**SUMMARY STATEMENT**

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**( Privileged Communication )**

***Release Date:*** **04/14/2024**
***Revised Date:***

***Application Number:*** **1F30CA295004-01**

**SUGARMAN,ANDREW**
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|---|---|
| ***Review Group:*** | **ZRG1 F10C-B (20) Center for Scientific Review Special Emphasis Panel Fellowships: Vascular and Hematological Systems, Surgical Sciences, Biomedical Imaging, and Bioengineering.** |
| ***Meeting Date:*** | **03/14/2024** |
| ***Council:*** | **MAY 2024** ***PCC:*** **EPTR** |
| ***Requested Start:*** | **07/01/2024** |

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|---|---|
| ***Project Title:*** | **High-Resolution Wide-Field 3D Histopathology for the Morphological Characterization of Prostate Cancer** |
| | ***Requested*: 3 Years** |
| ***Sponsor:*** | **Silverman, Justin** |
| ***Department:*** | |
| ***Organization:*** | **PENNSYLVANIA STATE UNIV HERSHEY MED CTR** |
| ***City, State:*** | **HERSHEY PENNSYLVANIA** |
| ***SRG Action:*** | **Impact Score:28 Percentile:17 +** |
| ***Next Steps:*** | **Visit https://grants.nih.gov/grants/next_steps.htm** |
| **Human Subjects:** | **X4-Human subjects involved - Exemption #4 designated** |
| **Animal Subjects:** | **10-No live vertebrate animals involved for competing appl.** |

**1F30CA295004-01 Sugarman, Andrew**

**RESUME AND SUMMARY OF DISCUSSION:** The proposed NRSA pre-doctoral fellowship application is centered on the mentored training of Andrew Sugarman, a dual-degree candidate, in the areas of novel imaging technology and statistical methodologies. The proposal is focused on the use of high-resolution wide-field three dimensional histopathology in morphological characterization of prostate cancer. The canidate was considered strong overall, with track record of academic excellence and productivity in the lab. Disscussion as to the impact of undergraduate training in biochemistry and proposed research was raised, but not a concern for all reviewers. Instutional environment was strong. The mentoring team was considered strong with complementary expertese. Score driving weaknesses discussed surrounded the appropriateness of the proposed training plan, which is focused on prostate cancer, for the candidates interest in hematology and oncology. Some panel members thought that the application did not support the major goals of the fellowship, stating that the training plan and training potential would be strengthened by more focus on the candidates long-term career goals. Conversely, others stated that this was not a score-driving concern because the proposal did support the applicant's goal of becoming a physician-scientist. The review panel discussion ended with consensus. The panel concluded that the proposed mentored research training would have a high impact on the candidate's potential for an independent scientific research career.

**DESCRIPTION (provided by applicant):** The diagnosis and grading of cancer rely on the examination of abnormal tissue and the morphology of the cells within. For example, the clinical evaluation of prostate cancer relies on the assessment of glandular and cellular morphology from histopathology images. However, prostate cancer patients suffer from high rates of inter- observer variability amongst pathologists in the clinic. Additionally, recent studies have shown that the angle and depth of slide sectioning also contribute to significant variation in tumor grading, further illustrating the need for a quantitative, 3-dimensional, volumetric approach to prostate cancer whole biopsy imaging. In the proposed work, we leverage high-resolution, wide-field micro-CT to generate volumetric images of entire prostate needle core biopsies within FFPE tissue samples and without the need for contrast-enhancing stain. We propose to apply this novel ”3D histopathology” to whole-biopsy prostate needle core specimens, which will include the quantification of variation of glandular shape as a function of position in 3D space. We also propose the development of a computational topology-based summary statistic for the measurement of tumor architecture in 3D space without relying on a black-box model. The central hypothesis of this fellowship application is that micro-CT can be adapted to generate 3D whole-biopsy images of prostate cancer and other soft-tissue tumor biopsies, revealing previously unmeasured variation in glandular structure and providing novel insight into previously unmeasured phenotypic heterogeneity. Preliminary results support the ability of our team to conduct this work, as we were able to collect proof-of concept micro-CT images of needle core biopsy sections that demonstrate readily discernible glandular lumen and cell nuclei. This advancement of 3D histopathology and computational topology will serve public health needs by improving the diagnosis of prostate cancer and potentially other soft-tissue malignancies. Through micro-CT parameter testing and 3D atlasing (Aim 1), histological comparison and non-inferiority testing (Aim 2), and 3D topological modeling (Aim 3), this proposal will contribute to our ability to measure tumor phenotype and heterogeneity.

**PUBLIC HEALTH RELEVANCE:** Cancer diagnosis relies on the assessment of cell and tissue morphology from histology, but methods to quantify these features are limited due to the 2-dimensional nature of slide-based imaging. This project aims to address these shortcomings by developing imaging and analytical approaches to perform 3D histopathology of soft tis- sue biopsies, with an emphasis on prostate cancer. We propose that this will yield unbiased visualization and measurement of tumor architecture otherwise inaccessible to traditional histopathology.

**CRITIQUE 1**

Fellowship Applicant: 3
Sponsors, Collaborators, and Consultants: 2
Research Training Plan: 2
Training Potential: 2
Institutional Environment & Commitment to Training: 2

**Overall Impact:** This is an interesting project. The underlying idea is that in order to effectively treat a patient with prostate cancer understanding the morphological characteristics (structure) of the abnormal cells is important. The project will use a high-resolution, wide-field micro-CT to generate volumetric images of the prostate needle core biopsy to generate a “3D histopathology” focusing on tumor architecture. Specifically, propagation-based phase-contrast CT (PBCT), has already been used by the co-sponsor to produce 3D images of prostate cancer and melanoma biopsy cells. In this project, Aim 1 is to optimize PBCT of Formalin-Fixed Paraffin-Embedded soft tissue biopsies. This will be done by developing a multi-tissue atlas specifying optimal imaging parameters for a given tissue type. Aim 2 is to evaluate the utility of PBCT for grading prostate cancer. This will be done by comparing PBCT grading with standard slide-based grading. Aim 3 will be to specifically use this technique for assessing prostate tumor phenotype and heterogeneity.

**1. Fellowship Applicant:**
**Strengths**

- Good applicant with BA in Biochemistry completed with honors in 2019.
- Applicant started a direct-entry PhD in 2020.
- Awarded NIH T32 Fellowship.

**Weaknesses**

- No first author publications seen.

**2. Sponsors, Collaborators, and Consultants:**
**Strengths**

- Supported by two complementary mentors with appropriate expertise (medicine, physics, computational biology, anatomical pathology). One sponsor appears to be relatively junior (completed MD in 2000) with co-sponsor being quite senior.

**Weaknesses**

- One sponsor appears to be relatively junior (completed MD in 2000) with co-sponsor being quite senior. Exact roles of co-supervisors remains to be determined.

**3. Research Training Plan:**
**Strengths**

- A detailed research plan is provided with appropriate timelines.

**Weaknesses**

- No significant weaknesses.

**4**. **Training Potential:**
**Strengths**

- Good applicant on a good team. Potential for training is strong.

**Weaknesses**

- No significant weaknesses.

**5**. **Institutional Environment & Commitment to Training:**
**Strengths**

- The study will be carried out through the Pennsylvania State University Hershey Medical Center with appropriate equipment and facilities.

**Weaknesses**

- No significant weaknesses.

**Protections for Human Subjects:**
Acceptable Risks and/or Adequate Protections

**Inclusion of Women, Minorities, and Individuals Across the Lifespan:**

- Sex/Gender: Not applicable.
- Race/Ethnicity: Not applicable.
- Inclusion/Exclusion Based on Age: Not applicable.

**Vertebrate Animals:**
Not Applicable (no vertebrate animals)

**Biohazards:**
Not Applicable (No Biohazards)

**Training in the Responsible Conduct of Research:**
Acceptable
Comments on Format:

- Acceptable

Comments on Subject Matter:

- Acceptable

Comments on Faculty Participation:

- Acceptable

Comments on Duration:

- Acceptable

Comments on Frequency:

- Acceptable

**Resource Sharing Plans:**
Acceptable

**Authentication of Key Biological and/or Chemical Resources:**
Not Applicable (No Relevant Resources)

**Budget and Period of Support:**
Recommend as Requested

**CRITIQUE 2**

Fellowship Applicant: 3
Sponsors, Collaborators, and Consultants: 4
Research Training Plan: 5
Training Potential: 4
Institutional Environment & Commitment to Training: 2

**Overall Impact:** This application comes from an aspiring physician scientist at Penn State University, who has had research experience in structural biology. The application proposes to shift the research training to 3D histopathology using medical imaging, computational tools and statistical analysis. The co-sponsor and sponsor have the required expertise. A major concern for this application is the technical gap between the candidate's academic background and the proposed research.

**1. Fellowship Applicant:**
**Strengths**

- The candidate has a strong academic record.
- The applicant already has 4 co-authored publications from his undergraduate research and one from graduate research.

**Weaknesses**

- There is some concern that the candidates' undergraduate background in Biochemistry may not be ideally suited to techniques development in imaging and machine learning. Previous experience has been in molecular dynamics simulations.

**2. Sponsors, Collaborators, and Consultants:**
**Strengths**

- The sponsor is also a physician scientist with expertise in statistical modeling. He is experienced in mentoring graduate students.
- The co-sponsor has expertise in micro-CT based imaging analysis and is well funded. The sponsor and co-sponsor have a track record of collaboration.
- Other collaborations are in place as required.

**Weaknesses**

- The co-sponsor and collaborators appear to have a more prominent role than the sponsor.

**3. Research Training Plan:**
**Strengths**

- The proposal aims to develop a unique phase contrast micro-CT based approach for 3D whole-biopsy images of soft tissues (prostate cancer). This can have wide applications in histopathology.

**Weaknesses**

- The research project is primarily centered on technique development in histology and image analysis for prostate cancer biopsies. It is unclear how this training can be utilized independently by the candidate for his long term career in hematology and oncology. The research training appears to be more suited to a clinical pathologist.
- The three aims appear to be sequentially dependent on each other raising concerns about the feasibility of Aims 2 and 3.

**4. Training Potential:**

**Strengths**

- The training plan includes hands on experience in tissue handling, synchrotron, image analysis and statistical models.

**Weaknesses**

- Training plan is centered on prostate cancer while the candidate wants to specialize in hematologic oncology and treat patients in bone marrow transplant in his future career.
- The application lack a comprehensive selection of graduate coursework in statistical models, machine learning or medical imaging to help mitigate the gap between the candidate's previous background and proposed research trajectory.

**5. Institutional Environment & Commitment to Training:**

**Strengths**

- The environment at Penn State is adequate with the requisite computational resources and medical center nearby. The equipment and resources (e.g. synchrotron) required are available through collaborations.
- The MSTP training program is robust.

**Weaknesses**

- None noted.

**Protections for Human Subjects:**

Acceptable Risks and/or Adequate Protections

**Inclusion of Women, Minorities, and Individuals Across the Lifespan:**

- Sex/Gender: Distribution justified scientifically.
- Race/Ethnicity: Not applicable
- Inclusion/Exclusion Based on Age: Not applicable.

**Vertebrate Animals:**

Not Applicable (no vertebrate animals)

**Biohazards:**

Acceptable

**Training in the Responsible Conduct of Research:**
Acceptable
Comments on Format:

- RCR training will be accomplished through graduate coursework and annual refresher.

Comments on Subject Matter:

- The requisite modules are incorporated in BMS591 course.

Comments on Faculty Participation:

- The training is provided by faculty.

Comments on Duration:

- The graduate course is for one semester.

Comments on Frequency:

- An annual seminar is offered as a refresher to RCR training.

**Resource Sharing Plans:**
Acceptable

**Authentication of Key Biological and/or Chemical Resources:**
Not Applicable (No Relevant Resources)

**Budget and Period of Support:**
Recommend as Requested

**CRITIQUE 3**

Fellowship Applicant: 1
Sponsors, Collaborators, and Consultants: 1
Research Training Plan: 3
Training Potential: 1
Institutional Environment & Commitment to Training: 1

**Overall Impact:** This is an F30 application from an MD/PhD student. The PI has experience in structural biology and molecular dynamic simulations of RNA structures, where he co-authored four papers during his undergraduate and gap-year. The PI's career goal is to become a Physician-Scientist and establish a new program in hematologic oncology. The referees attest to his curiosity, enthusiasm, dedication, and research productivity. The PI's research interests are at the intersection of anatomic pathology, high-resolution imaging, and computational methods of image analysis. His Co-Sponsors, Drs. Cheng and Silverman, both MD/PhD have expertise in pathology and computational sciences and collaborate on the development of a micron-resolution micro-CT. Other collaborators, Drs. Warrick and La Riviere will lend their resources and expertise in oncology and micro-CT technology. The PI will address a problem in the clinical diagnosis of prostate cancer that currently relies on the assessment of glandular epithelial morphology in biopsy samples. However, 2D histological images suffer from artifacts due to the sectioning angle that obscure cellular morphology. The mentors and the PI proposed to develop a novel ”3D histopathology” method for whole-biopsy prostate (needle core) specimens that includes a very high micron-resolution micro-CT imaging protocol and 3D topological

grading. The project, if successful, has the potential to make a crucial advance in cancer diagnosis. The PI is already working with the Sponsors and progressing in this direction.

**1**. **Fellowship Applicant:**
**Strengths**

- The PI has a strong academic record.
- They have had a productive undergraduate career in computation and structural biology of RNA; his skillset is an appropriate starting point from the proposed project.
- The PI is already gaining experience in the Sponsor lab, while contributing to research.
- He is currently studying the theoretical basis of image analysis.
- The PI is capable of managing multiple sensitive projects, as demonstrated before and on a synchrotron trip, working against the deadline and on the spot.
- The PI is committed to research and clinical career in hematologic oncology.

**Weaknesses**

- None noted.

**2**. **Sponsors, Collaborators, and Consultants:**
**Strengths**

- The Sponsors and collaborators have all the expertise, mentoring experiences, and resources to train the PI.
- The Sponsor, Dr. Cheng, who has an interest in pathology and computational phenomics, conceived the idea of 3D pathology and has been working in this direction for the past 15 years.
- The collaborator, Dr. Warrick, is an anatomic pathologist whose scientific expertise is in the mechanisms of carcinogenesis; he will guide the PI in selecting clinical samples for his research and collaborate on the pathology aspect of this project.
- The collaborator, Dr. La Riviera, will contribute to the PI’s training by including him in the work of his team of experts in x-ray physics, phase contrast, and tomographic image reconstruction. The PI has already collaborated with them on a synchrotron trip and developed an excellent working relationship.

**Weaknesses**

- It would've been better if Dr. Wariick and Dr. La Reviere provided biosketches so a reviewer could fully appreciate their contribution to science.

**3**. **Research Training Plan:**
**Strengths**

- The project addresses a gap in diagnostic imaging.
- The study is designed to determine the 3D structural architecture of prostate tissue to assess the applicability of micro-CT as a tool for the diagnostic analysis of prostate cancer samples in 3D.
- The PI will continue learning histopathology which Dr. Warrick.
- Together they will identify formalin-fixed and paraffin-embedded biopsy samples in the EMR system using Pathnet.

- The PI Imaging partake in two experimental imaging trips to the Advanced Light Source (ALS) at Lawrence Berkeley National Laboratory.
- They will work closely with Dr. Riviere from the University of Chicago on the phase-contrast micro-CT imaging experiments while deepening his understanding of medical physics and mathematics.
- He will continue learning statistical theory from his sponsor and co-mentor, Dr. Silverman.
- The PI has already produced 3D images of prostate cancer and melanoma with the highest resolution/field of view ratio to date, included in preliminary data and attest that the instruments and expertise in programming is already in place.

**Weaknesses**

- None noted.

**4**. **Training Potential:**

**Strengths**

- The proposed project will expose PI to imaging technology, computational imaging, and abstract mathematical image analysis which is complementary to his experience in structural biology.
- The training is aligned with the PI's research career goals.
- The Sponsors are MD/PhDs.
- Longitudinal clinical experience is integrated in the PhD phase through “Translational Research in Medicine” course ensures ongoing clinical experiential learning and one-on-one training with a clinician scientist preceptor.
- Students participate in the bi-monthly Clinical Research Conference and monthly student seminar series, where trainees present their research at least annually.

**Weaknesses**

- None noted.

**5**. **Institutional Environment & Commitment to Training:**

**Strengths**

- Commitment to training physician-scientists over the 30-year history of the MD/PhD program, currently graduating nine MD/PhD each year.
- Major expansion of facilities with the requirement of more than 70 MD and MD/PhD physician-scientists.
- Vibrant intellectual environment.

**Weaknesses**

- None noted.

**Protections for Human Subjects:**

Acceptable Risks and/or Adequate Protections

- De-identified biopsy samples that were followed by prostate resection will be used in the study. Thus, larger samples will remain available for additional diagnostic tests if indicated.

**Inclusion of Women, Minorities, and Individuals Across the Lifespan:**

- Sex/Gender: Not applicable.

- Race/Ethnicity: Not applicable.
- Inclusion/Exclusion Based on Age: Not applicable.

**Vertebrate Animals:**
Not Applicable (no vertebrate animals)

**Biohazards:**
Not Applicable (No Biohazards)

**Training in the Responsible Conduct of Research:**
Acceptable
Comments on Format:

- CITI training.
- in person Ethics course.

Comments on Subject Matter:

- Follows the textbook the Introduction to the Responsible Conduct of Research by Nicholas Steneck.

Comments on Faculty Participation:

- Faculty led.

Comments on Duration:

- One semester.

Comments on Frequency:

- Taken during PhD years.

**Applications from Foreign Organizations:**
Not Applicable (No Foreign Organizations)

**Select Agent Research:**
Not Applicable (No Select Agents)

**Resource Sharing Plans:**
Acceptable

- The research data will be disseminated in timely publications.
- De-identified 3D datasets will be made publicly available on the web-based open-source platform Neuroglancer after publication.
- All scripts and data analysis code will also be available on GitHub.

**Authentication of Key Biological and/or Chemical Resources:**
Acceptable

- Samples drawn from the EMR.

**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**

**COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.**

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Footnotes for 1F30CA295004-01; PI Name: Sugarman, Andrew Lee

+ Derived from the range of percentile values calculated for the study section that reviewed this application.

NIH has modified its policy regarding the receipt of resubmissions (amended applications).See Guide Notice NOT-OD-18-197 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-197.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**

**Center for Scientific Review Special Emphasis Panel**
**CENTER FOR SCIENTIFIC REVIEW**
**Fellowships: Vascular and Hematological Systems, Surgical Sciences, Biomedical Imaging, and Bioengineering.**
**ZRG1 F10C-B (20)**
**03/14/2024 - 03/15/2024**

**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-22-044 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-044.html, including removal of the application from immediate review.

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