SUMMARY STATEMENT

PROGRAM CONTACT:
Michele McGuirl
240-276-5421
mcguirlma@mail.nih.gov

(Privileged Communication)

Release Date: **07/05/2017**
Revised Date:

Application Number: **1 F99 CA222750-01**

FAN,JEAN
Presidents and Fellows of Harvard College
10 Shattuck Street #3
Countway 336B
Boston, MA 021150000

Review Group:	**ZCA1 RTRB-0 (A1)** **National Cancer Institute Special Emphasis Panel** **NCI Predoctoral to Postdoctoral Fellow Transition Award (F99/K00)**
Meeting Date:	**05/18/2017**
Council:	**AUG 2017** ***PCC:*** **O6TR**
Requested Start:	**09/01/2017**

Project Title:	**Statistical Methods for Characterizing Tumor Heterogeneity at the Single Cell Level**
	Requested**: null**
Sponsor:	
Department:	**Biomedical Informatics**
Organization:	**HARVARD UNIVERSITY**
City, State:	**CAMBRIDGE MASSACHUSETTS**
SRG Action:	**Impact Score:13**
Next Steps:	**Visit https://grants.nih.gov/grants/next_steps.htm**
Human Subjects:	**30-Human subjects involved - Certified, no SRG concerns**
Animal Subjects:	**10-No live vertebrate animals involved for competing appl.**
Gender:	**1A-Both genders, scientifically acceptable**
Minority:	**1A-Minorities and non-minorities, scientifically acceptable**
Children:	**3A-No children included, scientifically acceptable**
	Clinical Research - not NIH-defined Phase III Trial

1F99CA222750-01 Fan, Jean

RESUME AND SUMMARY OF DISCUSSION: The fellowship applicant proposes training in bioinformatics and genomics focusing on the analysis of genetic and transcriptional heterogeneity in chronic lymphocytic leukemia (CLL). The goal of the applicant's well designed thesis research is to develop methods to analyze the genetic heterogeneity and subclonal evolution of CLL at the level of single cells. Bioinformatic tools will be further developed to reconstruct genetic subclonal architecture and characterize the gene expression profiles of identified subclonal populations. In the K00 phase, the applicant will continue developing the necessary expertise to characterize heterogeneity in the tumor-microenvironment and develop methods to assess potential reciprocal interactions between subclones and their microenvironment over time in response to therapy. This work will produce innovative statistical methods that can be applied to diverse types of cancer. The applicant is superbly qualified with a longstanding commitment to cancer research and leadership. Glowing letters of recommendation describe the applicant in superlative terms as an intellectually curious critical thinker, who is skillful and creative. The applicant has been incredibly productive, publishing since high school, and has several high impact papers related to the application. These include first or co-first author papers in Nature Methods, Genome Research and Cancer Cell that describe state-of-the-art approaches to study cancer heterogeneity. In addition to being a talented software developer and bioinformatician, the applicant has received NSF and NIH fellowships, and serves as a leader encouraging girls to explore STEM careers. The research plan is cutting-edge, innovative, and engages an unusual combination of skills in cancer biology, statistical analysis, computation and software development. Preliminary results on transcriptional heterogeneity among single cells in a CLL sample are very promising and informative. The sponsor is a highly productive and well-funded pioneer in developing methods for analyzing genomic data, and the co-sponsor is a leader in the study of CLL genomics, which offsets the concerns of some reviewers that the sponsor is relatively junior. In addition, the training and career development plans are strong and the institutional environment is exceptional. Overall, this superb application is expected to have a very high impact by enhancing the applicant's potential for an independent career in cancer research.

DESCRIPTION (provided by applicant): Chronic lymphocytic leukemia (CLL) is a cancer that exhibits genetic and transcriptional heterogeneity along with a highly variable disease course among patients that remains poorly understood. Previous research has highlighted vast inter- and intra-patient genetic heterogeneity, with subclonal evolution commonly occurring in treatment settings leading to therapeutic resistance and relapse in many cases. In addition, our understanding of the role of co-existing non-cancer cells in the tumor-microenvironment remains limited. Therefore, characterization of these subclonal populations and their corresponding microenvironment will be paramount to enabling precision medicine and synergistic treatment combinations that target subclonal drivers and eliminate aggressive subpopulations thereby improving clinical outcome. In order to accurately dissect the genetic landscape and reconstruct the underlying subclonal architecture in CLL, measurements must be made on the single cell level. In the F99-phase of this proposed research, Jean Fan will continue developing statistical methods and computational software to analyze single cell RNA-seq data derived from CLL patient samples. Specifically, Jean will develop methods to identify aspects of genetic heterogeneity, such as the presence of small single nucleotide mutations and regions of copy number variation, in single cells. Jean will then reconstruct the genetic subclonal architecture and characterize the gene expression profiles of identified subclonal populations. In the K00-phase of this proposed research, Jean will characterize heterogeneity in the tumor- microenvironment and develop methods to assess potential reciprocal interactions between subclones and their microenvironment over time in response to therapy. The proposed work will yield innovative statistical methods to enable the identification and characterization of subpopulations in cancer and yield open-source software that can be tailored and applied to diverse cancer types. Ultimately, application of these developed methods to CLL will provide a better understanding of CLL development and progression.

PUBLIC HEALTH RELEVANCE: Intratumor genetic and transcriptional heterogeneity is a common feature across diverse cancer types, including chronic lymphocytic leukemia (CLL). Understanding how heterogeneity both within CLL cells and in relation to the composition and state of co-existing non-CLL cells in the micro-environment impacts clinical outcome and shapes therapeutic resistance is paramount to improving treatment strategies and enabling more personalized cancer treatments. This research proposal will develop statistical methods and computational software to analyze and connect these different aspects of heterogeneity to provide a better understanding of cancer development and progression, using CLL as a primary focus.

CRITIQUES: The written critiques of individual reviewers are provided in essentially unedited form in this section. Please note that these critiques and criterion scores were prepared prior to the meeting and may not have been revised subsequent to the discussions at the review meeting. The "Resume and Summary of Discussion" section summarizes the final opinions of the review committee.

CRITIQUE 1

Fellowship Applicant:	1
Sponsors, Collaborators, and Consultants:	1
Research Training Plan:	1
Training Potential:	2
Institutional Environment & Commitment to Training:	1

Overall Impact: This is an exciting application from an incredibly productive student who has been publishing since high school and has several high impact papers related to the application. She is also a role model for young girls interested in STEM careers. She is working in an outstanding environment developing state-of-the-art approached to study tumor heterogeneity. Some minor concerns exist but they are unlikely to significantly impact the progress of this individual.

1. Fellowship Applicant:
Strengths

- Already an accomplished researcher who has developed single cell genomic analysis approaches and applied them to CLL.
- NSF fellowship recipient
- F31 recipient.
- First or co-first author papers in Nature Methods, Genome Research, Cancer Cell and several high impact co-author papers.
- A role model who is highly active in promoting STEM activities to young girls and women by creating a non-profit company to empower girls in this area.

Weaknesses

- None noted.

2. Sponsors, Collaborators, and Consultants:
Strengths

- The sponsor is a pioneer in developing methods for analyzing genomic data including single cell genomics. He well-funded and can support the proposed studies.
- The co-sponsor is a leader in the study of CLL genomics.
- An active collaboration between the sponsor and co-sponsor's labs has been very productive.

Weaknesses

- Neither the sponsor or co-sponsor have an established track record of training graduate students. In fact, the applicant may be the only PhD student in both labs at this moment.

3. Research Training Plan:
Strengths
- Aim #1 resulted in the development of approaches to analyze the tumor heterogeneity in CLL.
- Aim #2 will apply these approaches to changes associated with ibrutinib treatment.
- Aim #2 will also test for heterogeneity of CNVs in highly expressed genes using single cell RNA-seq analyzing allelic expression.
- Use of multiple timepoint samples from CLL patients will allow for the applicant to dissect tumor evolution and subclonal dynamics.
- Aim #3 will apply some of the approaches in the first two aims to both CLL and non-CLL cells to determine dynamic effects in the micro-environment.

Weaknesses
- Aim #3 is exciting although not a very far stretch from Aim #2 in approach.

4. Training Potential/Development Plan:
Strengths
- Well-articulated plan provided by applicant focusing primarily on continuing to develop analytical skills, understanding biology and mentorship activities.

Weaknesses
- Not much offered by the sponsors.

5. Institutional Environment & Commitment to Training:
Strengths
- Environment is outstanding for both the research and training proposed.

Weaknesses
- None noted.

Protections for Human Subjects: Acceptable Risks and Adequate Protections
- Extra bone marrow or blood taken from consenting patients who are already having the procedure.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only): Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:
- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Excluding ages < 21 justified scientifically

Vertebrate Animals: Not Applicable (No Vertebrate Animals)

Biohazards: Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research: Acceptable
Comments on Format (Required):
- Courses taken in 2nd and 5th/6th year of training, two courses one didactic and one small group interactions

Comments on Subject Matter (Required):
- Appropriate RCR material

Comments on Faculty Participation (Required):

- 23 faculty members participated last year

Comments on Duration (Required):

- 21 hours

Comments on Frequency (Required):

- Twice during training

Applications from Foreign Organizations: Not Applicable

Select Agents: Not Applicable (No Select Agents)

Resource Sharing Plans: Acceptable

Budget and Period of Support: Recommend as Requested

CRITIQUE 2

Fellowship Applicant:	1
Sponsors, Collaborators, and Consultants:	4
Research Training Plan:	1
Training Potential:	4
Institutional Environment & Commitment to Training:	2

Overall Impact: The applicant is outstanding as measured by her record of accomplishment in academics and research to date. She seeks cutting-edge research training in an important trans-disciplinary area of cancer research and has identified an outstanding environment in which to secure it. The applicant's longstanding commitment to cancer research is evident. The Sponsor and Co-Sponsor team offer intellectual and technical resources well suited to meet the research training needs of the applicant. Research plans for F99 and K00 are thoughtful and well developed. Promising preliminary results lend confidence as to feasibility of F99 research plan. A few concerns of moderate significance were identified including insufficient information about the training plan for mentoring and other non-research skills, and the inexperience of the Sponsor in mentoring doctoral students.

1. Fellowship Applicant:
Strengths

- Applicant demonstrates a very strong academic record as an undergraduate and graduate student.
- Applicant has won competitive federal awards as a graduate student.
- Applicant demonstrates a longstanding commitment to cancer research including 1st author paper on cancer genetics from work done at NCI while in high school.
- Applicant has published 4 co-authored papers and 1 first author paper in high impact journals.
- Applicant demonstrates strong commitment to improving representation of women in STEM through significant mentoring and outreach activities.
- Letters of reference describe the applicant in superlative terms as an intellectually curious critical thinker, skillful and creative, rigorous, and among the strongest students in a highly competitive program.

Weaknesses

- None identified.

2. Sponsors, Collaborators, and Consultants:
Strengths

- Sponsor and Co-Sponsor together offer intellectual and technical resources directly relevant to the research training needs of the applicant.
- Sufficient funding is available to the Sponsor in support of the project.
- Co-Sponsor brings expertise in CLL and provides requisite data sets.
- Sponsor and Co-Sponsor are well published in high impact journals.

Weaknesses

- Sponsor is junior faculty with no experience mentoring doctoral students.
- Co-Sponsor has record of successful mentoring, but not clear whether it has involved doctoral students. Only 1 doctoral student presently in the lab.

3. Research Training Plan:

Strengths

- The research plan is cutting-edge, innovative, and engages an unusual combination of skills in cancer biology, statistical analysis, computation and software development.
- Applicant is building logically and effectively on experience in laboratory science and “dry lab” computational approaches to assemble an unusual and valuable skill set.
- Research plan is thoughtful, well developed, and provides clear justification for each research question and approach.
- Preliminary results on transcriptional heterogeneity among single cells in a CLL sample are very promising and informative. This lends confidence as to feasibility of the approach.
- Plans for the K00 phase represent a logical extension of F99 work, a productive direction, and a new challenge with significantly more complex substrate.

Weaknesses

- The applicant plans to use a data set from 7 CLL patients without discussion as to how this sample size was selected or validated.

4. Training Potential/Development Plan:

Strengths

- The applicant and sponsor articulate specific and appropriate goals.
- Program includes ample opportunity to present research work at seminars, journal clubs, workshops and major national conferences.

Weaknesses

- Little specific information is offered as to the training plan for non-research skills and professional development, e.g., communication skills, pedagogical guidance, interview and resume preparation, team management skills, and others.
- Relatively modest plans are described to develop mentoring skills. It is proposed in the F99 phase to mentor one undergraduate student on a summer project, but other specific training or experience is not described.

5. Institutional Environment & Commitment to Training:

Strengths

- The Department of Biomedical Informatics offers a highly collaborative intellectual environment on cross-cutting scientific themes.
- Intellectual and scientific environment is outstanding.

Weaknesses

- Little information provided about resources of the Graduate Program or institution for professional development of the applicant.

Protections for Human Subjects: Acceptable Risks and Adequate Protections

- Adequate protections are in place.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only): Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:
- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Excluding ages < 21 justified scientifically
- Children not formally excluded, but disease occurs in adults.

Vertebrate Animals: Not Applicable (No Vertebrate Animals)

Biohazards: Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research: Acceptable
Comments on Format (Required):
- Didactic case-based presentations and small group discussions

Comments on Subject Matter (Required):
- Adequate range of topics presented

Comments on Faculty Participation (Required):
- Faculty-led presentations and small group discussions.

Comments on Duration (Required):
- 21 hours shared between two courses

Comments on Frequency (Required):
- Two courses taken in 2nd year and 5/6th year

Applications from Foreign Organizations: Not Applicable

Select Agents: Not Applicable (No Select Agents)

Resource Sharing Plans: Acceptable

Budget and Period of Support: Recommend as Requested

CRITIQUE 3

Fellowship Applicant:	1
Sponsors, Collaborators, and Consultants:	2
Research Training Plan:	1
Training Potential:	1
Institutional Environment & Commitment to Training:	1

Overall Impact: This is an outstanding application by a graduate student in Bioinformatics and Integrative Genomics program at Harvard University, who plans to enhance her training in Bioinformatics and Genomics methods focusing on study of cancer heterogeneity at the single cell level. The research plan and training are well thought-out. The research and training plan in gene regulation and cancer are excellent. Overall, the proposed research and training plan will enable the candidate to be an independent cancer bioinformatician. The primary mentor is a well-known expert in Bioinformatics and co-sponsor provide the mentorship and training in cancer research. The PI has outstanding track record of peer-reviewed publications in top journals and development of software for cancer genome data analysis. Overall, I rate this application in “high impact range” because of the noted strengths.

1. Fellowship Applicant:

Strengths

- The applicant Ms. Jean Fan, who obtained BS in Biomedical Engineering from Johns Hopkins, has strong background in Applied Mathematics and Statistics.
- The publication record and scientific productivity is outstanding, publishing in top journals, such as Cancer Cell and Genome Research.
- Excellent track record of software development – developed software for inferring spatial localization of single cells and pathway and gene set over-dispersion analysis to identify and characterize transcriptional subpopulations (Fan et al, Nature Methods 2016)
- Application of computational skills for analysis of locally disordered methylation (Landau et al, Cell 2014), clonal evolution in developing drug resistance (Burger et al, Cancer Discovery 2015), and impact of SF3B1 mutation (Wang et al, Cancer Cell 2016) in chronic lymphocytic leukemia.
- Currently, the applicant is working on development of computational approaches to link transcriptional and genetic heterogeneity at the single cell level using a Bayesian hierarchical models for inferring copy number alteration from single cell RNA-seq data with applications to multiple myeloma
- Overall, the applicant has outstanding prior training in computational methods – strong foundations for her future goals.

Weaknesses

- None noted.

2. Sponsors, Collaborators, and Consultants:

Strengths

- The applicant's research interests are in the broad area of cancer genetics and cancer heterogeneity – specifically to unravel the transcriptional and genetic heterogeneity at the single cell level by using cutting-edge statistical approaches.
- The primary sponsor, Dr. Peter V. Kharchenko, an Assistant Professor of Pediatrics, Harvard Medical School, Boston, MA provides the necessary expertise and advice in the area of Bioinformatics
- The co-sponsor, Dr. Catherine Ju-Ying Wu, provide the mentorship in cancer.
- There is a good track record of collaboration with co-sponsor based on publications and presentation at conferences.

Weaknesses

- None noted.

3. Research Training Plan:

Strengths

- The laboratory of the main sponsor (Dr. Peter V. Kharchenko) has the necessary expertise in statistical analysis, method benchmarking, method validation, software development, software documentation, and various programming languages such as R and C++ – matching the technical training needs of the applicant. The mentor has well-funded research program, although not from NCI.
- The co-sponsor provides the necessary mentorship and technical expertise in the area of the single cell RNA-seq, also provides data access to previous NGS datasets that will be used in this project.
- Both mentors have excellent track record in training pre- and post-doctoral fellows.

Weaknesses

- None noted.

4. Training Potential/Development Plan:

Strengths

- The training plan for development of Bioinformatics methods for NGS data is very strong.
- The plan to transition into cancer bioinformatics area is well thought-out.

Weaknesses

- None noted.

5. Institutional Environment & Commitment to Training:

Strengths

- The resources and rich intellectual environment at Harvard University and Dana-Farber Cancer Research Institute are outstanding

Weaknesses

- None noted.

Protections for Human Subjects: Acceptable Risks and Adequate Protections

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

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Excluding ages < 21 justified scientifically

Vertebrate Animals: Not Applicable (No Vertebrate Animals)

Biohazards: Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research: Acceptable
Comments on Format (Required):
Comments on Subject Matter (Required):
Comments on Faculty Participation (Required):
Comments on Duration (Required):
Comments on Frequency (Required):

Applications from Foreign Organizations: Not Applicable

Select Agents: Not Applicable (No Select Agents)

Resource Sharing Plans: Acceptable

Budget and Period of Support: Recommend as Requested

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

PROTECTION OF HUMAN SUBJECTS: ACCEPTABLE

INCLUSION OF WOMEN PLAN: ACCEPTABLE

INCLUSION OF MINORITIES PLAN: ACCEPTABLE

INCLUSION OF CHILDREN PLAN: ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

Footnotes for 1 F99 CA222750-01; PI Name: Fan, Jean

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

MEETING ROSTER

National Cancer Institute Special Emphasis Panel
NATIONAL CANCER INSTITUTE
NCI Predoctoral to Postdoctoral Fellow Transition Award (F99/K00)
ZCA1 RTRB-0 (A1)
05/18/2017 - 05/19/2017

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

CHAIRPERSON(S)

LEVY, LAURA S, PHD
VICE PRESIDENT FOR RESEARCH AND PROFESSOR
DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY
TULANE UNIVERSITY SCHOOL OF MEDICINE
NEW ORLEANS, LA 70112

MEMBERS

ALARID, ELAINE T, PHD
PROFESSOR
DEPARTMENT OF ONCOLOGY
MCARDLE LABORATORY FOR CANCER RESEARCH
UNIVERSITY OF WISCONSIN AT MADISON
MADISON, WI 53706

ANDERSEN, BOGI, MD
PROFESSOR
DEPARTMENTS OF MEDICINE AND BIOLOGICAL CHEMISTRY
SCHOOL OF MEDICINE
UNIVERSITY OF CALIFORNIA AT IRVINE
IRVINE, CA 92697

BOISE, LAWRENCE H., PHD
PROFESSOR
GCC DISTINGUISHED SCHOLAR
DEPARTMENT OF HEMATOLOGY & MEDICAL ONCOLOGY
WINSHIP CANCER INSTITUTE
EMORY UNIVERSITY SCHOOL OF MEDICINE
ATLANTA, GA 30322

BOUTON, AMY H, PHD
PROFESSOR AND ASSOCIATE DEAN FOR GRADUATE AND
MEDICAL SCIENTIST PROGRAMS
DEPARTMENT OF MICROBIOLOGY, IMMUNOLOGY
AND CANCER BIOLOGY
UNIVERSITY OF VIRGINIA SCHOOL OF MEDICINE
CHARLOTTESVILLE, VA 22908

CAMPBELL, MORAY J, PHD
RESEARCH ASSOCIATE PROFESSOR
DIVISION OF PHARMACEUTICS AND
PHARMACEUTICAL CHEMISTRY
THE OHIO STATE UNIVERSITY
COLUMBUS, OH 43210

CHIAO, PAUL J, PHD
PROFESSOR
MOLECULAR AND CELLULAR ONCOLOGY
DEPARTMENT OF SURGICAL ONCOLOGY RESEARCH
UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER
HOUSTON, TX 77030

COOK, LINDA S, PHD
PROFESSOR
DEPARTMENT OF INTERNAL MEDICINE
DIVISION OF EPIDEMIOLOGY, BIOSTATISTICS,
AND PREVENTATIVE MEDICINE
UNIVERSITY OF NEW MEXICO
ALBUQUERQUE, NM 87131--000

COX, ADRIENNE D, PHD
CHIEF, DIVISION OF CANCER BIOLOGY
DEPARTMENTS OF RADIATION ONCOLOGY AND
PHARMACOLOGY
LINEBERGER COMPREHENSIVE CANCER CENTER
UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
CHAPEL HILL, NC 27599

CREIGHTON, CHAD, PHD
ASSOCIATE PROFESSOR OF MEDICINE
DIVISION OF BIOSTATISTICS
DAN L. DUNCAN CANCER CENTER
M.D. ANDERSON CANCER CENTER
BAYLOR COLLEGE OF MEDICINE
HOUSTON, TX 77030

DAVULURI, RAMANA V, PHD
PROFESSOR
DEPARTMENT OF PREVENTIVE MEDICINE-HEALTH AND BIOMEDICAL INFORMATICS
FEINBERG SCHOOL OF MEDICINE
NORTHWESTERN UNIVERSITY
CHICAGO, IL 60611

DJEU, JULIE Y, PHD
PROFESSOR AND GARCIA ENDOWED CHAIR IN CANCER LEADERSHIP; CO-LEADER, IMMUNOLOGY PROGRAM
DEPARTMENT OF IMMUNOLOGY
DIVISION OF BASIC SCIENCE
H. LEE MOFFITT CANCER CENTER
TAMPA, FL 33612

DONOGHUE, DANIEL J, PHD
PROFESSOR
DEPARTMENTS OF CHEMISTRY & BIOCHEMISTRY
MOORES CANCER CENTER
UNIVERSITY OF CALIFORNIA, SAN DIEGO
LA JOLLA, CA 92093-0367

ECKERT, KRISTIN A, PHD
PROFESSOR
DEPARTMENT OF PATHOLOGY, BIOCHEMISTRY, AND MOLECULAR BIOLOGY
PENNSYLVANIA STATE UNIVERSITY
HERSHEY, PA 17033

EDWARDS, JEREMY S, PHD
PROFESSOR
DEPARTMENTS OF MOLECULAR GENETICS AND MICROBIOLOGY
UNIVERSITY OF NEW MEXICO, SCHOOL OF MEDICINE
ALBUQUERQUE, NM 87131

GIMOTTY, PHYLLIS A., PHD
PROFESSOR, CORE DIRECTOR BIOSTATISTICS
DEPARTMENT OF BIOSTATISTICS AND EPIDEMIOLOGY
PERELMAN SCHOOL OF MEDICINE
UNIVERSITY OF PENNSYLVANIA
PHILADELPHIA, PA 19104-6021

GMEINER, WILLIAM H., PHD
PROFESSOR
DEPARTMENT OF CANCER BIOLOGY, PHYSIOLOGY, AND PHARMACOLOGY
SCHOOL OF MEDICINE
WAKE FOREST UNIVERSITY
WINSTON-SALEM, NC 27157

GRAVES, EDWARD E, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF RADIATION ONCOLOGY
MOLECULAR IMAGING PROGRAM
STANFORD UNIVERSITY
STANFORD, CA 94305

GREENBERG, MARC M, PHD
PROFESSOR
DEPARTMENT OF CHEMISTRY
JOHNS HOPKINS UNIVERSITY
BALTIMORE, MD 21218

KHALED, ANNETTE R, PHD
PROFESSOR
BURNETT SCHOOL OF BIOMEDICAL SCIENCES
UNIVERSITY OF CENTRAL FLORIDA
ORLANDO, FL 32827

MANOR, DANNY, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF NUTRITION AND PHARMACOLOGY
CASE WESTERN RESERVE UNIVERSITY
CLEVELAND, OH 44106

MUKHOPADHYAY, DEBABRATA, PHD
PROFESSOR
DEPARTMENT OF BIOCHEMISTRY, MOLECULAR BIOLOGY AND BIOMEDICAL ENGINEERING
MAYO CLINIC CANCER CENTER
MAYO CLINIC JACKSONVILLE
JACKSONVILLE, FL 32224

MURTAUGH, LEWIS C, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF HUMAN GENETICS
THE UNIVERSITY OF UTAH
SALT LAKE CITY, UT 84112

NAKSHATRI, HARIKRISHNA, PHD, BVSC
PROFESSOR OF SURGERY
DEPARTMENT OF SURGERY
INDIANA UNIVERSITY SCHOOL OF MEDICINE
INDIANAPOLIS, IN 46202

OSHEROFF, NEIL, PHD
PROFESSOR OF BIOCHEMISTRY AND MEDICINE
JOHN G. CONIGLIO CHAIR IN BIOCHEMISTRY
DEPARTMENT OF BIOCHEMISTRY
VANDERBILT UNIVERSITY SCHOOL OF MEDICINE
NASHVILLE, TN 37232-0146

OSIPO, CLODIA, PHD
ASSOCIATE PROFESSOR OF PATHOLOGY
DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY
LOYOLA UNIVERSITY MEDICAL CENTER
MAYWOOD, IL 60153

PENALVA, LUIZ OTAVIO, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF CELL SYSTEMS AND ANATOMY
GREEHEY CHILDREN'S CANCER RESEARCH INSTITUTE
UNIVERSITY OF TEXAS HEALTH SAN ANTONIO
SAN ANTONIO, TX 78229

RATNER, LEE, MD, PHD
PROFESSOR
DEPARTMENTS OF MEDICINE, MOLECULAR MICROBIOLOGY
AND PATHOLOGY AND IMMUNOLOGY
WASHINGTON UNIVERSITY SCHOOL OF MEDICINE
ST. LOUIS, MO 63110

SIRACUSA, LINDA D, PHD
PROFESSOR
DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY
COLLEGE OF BIOMEDICAL SCIENCES
THOMAS JEFFERSON UNIVERSITY
PHILADELPHIA, PA 19107

TANNOUS, BAKHOS A, PHD
ASSOCIATE PROFESSOR AND DIRECTOR OF
INTERDEPARTMENTAL NEUROSCIENCE CENTER
DEPARTMENT OF NEUROLOGY
MASSACHUSETTS GENERAL HOSPITAL
HARVARD MEDICAL SCHOOL
CHARLESTOWN, MA 02129

WONG, PAK KIN, PHD
PROFESSOR
DEPARTMENT OF BIOMEDICAL ENGINEERING
PENNSYLVANIA STATE UNIVERSITY
UNIVERSITY PARK, PA 16802

ZHANG, RUIWEN, MD, PHD
PROFESSOR AND CHAIR
DEPARTMENT OF PHARMACEUTICAL SCIENCES
TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER
AMARILLO, TX 79106

SCIENTIFIC REVIEW OFFICER

RANSOM, DAVID G
SCIENTIFIC REVIEW OFFICER
RESOURCES AND TRAINING REVIEW BRANCH
DIVISION OF EXTRAMURAL ACTIVITIES
NATIONAL CANCER INSTITUTE
NATIONAL INSTITUTES OF HEALTH
ROCKVILLE, MD 20850

EXTRAMURAL SUPPORT ASSISTANT

KINNEY, LESLIE
EXTRAMURAL SUPPORT ASSISTANT
DIVISION OF EXTRAMURAL ACTIVITIES
NATIONAL CANCER INSTITUTE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

PROGRAM REPRESENTATIVE

MCGUIRL, MICHELE, PHD
PROGRAM DIRECTOR
CANCER TRAINING BRANCH
NATIONAL CANCER INSTITUTE
ROCKVILLE, MD 20850

RADAEV, SERGEI, PHD
PROGRAM DIRECTOR
CANCER TRAINING BRANCH
NATIONAL CANCER INSTITUTE
BETHESDA, MD 20892

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