes it more likely that a successful training program is constructed with input from faculty members who may not even have worked together before within the institution.

Potential candidates for mentored training by our Department begin with discussions with Dr. Quigley and other faculty to develop initial ideas of the area in which they wish to work. A potential lead mentor is chosen and discussions of specific training programs and mentorship group members are chosen. Lead mentors and their groups have one or more R01 grants supporting their work, and many have other NIH and private foundation funds to provide a basic framework on which mentored training is supported. The lead mentor and mentor group then discuss with the candidate the ongoing funded work in the senior lab, as well as the methodologies that are ongoing that could be learned by the candidate. Specific ideas for research that supplements ongoing work are generated; or, in some cases, entirely new specific aims are generated by synthesis of more than one mentor’s laboratory efforts to produce a training experience that is compatible with the candidate’s potential.

To illustrate the breadth of patient-oriented and laboratory research programs within the Wilmer Institute, the following is a list of research groups and their faculty leaders:

<b>Group</b>	<b>Lead Mentors</b>	<b>Team Members</b>
Artificial Tissue Generation	Jennifer Ellisseeff	W Grayson, J Green
Big Data Analysis (Bioinformatics)	Michael Boland	J Qian
Clinical Trials and Biometry	Neil Bressler	O Schein, B Hawkins
Cornea Research	John Gottsch	A Jun, S Chakravarti, O Schein
Epidemiology	Sheila West	D Friedman, H Quigley
Experimental Pathology	Gerard Lutty	H Quigley, M Tso, C Eberhardt
Glaucoma	Harry Quigley	H Jampel, D Friedman, D Zack
Low Vision	Robert Massof	J Goldstein, G Dagnelie
Neuroscience	Jeremy Nathans	N Miller, N Marsh-Armstrong
Ocular Genetics	Don Zack	J Gottsch, S Chakravarti
Ocular Immunology	Jennifer Thorne	R Weinberg, Nicholas Butler
Optic nerve trauma	Jeffrey Mumm	Don Zack, Harry Quigley
Pediatric and Strabismus	David Guyton	M Repka, K Simons
Retinal Molecular Biology	Donald Zack	Elia Duh, V Canto-Soler, S Merbs

Retinal Disease Models	Peter Campochiaro	D Zack, G Lutty
Retinal Clinical Studies	Neil Bressler	P Campochiaro, J Handa, S Solomon
Sustained Drug Delivery	Justin Hanes	Jie Fu
Vitreoretinal Disease	James Handa	G Lutty, P Gehlbach, E Duh

### **b. Examples of Mentorship Opportunities within Wilmer/Hopkins Centers**

**The Division of Ocular Immunology** specializes in research and clinical patient care of patients with uveitis. The group is headed by Senior Scientists Richard Semba and Jennifer Thorne, the latter two being past K awardees in the Wilmer program, as was John Kempen (now faculty at University of Pennsylvania). The group holds several NIH-funded grants, including leadership roles in epidemiologic studies and multicenter clinical trials. Approximately 90% of patients with HIV-related ocular disease and other immune-mediated ocular disorders in the Baltimore metropolitan area are managed here, providing outstanding opportunities for clinical research. A database of all AIDS patients has been maintained for 20 years. The Division of Ocular Immunology has weekly administrative and educational meetings in which K awardees are both presenters and participants.

**The Dana Center for Preventive Ophthalmology** is a joint undertaking of the Wilmer Institute and the School of Public Health to bring a public health approach to the prevention and control of blindness in the U.S. and around the world. Activities include research, training, and development/implementation of blindness control programs. The center conducts research on the epidemiology and control of eye diseases both domestically and internationally. Faculty epidemiologists and biostatisticians include Drs. Sheila West, Oliver Schein, Beatriz Munoz, David Friedman, and Harry Quigley, as well as Drs. Joanne Katz and James Tielsch (at the School of Public Health). The Center houses Wilmer’s Biostatistical Core Facility. Numerous observational and interventional epidemiologic studies are ongoing on a variety of domestic and international topics. Notable studies include elucidation of the role of Vitamin A in the prevention of blindness and early childhood mortality, cataract surgery outcomes studies, numerous eye disease surveys in several countries, development of reproducible systems for grading cataract, xerophthalmia, trachoma and glaucoma for epidemiologic research; development of a community-based intervention strategy to prevent trachoma; and population-based assessment of the functional impact of vision loss in elderly persons in a U.S. community (Salisbury, Maryland). The Gates Foundation has made a \$10 million grant to the Dana Center for eradication of trachoma. The Dana Center is a World Health Organization Collaborating Centre for the prevention of blindness. Scholars who choose mentored research in this area have received both MPH and PhD degrees in health sciences, epidemiology and international health, including David Friedman, Nathan Congdon, Lydia Giardano, Michael Boland, and Pradeep Ramulu.

**The Ocular Genetics Group**, led by John Gottsch, Shukti Chakravarti and Don Zack, provides opportunities for clinician—scientists to develop skills in methods of genetic analysis of ocular diseases,

matched by training in epidemiological methods. In combination with our Retinal Development and Retinal Molecular Biology groups, training experiences have been developed in the manifestations of retinal disease, corneal degenerations, and glaucoma. Studies by this group have defined the genetic disorder of color vision in a Pacific Island group (Pingalap Island), identified markers associated with Fuchs corneal dystrophy, and identified relationships between abnormalities of ocular development and specific gene defects. A past K08 scholar, Dr Albert Jun, studied the genetics of Fuchs corneal dystrophy with this group and now has his own R01, having developed a mouse model of the disease. A present K12 Scholar, Allen Eghrari, has a K program based in Fuchs dystrophy research with this group.

**The Retinal Disease Group**, led by Dr. Peter Campochiaro, has included training programs for several past K awardees, including Neal Adams and Jennifer Sung. Research by this group has pioneered the production of models of retinal neovascularization similar to that in age-related macular degeneration (AMD) in mice. Boasting one of the largest colonies of transgenic mice at Johns Hopkins, they have developed several potential therapies for AMD. Mentor groups based in this area have accessed other department faculty at Johns Hopkins Medical School, including Lasker Award winner Dr. Solomon Snyder, Chair of Neuroscience, and 2008 Champalimaud Foundation award winner, Jeremy Nathans, Professor of Neuroscience and Ophthalmology.

**The Glaucoma Research Group**, led by Dr. Harry Quigley, Friedenwald Awardee of ARVO, has a broad range of research activities, including laboratory studies in animal models of glaucoma, gene therapy experiments, neuroprotection research, experimental surgical therapy, epidemiological modeling of disease progression, large database studies of adherence with therapy, participation in multicenter clinical trials, development of algorithms for progression measurement in structure and function, and risk assessment and calculation in decision theory. The K programs of Drs Michael Boland, Pradeep Ramulu, Derek Welsbie, and Ian Pitha included members of the Glaucoma Group, as well as faculty from the Departments of Medicine, Biomedical Engineering, and the School of Public Health.

**The Retinal Molecular Biology Group**, led by Don Zack, Peter Gehlbach, Valeria Canto-Soler, and Elia Duh studies mechanisms of molecular events related to normal development, as well as outer and inner retinal disease. Dr. Canto-Soler has produced initial ocular structures from stem cells, and Dr. Zack has developed retinal ganglion cell-like neurons from induced pluripotent cells. The methods of gene array, bioinformatics, isolated cell culture, laser capture microdissection, and molecular biological techniques are housed in the Wilmer Molecular Biology laboratories. Dr. Zack has been a significant participant in K training mentor groups for Drs. Stuart McKinnon, Ron Farkas, Peter Gehlbach, Elia Duh, and Derek Welsbie during their training at Wilmer. Gehlbach and Duh are both past K awardees.

**The Center for Clinical Trials** is a cooperative venture of the Departments of Epidemiology, Biostatistics, and International Health at the School of Public Health, and of the Departments of Ophthalmology, Medicine, and Oncology in the School of Medicine. The goal of the Center is “to promote the use of clinical trials as an evaluation method and to facilitate research and teaching efforts in relation to clinical trials and other studies”. One Center effort toward this goal has been the establishment of the Training Program in Vision Research, one of two such programs in the nation, which has included the training of vision researchers for over ten years. This program offers a monthly

seminar series, and annual presentations by participants of research in progress. The senior personnel of the Center have extensive background in collaborative design, conduct, and analysis of multicenter clinical trials and prospective observational studies (many in vision—related research), including the Diabetic Retinopathy Study, the Glaucoma Laser Trial, the Coronary Drug Project, the University Group Diabetes Program, the Childhood Asthma Management Program, and other major trials.

**The Departments of Epidemiology and International Health**, School of Public Health has long-standing relationships with the Wilmer Institute for CSTP training and research. The former Dean of the Bloomberg School of Public Health, Alfred Sommer, MD, was a Wilmer faculty member and founded the Dana Center for Preventive Ophthalmology described above. He directly participates in training in our PHO program, whose graduates receive the MPH degree. He is a present mentor of Alan Eghrari a K12 scholar. Wilmer scholars have participated in departmental seminars, and the Division of Chronic Diseases journal club, which meets biweekly. In addition, the School sponsors a large number of special seminars on topics of general public health interest, to which scholars will have access. The Department of Epidemiology, through cross-appointed members of the Wilmer faculty, including Advisory Committee member Dr. Sheila West and Dana Center Director David Friedman, offers full access to the academic resources of the School of Hygiene and Public Health. Faculty in International Health has served as mentors in clinician—scientist (K23 and K12) programs based in the Wilmer Institute, including Drs. James Tielsch and Joanne Katz. The interactions possible with these investigators broaden the scope of research to include a large number of patient—oriented health issues of worldwide interest.

**The Johns Hopkins Program for Medical Technology and Practice Assessment** is a center with the mission to define clinical, management and policy strategies that will contain health care costs while preserving or enhancing quality of care. To achieve this mission, Program faculty conduct research in technology assessment, analysis of alternative clinical management strategies and practice variations, analysis of health care financing, development and application of methods for measuring quality of care, and use of practice guidelines and medical education to develop strategies for improving health care. The Program places a major emphasis on economic costs and quality of life in addition to clinical outcomes. The Program brings together physicians from a variety of clinical disciplines as well as economists, health services researchers, clinical epidemiologists, and statisticians. These include experts in health policy, decision analysis, and measurement of health status, medical informatics, medical ethics and clinical education. The resulting broad expertise enhances the ability to conduct multidisciplinary research. For many years, the Program and its faculty have collaborated with the faculty and scholars in the Wilmer Institute on a variety of projects. The Program is committed to continuing this highly successful relationship and will serve as a valuable resource for the proposed Mentored Clinical Research Scholar Program. One of the recent past scholars, Dr. David Friedman, conducted an extensive evaluation of the costs and outcomes of cataract surgery in collaboration with this Program.

**The Big Data (Bioinformatics) Center** can provide trainees with mentored research experience in the field of “big data” or data science. This experience could take the form of analyzing genomic, proteomic, and high-throughput screening image data produced by the laboratories of Don Zack and Derek Welsbie. These large data sets are increasingly critical to identifying new targets for therapy and

the pharmaceutical compounds that might alter the biology in the desired way. In addition, we have access to large clinical data sets now that all of our clinical systems are electronic. Under the guidance of Michael Boland (a past K awardee), trainees could carry out analyses of data from our electronic health record (history, exam data, procedures, diagnoses, etc.) as well as the data obtained with the large volume of in-office testing performed in ophthalmology. Taken together, these data will allow us to identify important risk factors for the initial diagnosis of disease its worsening.

c. **Examples of successful K12 applications** from scholars Ian Pitha and Akrit Sodhi, both of which were subsequently funded as individual K08s is attached (Appendix 1 K Program for Ian Pitha and Appendix 4 K Program for Akrit Sodhi). Pitha's area of research is the development of sustained delivery drugs for eye disease, particularly eye pressure lowering and in glaucoma, as well as treatment of retinal diseases. It illustrates the team of mentors exhibiting a multidisciplinary set of training goals, includes specific didactic coursework, and involves mentors from the areas of Glaucoma, Biomedical Engineering and Chemistry at Johns Hopkins, as well as Dr. Henry Edelhauser of Emory University, an eminent expert on the relevant area of drug delivery to the eye. Sodhi's work examines the role of HIF1 in ocular neovascularization in unique transgenic mouse models, using a multi-faculty group that includes a non-ophthalmology faculty member, Greg Semenza, as lead mentor.

## 5. Selection of scholars by the K12 Committee

Candidates are generally selected each year in October, typically to begin in the following July. When one of our K12 scholars has been individually funded after submission for a K08 or K23, we can also fill that funded slot with candidates who are in the application process at the time of the year that the vacancy occurs. During the application process, faculty members who will serve as mentors for a candidate communicate with the committee in both written statements and personally about the candidate and program. The Committee assures that the limited percent clinical effort would not expand to interfere with research training. This has occasionally required the Committee to intervene with the Department or Division on behalf of the mentee. Members of the K12 Committee who are to serve as mentors for a particular candidate are recused from voting on that application. Instead, they are interviewed by the committee to gather additional information about the proposed program. The applications are scored on a CSR-type scale (1—10) and the best scored application is offered an available K12 slot. The remaining applicants are assisted in submitting their individual K08 or K23 application by the committee.

## 6. Scholar Retention and Transition to K08/K23

a. **From selection to program start date:** The time between selection in the Fall of the year prior to beginning of training allows a finalization between the candidate and mentor group of the detailed plan for the initial year of training and an overall plan. Formal didactic courses are applied for during the months prior to arrival. Most scholars have formal coursework relevant to their individual research

training plan. The required coursework for all participants includes: 1) one course in Federal regulations on human subjects research and bioethics; 2) instruction in scientific integrity (conflict of interest, responsible authorship, policies for handling misconduct); 3) training in the responsible conduct of human and animal research; and 4) biostatistics and data management, including study design, analysis, and security of data records. These required areas are selected by participants from the catalog of the School of Medicine and School of Public Health, as approved by the mentor and K12 Committee. In addition to the required didactic coursework, a variety of courses have been useful to our scholars. These are selected with the advice of the mentor and K12 Committee. For some candidates, it is appropriate to take specific coursework that is included in the Visual Neuroscience Training Program. Others have matriculated for specific advanced degrees (MPH, MHS, PhD).

Between the acceptance of an applicant (typically in October for a start date in July), the K12 Committee and Ms. Tracey, the administrator, help the candidates with the establishment of salary and benefits based on the percent effort allocated to research and clinical activities, assignment of appropriate office space, assistance in housing, information on initial courses that are required in ethics, animal or human research, electronic systems, diversity, and privacy regulations. The central office is a great advantage to both mentees (who are new to such processes) and to mentors—allowing them to concentrate on research training instead of many of the financial and administrative tasks.

Those accepted for our K12 program are appointed at the faculty rank of Assistant Professor by the Department of Ophthalmology, with commensurate salary and benefits. This requires that they are capable of independent clinical activity as appropriate for their ophthalmic skills, though this clinical activity is limited to less than 25% of their overall effort, with 75% or more of their effort devoted to mentored research training. All candidates will therefore have completed their clinical training prior to entering the K12 program.

Each scholar is given help to acquire physical space and technical help to conduct research by interaction between the K12 central office and the lab of the lead and other mentors. We also help in obtaining approvals for human or animal research, which at Hopkins includes passing a group of computer-based courses that qualify the scholar to apply for either animal approval or human subjects research.

**b. Evaluations during the training period:** Each mentor—scholar group that is funded is evaluated at least twice yearly by the K12 committee, whether they are still on the K12 or have moved to a K08 or K23. The committee meets in person with both the mentee and the mentor faculty separately, after receiving a completed form with standard questions regarding the program, its progress, and plans for the coming year (Appendix 5 Annual Program Evaluation Forms.pdf; Appendix 6 Mentor Annual Evaluation Examples.pdf). Written formal recommendations for improvement or change in program are provided from the K12 committee after in person interviews with mentors and scholar (Appendix 7 Annual Program Evaluation Summaries.pdf). Timelines for accomplishment of key goals leading to independent multidisciplinary research to be funded by the R mechanism grants that are to be submitted by the 3<sup>rd</sup> year of funding. Planning for retention at Wilmer or transition to another institution as a full-time faculty member is part of each review in the last 2 years of a K program. In

addition, all K awardees meet twice yearly as a group to discuss issues of mutual interest and how problems in their programs have been solved. Based on experience with over 30 K awards, Dr. Quigley and the K12 Committee use the following guidelines in planning and oversight of K training.

- Planning should begin 1 year before the K award starts (the type of training, courses, apprenticeship at the “bench” (even when the bench is a computer or a clinical imaging instrument), and off-site learning).
- The first year plan is the best time for course work or acquisition of methodological skills.
- A transition from the K12 program to an individual K08/K23 is expected to be submitted in the first year of K12 funding. It is resubmitted if not funded after suitable revision based on the review.
- Plans for years 2-4 should include goals for productivity and the writing of an initial R01, R03, or R21 proposal that will follow the K award.
- Plans at year 3 should include a plan for transition to faculty status at this or another institution. If the latter, specific plans to assist in finding a job should ensue.
- The future research program of the scholar should be specified and an agreement to coordinate or differentiate it from that of the mentor group should be planned.

The ongoing review by the K12 Committee is to assure the ongoing commitment to the time and resources needed for training by the mentors. Specific research projects should depend upon the training objectives, not upon what work the mentor wishes to accomplish in his/her lab. On the other hand, mentees should be willing to defer to the mentor(s) on research subject matter, particularly when their favorite idea is impractical. Individual meetings on a regular basis of the mentor(s) and mentee should occur and reports of these sessions to the K12 Committee are made. A full annual review of each K program is made by the K12 Committee, with separate meetings with mentee and mentors, written evaluations, and summary suggestions by the Committee for improvement or change (Appendix 7).

### **c. Instruction in the Responsible Conduct of Research**

Individuals appointed to the K12 program are required to comply with the instructions for Plan for Instruction in the Responsible Conduct of Research as provided in Chapter 8 of the SF424 (R&R) Application Guide. This is accomplished through web-based courses in the responsible conduct of human research, as well as courses in the conduct of animal experimentation required by and administered through the Office of Research Administration of Johns Hopkins. These are undertaken in the first year of the program. The committee will establish the areas in which required courses are to be taken by every scholar, including, but not limited to: Instruction in the Responsible Conduct of Research, Federal Regulations on Human Subjects and Animal Research, Bioethics, Instruction in Scientific Integrity (conflict of interest, responsible authorship, policies for handling misconduct), Biostatistics and Data Management, including study design, analysis, and security of data records. In addition, seminars on the

above subjects are given and required for attendance of all faculty annually, including the K awardees. This exceeds the requirement for 8 contact hours of instruction in these subjects every 4 years.

#### **d. Existing Policy for Off-Site Career Development and Leave of Absence**

A career development experience at another institution has been permitted in several of our K programs when the proposed experience is directly related to the purpose of the award. In general, these have been 3 months or less and thus do not require NEI-NIH approval. Salary support continues during such off-site work. Leave of absence may be taken without award support but may not exceed 12 months. The approval process for a leave of absence are identical to that described in the previous paragraph, and may be granted under certain circumstances (for examples, see the Background section above). The K award will be placed in a no-cost extension for the duration of the unpaid leave and no charges to the grant will be allowed during that period. Such leave does not reduce the total number of months of support for which an individual is funded.

### **7. Career Development—The Transition from K to Faculty Status and Grant Support**

#### **a. Following written timelines and requirements**

Mentees have written plans for expected learning goals and timelines for their accomplishment. These are provided and constantly updated by lead mentors. Progress in these goals is reported by the scholar to the mentor, departmental committee (twice yearly) and NEI (annually). They are given productivity goals include the effective use of protected time. A low work ethic requires immediate recognition and remediation. The vast majority of time on a K award is training, not unrelated clinical activity. The limit on clinical activity must be clearly and fairly enforced. In our experience, this presents no hardship to maintaining clinical expertise. Our several K awardees find it useful to meet and to compare notes on successes and problem solving. Both mentees and mentors are given direct access to the K12 Committee to complain about failures of their program to achieve its goals. Our experience is that no training program functions perfectly without active management.

#### **b. Management of difficulties**

We mandate ongoing oversight, since conflicts between mentors and mentees are not only likely, but inevitable. Intelligent, obsessive people placed in close proximity where the stakes are high will generate the need for mediation in a constructive manner. Issues that often require attention are: space allocated to scholar, secretarial/technical support, and how budgeting is accomplished. Annual goals include acquisition of specific research skills, peer-reviewed publication, presentation of research findings at local and national meetings, and grant proposal writing. The K12 Committee's use of periodic review to perform evaluation and mediation has substantially improved our K training programs.

K awardees have faculty status, but are also still in mentored training, so it is useful to co-sign a letter at the start of the program that the appointment is reviewed annually and that any permanent faculty position is dependent upon satisfactory progress in training as judged by the Department Chair,

advised by the K12 Committee. The salary is discussed prior to arrival and is equal to other faculty members with similar experience. For scholars who are judged appropriate to stay permanently on the Wilmer faculty, this decision is made during the second to last year of K training. For those who will seek faculty appointment elsewhere, the K committee and Dr. Quigley begin work at a similar time prior to the final year in making recommendations and inquiries for the scholar at suitable University and other sites.

### **c. Developing presentation skills**

Every developing scientist benefits from the opportunity to present their work at a variety of venues, and to that end, all present orally to their individual laboratory or clinical research groupings several times per year. In addition, all are required to present work by the second year of training at both the annual Wilmer Research Meeting and at appropriate national meetings. All of our K awardees present material at ARVO and will also give presentations before national sub-specialty meetings. Mentors and Advisory Committee members review these talks prior to their being given and give post-presentation feedback to improve communication skills. The program of lectures and seminars at Wilmer includes a biweekly Friday Afternoon Research Meeting (FARM) and the monthly Wilmer Science Seminar Series. FARM presentations are by clinical and lab Wilmer scientists, while the Seminar Series brings outside scientists to present on a wide variety of subjects. Wilmer has 10 endowed lectureships that are given as part of continuing medical education courses and as separate presentations by internationally known lecturers. These are often given by clinician—scientists.

### **d. Planning independent grant support**

During the third year of training, the lead mentor and K12 PI and committee have discussions with the scholar about their career path. This includes not only the submission of R level proposal(s), but the University location where these proposals would occur—Wilmer or other institution. For those to stay at Wilmer/Hopkins, negotiations are initiated with the Department and Division which the scholar has selected. The transition in terms of research time, clinical activity, office and lab space, supporting staff, and clinical sites of practice are included in such discussions.

Throughout the K mentorship period, each Scholar participates in a program of the Wilmer Department of Ophthalmology's **Committee for Assistant Professors**. This group assigns a mentor, an Associate or Full Professor, who provides guidance in career development and ensures the junior faculty member is on track for career development and promotion. For K awardees, this is sometimes the K mentor, but not always, as the additional perspective from an "outside" faculty member is often helpful. For new recruits to the department who may not know the senior faculty, the committee can provide potential names of faculty who have similar research interests. Each Scholar is given a list of expectations for the mentoring process that includes the following steps for grant review and submission of R level and other grants:

1. First, there is an informal presentation at a quarterly luncheon of the specific aims, background and significance of a grant proposed by the Scholar, with an outline of methods. This is by design NOT a formal presentation of finished work but rather a set of ideas with some idea of

importance. The mentor is required to attend along with other senior faculty. The goal is provide early feedback on ideas and possible approaches. The presentation lasts 20 minutes with 40 minutes for feedback. The seminar must be scheduled at least two months ahead of grant deadline, but could be at any time the Scholar wishes assistance.

2. A draft of the specific aims, significance, and methods is given to the mentor and two other committee members for detailed review and comments, to be returned in one week. The draft is due one month before the grant is due at administration. At that point, the mentor can discuss with the mentee if any further reviews are needed, and deadlines for those reviews

3. The mentee will signal to administration an intent to file a grant one month before it is due, and be assigned a specific grants administrator to help with the process, ensuring all paperwork such as other NIH bio sketches, support pages, budgets and justifications, resources, data sharing plans, human and animal concerns are filled in properly.

## **8. Institutional Environment and Commitment to the Program**

a. **The Department**, represented by the Chair, Peter McDonnell (see Appendix for letter from Dr McDonnell), has been actively interested during our past K programs, making sure that the essential time is provided for the P.I., K12 committee, and mentors to carry out their functions in this program. While there has been no recent need for intervention at a Department level, the required protected time for scholars (9 person months, equivalent to 75% or more) has the department's approval. The overall salary is guaranteed by the Department (including the portion not covered by the K award). We have not had a single K awardee whose clinical activity did not pay for the non-grant funded effort. Dr. McDonnell established both the K committee and the Assistant Professor's Committee as described here to assure the highest likelihood of successful career development.

b. **Faculty**: A major institutional commitment is the extensive time given by our faculty, both those on the K12 Committee and the other mentors, to assist in training and planning for each candidate. This begins with the first contact with a young scientist inquiring about the possible application for a K award, through introducing mentors to the candidate and scheduling planning meetings, assisting in the writing of a full K award application prior to being considered for our program. Daily work at the bench or in the clinical research area as well as weekly lab meetings are a regular commitment of the faculty. Assessments of the K award programs in detail are part of our regular system and require considerable time in interviewing mentors, mentees, meeting with both together, then providing written feedback to them with suggested improvements.

c. **Staff**: The K program benefits greatly from the modest percent effort provided to Ms. Patricia Tracey, who has 20 years' experience in managing and assisting ophthalmological training programs at Wilmer, working in Dr. Quigley's office. She is the coordinator of each K program from first contact to graduation to a faculty position. She personally assists candidates for the K program in constructing their application in NIH format and in constructing the initial budget information. She is the research finance

person to monitor budgets and submit timely reports on new, continuing and completed K scholar programs. She shows them how to submit the grant electronically, submit regular grant progress reports and financial statements, qualify for and apply for student debt repayment programs, and finding occupational assistance for spouse/partners, as well as housing advice. She assists in advertising the program, matching scholars and faculty mentors, association with University research administration, Human Subjects Committees, Animal Care Committees, and Departmental evaluations. She provides liaison between the School of Medicine, the School of Hygiene, and scholars, in terms of credentialing, benefits, tuition, and communications.

d. **Core Facilities:** The cost of research performed by each K awardee is provided by the faculty, since it is never fully covered by the K award's supply money. In many cases, these costs are covered by private donations, foundation support, and the writing of grants to fund the work with the mentee. Laboratory technical help is provided in most labs. Further assistance comes from the Department **Core Facility Grant** that has modules useful in some aspect of nearly all of our K award programs. The 5 Core Facility Modules are:

The **Biostatistics** Core, headed by Sheila West, PhD, is a major contributor to research training and productivity at the Institute. With senior biostatisticians serving on its staff, this group participates in training in a variety of ways. It provides didactic lectures during the year to Institute staff. It consults before, during and after the design and implementation of research projects. All K awardees have accessed assistance from the Biostat Core.

The **Bioinformatics** Core, headed by Don Zack, MD PhD, has 3 employees performing data analysis on genomics and proteomics data. These experts are available for consultation and data analysis of work in this area.

The **Imaging** Core, headed by Harry Quigley, MD, has 3 confocal microscopes, a transmission electron microscope, inverted microscope, fluorescence microscope, and automated image analysis technologies, all of which are available to K scholars where appropriate to their work. Training in the use of the equipment is provided by the module staff.

The **Animal Care** Core, headed by Gerard Luty, PhD, has one of several animal facilities available for animal housing from mice to monkeys, and contains two operating room suites with Zeiss ceiling mounted microscopes, along with lasers, ERG equipment, and sterile instrumentation.

The **Nanomedicine** Core, headed by Justin Hanes, PhD, provides support for projects in animal and human research for which sustained delivery of drugs or chemicals are appropriate.

d. **Office/Equipment/Other Facilities:** Each scholar has been provided with office space, access to computer network access and basic secretarial support through the office of the primary mentor. Salary and benefits assistance and budget management are provided either in the mentor office or by Ms Tracey, the K12 administrative assistant. A desktop workstation computer is provided for candidate use with full access to all the web-based resources of The Johns Hopkins Medical Institutions, including the Welch Medical Library, the Lillienfeld Public Health Library, and the Friedenwald Library of the

Wilmer Ophthalmological Institute. These libraries contain in their collections virtually every modern journal or text (both on-line and in print) and those not available on site can be obtained through inter-library loan.

e. **A Letter of Commitment from the Department Chair**, Peter McDonnell is included in Appendix (Appendix 8 Ophthalmology Chairperson Peter McDonnell Statement of Commitment.pdf).

## **9. Plans for the next 5 year period**

Based on the experience we have gained in the 27 years of clinician—scientist training under K awards at Wilmer, including the first 11 years of this K12 program, we have an established record of developing future faculty members in Departments of Ophthalmology. We believe that our approach of selecting new K12 scholars and encouraging all applicants to apply for individual K08 and K23 funding maximizes the opportunities at Wilmer for training in the broad spectrum of research areas that we can offer. This will remain unchanged.

During the last 5 years, the faculty available for serving as experienced mentors has expanded greatly, in part due to new faculty recruitment and in part due to the maturing of past junior faculty—several of whom came through the K program.

The new Smith Building for clinical research, with its 200,000 square feet of lab, office and meeting space, has plenty of room for mentees to work, as well as providing a superb interactive environment with scientists in their mentor group and other mentees. Office space for each K12 scholar has been provided by the Department in Smith if they are laboratory-based. The renovation of the former lab facility, the 40,000 square foot Woods Building, provides clinical research office space for clinically based K awardees and the research coordinator staff of their Divisions.

We have rotated off 3 members of the K12 committee and replaced them with 3 new members with a variety of backgrounds. Half of the faculty committee are women and one is African-American. Two of the newer members are past K awardees, making their advice and opinions more relevant to the present scholars.

We will propose that a new Scholar slot be open each year for 5 years, as we have had in our previously funded periods. At the last application time, we had 4 full K applications for one annual slot. Since we have been successful in moving K12 applicants to K08 or K23 individual awards, this also allows us to expect that more than 5 total scholars can be accommodated during the grant period.

Based on the answers to the questionnaire filled out by past and present K12/K08/K23 awardees at Wilmer, we will pay close attention to several issues (see Appendix 3). Among the most cogent of these issues was the identified need among half of the respondents for more financial support for the research costs of the K awardees. We will initiate discussions with each lead mentor prior to the arrival of each K scholar about the potential sources for research funding to supplement the supply budget of each scholar. This will include outside funding agency proposals, development donations to

the lab of the mentor group, and funding from the Department's Pooled Professor funds, which can be applied for by K awardees.

## **10. K12 Principal Investigator and Committee Members**

### **Program Management: Principal Investigator and K12 Committee**

#### **a. Principal Investigator:**

Harry A. Quigley, MD, A. Edward Maumenee Professor of Ophthalmology, Director of Glaucoma Center of Excellence, has been a faculty member at Wilmer since 1977. He has been the principal investigator of several R01 grants (one of which has been continuously funded for 37 years). He was the principal investigator of the T32 Wilmer Fellowship Training Grant for 10 years, a member of the Vision Research Review Committee for 4 years (the study section reviewing training programs for the National Eye Institute), recently served 4 years on AED Study Section, elected head of the Association for Research in Vision and Ophthalmology for 5 years, and elected Editor-in-Chief of Investigative Ophthalmology and Visual Science. He is a Friedenwald Awardee of ARVO. Dr. Quigley's research interests include the pathogenesis, epidemiology, diagnosis and therapy of glaucoma, clinical trials, disease prevalence surveys, longitudinal observational studies, and laboratory research.

Dr. Quigley has served as mentor for more than 50 clinician—scientists, in F32 and T32 fellowships, K08, K23 and K12 programs. Among these, a representative list of those now in full-time academic positions, each of whom has successfully competed for R01 funding after training is given below (with present position):

Claude Burgoyne, MD Professor, Devers Eye Institute (**F32 fellow**)  
Anne L. Coleman, MD PhD Stark Professor, Jules Stein, UCLA (**F32 fellow**)  
David S. Friedman, MPH MD Professor, Wilmer Eye Institute (**K23 mentee**)  
Lucian del Priore, MD Professor, Columbia University (**F32 fellow**)  
Henry D. Jampel, MD Odd Fellows Professor, Wilmer Eye Institute (**F32 fellow**)  
Mark Juzych, MD Dean, Kresge Eye Institute, Detroit  
Stuart McKinnon, MD PhD Associate Professor, Duke University (**K08 mentee**)  
John Morrison, MD Kenneth Swan Prof, Oregon Health Sciences (**F32 fellow**)  
Louis Pasquale, M.D. Assoc Prof, Director Glaucoma, Harvard (**F32 fellow**)  
Rohit Varma, MD Chair, University of Southern California  
Donald Zack, MD PhD Professor Johns Hopkins University (**K08 mentee**)  
Michael Boland MD PhD Associate Professor, Johns Hopkins (**K12 mentee**)  
Pradeep Ramulu MD PhD Associate Professor, Johns Hopkins (**K12--K23 mentee**)  
Ian Pitha MD PhD Assistant Professor, Johns Hopkins (**K12—K08 mentee**)

#### **b. The K12 Committee functions:**

The K12 Committee meets quarterly to discuss the overall program, to vote on new candidates, to review activities and progress of the scholars, and to prepare progress reports and new applications. The responsibilities in the recruitment, selection, retention, and career fostering activities are summarized in more detail in the main body of this proposal. Monitoring of each program by the committee is a formal process using information collected from mentor(s) and the scholars, on which every aspect of the past results, present activities, and future plans are accounted, and compared to the updated plan of the previous year (see Appendix 5, 6, 7). This includes determination that required didactic course material has been completed, as well as review of additional courses taken toward the fulfillment of training goals. The committee requests notification of failed courses by any participant in the Program from the Dean's offices, so that remedial mentorship can be applied and redirection of effort made, where appropriate. After committee review of these reports, the mentee and mentor(s)

are asked to appear before the committee separately to respond to questions and to receive constructive advice. The Committee and its staff person summarize the status and progress of each candidate and each mentor in a formal letter with specific recommendations sent to mentee, mentors and Department Chair. The committee pays specific attention to the percent of time spent by scholars in various activities in relation to their individual training program. Review of financial and budgetary interactions of the K12 program and the related financial needs of scholars are within the committee's mandate. The PI and Committee prepare the annual progress report that summarizes the success or shortcomings of scholars, including degrees earned, publications, talks given, courses taken, faculty positions acquired satisfaction survey results, problems and their solutions, financial report, and interaction with other training programs.

**c. The members of the K12 Committee** are Oliver Schein, MD, MPH, Sheila West, PhD, James Handa, MD PhD, Shannath Merbs MD PhD, Jennifer Elisseeff PhD, Pradeep Ramulu MD PhD, and Sharon Solomon MD PhD.

**Oliver D. Schein** is the Burton E. Grossman Professor of Ophthalmology at Wilmer with a joint appointment in Epidemiology at the Johns Hopkins University Bloomberg School of Public Health. He has been principal investigator on numerous federally funded clinical research grants, applying epidemiologic methods to ocular disease and technology, using case-control designs, survey sampling, observational cohorts, population-based studies, randomized clinical trials, decision analysis, and techniques to assess patient preferences. In 1999, Dr. Schein was awarded a Mid-Career Investigator Award in Patient Research (K24) in recognition of past productivity and mentorship. His research has elucidated outcomes of cataract surgery, health services research related to cataract management, epidemiology of dry eye, and technology assessment. Dr. Schein serves on the American Academy of Ophthalmology Quality of Care Committee and has been a co-author of its Preferred Practice Pattern on Cataract Surgery. He has acted as research mentor to a variety of young physicians and Public Health School degree candidates. A selection of his past mentees (and their present academic achievement) is:

David Friedman, MD PhD Professor, Wilmer Eye Institute (**K23 mentee**)

Nathan Congdon, MD MPH faculty, Chinese University of Hong Kong (**K23 mentee**)

Ellen Freeman, PhD Assistant Professor, University of Montreal

Michael Boland MD PhD Assoc Professor, Wilmer Eye Institute (**K12 mentee**)

Cheryl Enger, PhD Research Biostatistician, Boston

Cesar Vicencio, MD MPH Ministry of Health, Chile

Seang-Mei Saw, PhD Research faculty, Singapore National Eye Centre

Susan Vitale, PhD Faculty, National Institutes of Health

Emily Gower, PhD Associate Professor, Wake Forest University

**James Handa** is the Robert Bond Welch Professor of Ophthalmology, specializing in medical and surgical management of vitreoretinal diseases, especially age-related macular degeneration and diabetic retinopathy. He is an expert in intraocular oncology and retinoblastoma, devoting significant effort to research related to the early causes of age-related macular degeneration, using molecular pathological approaches to understand how the eye transforms from normal aging to early macular degeneration. His most recent research examines the role of advanced glycation end product mediated cholesterol deposition in Bruch's membrane and local state administration for the treatment of age-related macular degeneration. He was a K11 awardee and has present R01 funding from NIH. His mentees have included:

David DiLoreto, MD PhD Assistant Professor, U Rochester (**K08 mentee**)

Rajendra Apte, MD PhD Asst Professor, Washington University (**K08 mentee**)

Neal Adams, MD past Chair, Ophthalmology, Texas Tech, **(K08 mentee)**  
Itay Chowers, MD Asst Professor, Hadassah University, Jerusalem, Israel  
Howard Ying, MD, PhD Assistant Professor, Wilmer Eye Institute **(K12 mentee)**  
Wen Hsiang Lee, MD PhD Asst Professor, Bascom Palmer Eye Institute, U Miami  
Diana Do, MD Assistant Professor, Wilmer Eye Institute  
Eric Tourville, MD Asst Professor, Universite Laval, Canada  
Yuko Yamada, MD Assistant Professor, Kobe University, Japan  
Kati Ebrahimi, MD present K12 **(K12 mentee)**

**Sheila K. West** is the El Maghraby Professor of Ophthalmology and has participated in mentored training for many clinician-scientists. She is jointly appointed in the School of Medicine and the School of Public Health (Epidemiology). She directs a community-based study of prevalence of trachoma in Tanzania that developed a successful intervention in hyperendemic areas, producing the present World Health Organization guidelines for this disease. Her publications documented for the first time the association between cataract and both cigarette smoking and sunlight exposure in field studies of Chesapeake Bay Watermen. She recently led the Hispanic Eye Study (Proyecto VER) in Arizona, determining that glaucoma is highly prevalent as a cause of blindness in this growing population. She served as President of ARVO, has been on the National Advisory Eye Council, and is Editor in Chief of Ophthalmic Epidemiology. Her mentees (and present positions) have included:

Nathan Congdon MD PhD Associate Professor, Hong Kong **(K23 mentee)**  
David Friedman MD PhD Profesor, Wilmer **(K23 mentee)**  
John Kempen, MD, PhD Associate Professor, Scheie Eye Inst. **(K23 mentee)**  
Gergory Greene Center for Disease Control and Prevention  
Bonnie Swenor, PhD Assistant Professor, Wilmer Eye Institute  
Tinsay Woreta, MD, MPH Assistant Professor, Johns Hopkins  
Alexander Jenson, MPH Residency Training, Johns Hopkins  
Meraf Wolle, M.D. Residency Training, Wilmer

**Shannath Merbs, MD PhD** is Assistant Professor of Ophthalmology since 1997, **receiving a K08 award**, and is a fellowship-trained surgeon in the Division of Oculoplastic surgery. She holds joint appointment as an assistant professor of Oncology. Dr. Merbs treats diseases such as congenital defects, benign and cancerous growths, tear duct problems, and the ocular effects of thyroid disease, as well as traumatic injuries to the eyelids, tear drainage system and bones of the eye socket. Her laboratory research program is in the field of ocular oncology, studying the molecular genetic changes that lead to uveal melanoma, the most common ocular malignant tumor. Her present funded research aims to determine the genetic changes that lead to cancer formation and metastasis. She has experience in mentoring the following past students:

Benjamin Shalev, MD Chief Attending Oculoplastic Surgeon, Tel Aviv  
Tonya Stefko, MD Asst Professor of Ophthalmology, U. Pittsburgh  
Paola Parrella, MD Senior Researcher, Unit di Patologia Molecolare e Terapia Genica, Italy

**Sharon D. Solomon, MD PhD** is the Katharine M. Graham Associate Professor of Ophthalmology at the Wilmer. Dr. Solomon's clinical expertise includes medical and surgical treatment of age-related macular degeneration, diabetic retinopathy, and retinal detachment. Dr. Solomon received her A.B. in biochemistry and molecular biology from Harvard. She has served as principal investigator at Wilmer on a number of NIH-sponsored clinical trials through the Diabetic Retinopathy Clinical Research Network (DRCRN), is a co-investigator for the Wilmer Photograph Reading Center and participated in the Submacular Surgery Trials for age-related macular degeneration. Dr. Solomon has participated in the

medical and surgical training of numerous vitreoretinal fellows at the Wilmer Eye Institute, dating from 2002 to the present, including recent K awardees.

Peter Gehlbach, MD PhD Associate Professor, Wilmer (**K08 mentee**)

Elijah Duh, MD PhD Associate Professor, Wilmer (**K08 mentee**)

**Pradeep Ramulu MD PhD** is Associate Professor of Ophthalmology who has served in a mentorship role for several students and fellows, and he is also an Associate Faculty member at the Johns Hopkins Center on Aging and Health. He is a past K12/K23 recipient at Wilmer and has an R01 to investigate falls and mobility outcomes in patients with glaucoma to understand the reasons for disability amongst the visually impaired, with an aim toward rehabilitating patients with visual impairment. Prominent publications include the first description of how physical activity is affected by visual impairment and the first report of the profound impact of visual impairment on work status in a nationally representative sample. Dr. Ramulu has previously received funding from the National Eye Institute, Research to Prevent Blindness, the Glaucoma Research Foundation, and the American Geriatric Society. Previous mentees (and present positions) have included:

Eugenio Maul MD MPH Faculty, Pontificia Universidad, Chile

Sabyasachi Sengupta MBBS Faculty, Aravind Eye Institute, India

Cheryl Sherrod MD MPH Research Fellow, National Eye Institute

Suzanne van Landingham MD Ophthalmology Resident, Wilmer

Jamie Brown BS Medical Student, University of Texas/Houston

Priya Matthews MD, MPH Ophthalmology Resident, Columbia University

Emilie Chan MS Medical Student, Columbia University

Chad Hochberg BS Medical Student, University of Chicago

Angeline Nguyen BS Medical Student, Johns Hopkins University

**Jennifer Elisseeff** received a PhD in Medical Engineering from the Harvard-MIT Division of Health Sciences and Technology, with a postdoc at the National Institute of General Medical Sciences Pharmacology Research Associate Program, National Institute of Dental and Craniofacial Research. In 2004, Elisseeff cofounded Cartilix, Inc., a startup that translated adhesive and biomaterial technologies for treating orthopedic disease, acquired by Biomet Inc in 2009. In 2009, she also founded Aegeria Soft Tissue and Tissue Repair. Dr. Elisseeff is the Jules Stein Professor at Wilmer and directs the Translational Tissue Engineering Center in collaboration with Biomedical Engineering. She serves on the Scientific Advisory Boards of Bausch and Lomb, Kythera Biopharmaceutical, and Cellular Bioengineering Inc. Dr. Elisseeff has received the Carnegie Mellon Young Alumni Award, Arthritis Investigator Award from the Arthritis Foundation, Yasuda Award from the Society of Physical Regulation in Medicine and Biology, and was named by *Technology Review* magazine as a top innovator under 35 in 2002 and top 10 technologies to change the future. In 2008, Dr. Elisseeff was elected a fellow in the American Institute for Medical and Biological Engineering and a Young Global Leader in the World Economic Forum. She has published over 120 articles, book chapters and patent applications and given over 130 national and international invited lectures.

Her many trainees are abstracted below:

Shyni Varghese Associate Professor, UCSD

Tae Gyun Kim Professor, Director Orthopedics, SNU, S. Korea

Myoung Soo Kim Pusan National University, S. Korea

Nerea Garagorri U of Basque Country, Spain

Dong-an Wang Professor, Nanyang Tech. University, Singapore

Zijun Zhang Assist Professor, Orthopedics, St Louis University

Lorenzo Moroni Associate Prof, University of Twente, Netherlands

Tara Deans Assistant Professor, University of Utah  
Marcos Garza Associate Professor, Marantha Baptist University  
Vince Beachley Assistant Professor, Rowan University  
Anirudha Singh Instructor, JHU  
Chaekyu Kim Current  
Xiaokun Wang Current  
Matthew Wolf Current  
Sven Sommerfeld Current

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