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SUMMARY STATEMENT
(Privileged Communication)

Release Date: 07/15/2016
Revised Date:

Application Number: 1 F31 EB023784-01

TRUONG,DANH
AZ Board of Regents on behalf of Arizona
State Uni
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Review Group: ZRG1 F09B-B (20)
Center for Scientific Review Special Emphasis Panel
Fellowships: Oncological Sciences
Meeting Date: 06/27/2016
Council: OCT 2016 *PCC:* TTEZW
Requested Start: 12/01/2016

Project Title: Microengineered Tumor-Stroma Platform Investigating the
Biochemical and Biophysical Influence of Fibroblasts in Cancer
Invasion and Drug Resistance *Requested: 3 Years*
Sponsor: Nikkhah, Mehdi
Department: Biological and Health Systems
Organization: ARIZONA STATE UNIVERSITY-TEMPE CAMPUS
City, State: TEMPE ARIZONA
SRG Action: Impact Score:29 Percentile:20
Next Steps: Visit http://grants.nih.gov/grants/next_steps.htm
Human Subjects: 10-No human subjects involved
Animal Subjects: 10-No live vertebrate animals involved for competing appl.

ADMINISTRATIVE NOTE

1F31EB023784-01 Truong, Danh

ADMINISTRATIVE NOTE

RESUME AND SUMMARY OF DISCUSSION: This initial pre-doctoral fellowship application submitted by Danh Truong proposes to further develop a micro-engineering platform for three-dimensional modeling of cell-cell, tumor-stroma and drug-stroma interactions that incorporates a perfusable vasculature that will provide the basis for future biophysical models of tumor growth and treatment. The excellent applicant has a mixed academic record but is strongly supported by letters of reference and has demonstrated scientific productivity by co-authoring four manuscripts. The research environment at Arizona State University was deemed to be excellent. The educational plans are detailed and will provide the applicant an opportunity to master new scientific methods and leadership skills. Thus the applicant, environment and training potential were judged to be excellent. The team of sponsors and research training plan had a modest negative-score driving effect on the overall score. The technological advancement proposed in the research plan was viewed as innovative and essential. However, there was a concern that adding more than two cells types, specifically adding immune cells, was not addressed. While the primary sponsor, Dr. Nikkhah, possesses the needed expertise and funding to support this application, there was concern that Dr. Nikkhah's laboratory currently has a large number of trainees. Even with an involved co-sponsor, Dr. LaBaer, who can provide essential cell biology expertise, the panel remained concerned that the large number of trainees in Dr. Nikkhah's lab would diminish the individualized training available to Mr. Truong. The panel considered the positive aspects of the application to outweigh the negative concerns, which lead the panel to conclude that, if funded this application would have a high positive impact on the future scientific career of Mr. Truong.

DESCRIPTION (provided by applicant): Breast cancer is the second cause of mortalities among women in the United States. Although there has been a major thrust in cancer therapeutic research, the majority of clinical studies fail due to not taking into account the complex interactions in the tumor-stroma microenvironment, such as cell-cell and cell-ECM, that generally up-regulate drug resistance. Preclinical studies are often being conducted within 2D mono-layer assays of mono-culture of cells, which do not represent the tumor microenvironment inside the body. There is ample evidence suggesting that stromal cells impart drug resistance to cancer cells but there are few models that can recapitulate the tumor-stroma microenvironment with multi-parametric control to study this phenomenon. Although in vivo models enable organism-level studies, key parameters, such as cell- and ECM-types, cell-cell signaling, and drug transport, prove challenging to control. This has created a need to develop a model that can precisely control these parameters to study such behavior in vitro. Current models do recapitulate certain aspects of the tumor-stroma, such as the primary tumor region, but without a stromal region, vasculature, and 3D matrices. This has created a disruption in cell-cell and cell-ECM interactions that may affect drug responsiveness. To that end, this proposal describes the application of a developed tumor-stroma microfluidic platform investigating pharmacological effects within a co-culture system of breast cancer and stromal cells. The developed model is a microengineered device featuring well-defined spatial organization of cells and precise control of biochemical cues containing localized tumor constructs, 3D hydrogel matrices, and media perfusion channels. The goal of this project is to validate and apply a three-dimensional tumor-stroma platform for fundamental tumor-stroma interactions and pharmacological studies. Aim 1 focuses on the investigation of how fibroblasts within the tumor-stroma system affect the growth and invasiveness of the cancer. Aim 2 focuses on the communication between fibroblasts and cancer cells. We will investigate the CXCL12/CXCR4 pathway and its role in doxorubicin resistance. AMD3100, a CXCR4 inhibitor, will be introduced to the tumor- stroma microenvironment to enhance the effectiveness of doxorubicin. Finally, Aim 3 will utilize the model to study drug transport. Fibroblasts deposit ECM into the stroma limiting the effectiveness of drug delivery. We intend to create a cell-free remodeled stroma to isolate the physical alterations from cell-cell signaling for the study of drug penetration. The results from this project will

validate our platform and provide expansive use of it for fundamental cancer biology and pharmacological studies.

PUBLIC HEALTH RELEVANCE: Breast cancer is the second leading cause of death among American women highlighting a need to fabricate targeted platforms recapitulating the tumor microenvironment for aggressive development of cancer therapeutics. The goal of this proposal is to develop and validate our complex tumor-stroma model describing the role of fibroblasts in cancer invasion and pharmacological studies. This should translate into a novel drug- screening tool utilizing a physiologically relevant 3D tumor microenvironment. The results from this project will likely affect the drug development pipeline by providing an alternative and complementary testing environment for current used models.

Critique 1

Fellowship Applicant: 3

Sponsors, Collaborators, and Consultants: 3

Research Training Plan: 2

Training Potential: 3

Institutional Environment & Commitment to Training: 3

Overall Impact/Merit: This proposed research plan would develop a 3D tumor-stroma micro-platform for breast cancer. The technology will permit study of tumor growth, tumor invasion, and drug-tumor interaction in a single cell basis and will be greatly beneficial to the understanding of cancer biology. The applicant is a predoctoral candidate 2 year into the program for a PhD in Biomedical Engineering since 2014 (for a 5-year program to complete in 2018). The candidate has good scholastic performance and is greatly motivated to perform the proposed research with prior involvement in the relevant research. The mentor has relevant expertise and is an expert in the proposed technology. That said, some weaknesses have been noted. There are some needs for Mr. Truong to learn to write peer-reviewed publications. Funding this application for the requested 3 years would help him to complete the PhD degree and grow into competent scientist.

1. Fellowship Applicant:

Strengths

- The scholastic performance of the candidate was good with a mixture of A's and B's.
- Biomedical engineering background of the candidate is a good fit for the proposed project.
- The letters of recommendations speak highly of his relevant research experiences and hard work ethic.

Weaknesses

- The candidate has no first authored peer-reviewed publications.

2. Sponsors, Collaborators, and Consultants:

Strengths

- The sponsor, Dr. Mehdi Nikkhah, is an assistant Professor of Bioengineering at ASU and has extensive experience and NIH funding for microengineering of tissue.
- The co-sponsor, Dr. Joshua LaBaer, MD, PhD, is a Piper Chair of Personalized Medicine at ASU.

Weaknesses

- None noted.

3. Research Training Plan:

Strengths

- The specific aims are logically laid out for the duration of PhD training period from (1) develop a 3D co-culture cell platform to assess the tumor growth and invasion; to (2) study the role of anti-cancer drug resistance on the 3D micro-platform; to (3) assess the role of fibroblast-induced desmoplasia in doxorubicin penetration and function.
- Strong preliminary data to show the feasibility to construct a 3d tumor-stroma platform integrated with perfusable vasculature.

Weaknesses

- None noted.

4. Training Potential:

Strengths

- The candidate will learn a lot of innovative technology in microengineering.

Weaknesses

- The candidate will benefit from learning scientific writing to develop writing skills for grantsmanship and peer-reviewed publications.

5. Institutional Environment & Commitment to Training:

Strengths

- Arizona State University provides adequate environment for the proposed research.

Weaknesses

- None noted.

Protections for Human Subjects:

Not Applicable (No Human Subjects)

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research:

Acceptable

Comments on Format (Required):

- CRC training course is provided online in partnership with University Miami's Collaborative Institutional training initiative (CITI).

Comments on Subject Matter (Required):

- No information provided on the subject matter except for animal training and human subject training.

Comments on Faculty Participation (Required):

- Faculty participation is as needed basis.

Comments on Duration (Required):

- No information is provided on the duration of the RCR training.

Comments on Frequency (Required):

- No information is provided on the frequency of the RCR training.

Select Agents:

Not Applicable (No Select Agents)

Resource Sharing Plans:

Not Applicable (No Relevant Resources)

Budget and Period of Support:

Recommend as Requested

- Funding for 3 years is adequate.

Critique 2

Fellowship Applicant: 3

Sponsors, Collaborators, and Consultants: 4

Research Training Plan: 3

Training Potential: 3

Institutional Environment & Commitment to Training: 3

Overall Impact/Merit: The purpose of this application is to train Danh Truong to develop and validate a platform for 3D tumor-stroma model to analyze the role of fibroblasts in cancer invasion and pharmacological effect. Breast cancer is the second leading cause of death among American woman and the 3D model could provide a better readout system to test pharmaceutical reagent than 2D cell culture system. Therefore, the proposed study is important. The key strengths of this application are the strong motivation of applicant, and the productive progress (two papers and one submitted manuscript) of applicant in the laboratory. The proposed studies are with expertise of the primary sponsor, Dr. Mehdi Nikkhah. Dr. Joshua LaBaer is a very strong co-sponsor in the application. The key weakness is the primary sponsor has limited experience for mentorship and lacks tracking record for training. Nevertheless, funding this application for the requested 3 years would have a major impact on Mr. Truong's graduate study.

1. Fellowship Applicant:

Strengths

- Applicant's academic record is excellent and his research experience in the current lab is outstanding.
- For <2 year in Biomedical engineer Ph.D. program at Arizona State University, he has worked on several projects and has one first author manuscript submitted, and two co-authorship paper published, including one with equal contribution of first authorship.
- Applicant has great passion for teaching other minority undergraduate students in STEM in the laboratory.

Weaknesses

- None noted.

2. Sponsors, Collaborators, and Consultants:

Strengths

- The primary sponsor, Dr. Mehdi Nikkhah was a recipient of NIH NRSA F32 Fellowship trainee for 6 months.
- Dr. Nikkhah's research interest match to applicant's research training plan.
- Co-sponsor, Dr. Joshua LaBaer has extensive experience for proteomics and autoantibody biomarkers cancer biomarker.
- Co-sponsor, Dr. LaBaer has a track record of mentoring.

Weaknesses

- Dr. Nikkhah is a faculty member in Arizona State University since 2014 and there is no established track record of mentoring.
- The sponsor has one NSF funding that will end in 2017.

3. Research Training Plan:

Strengths

- The proposed research plan will use a new microengineered platform to validate 3D co-culture of tumor cell with cancer associated fibroblasts or normal fibroblasts with perfusable vasculature to study how fibroblasts affect tumor growth and invasion, the role of CXCL12/CXCR4 blocker AMD3100 to chemotherapeutic effect of doxorubicin, and the fibroblast induced desmoplasia in doxorubicin penetration. The proposed research is highly relevant to cancer microenvironment study.
- The applicant engineered the platform and produced preliminary study, therefore, the training plan is consistent with the applicant's stage of research development.
- The research training plan provides the applicant with individualized and supervised experience.

Weaknesses

- The research plan needs more emphasis on the biology of cancer, microenvironment and host immune system.
- The current platform is still at an infant stage of mimicking tumor microenvironment in vivo.
- The outcome from the proposed study, at most, provides the hint for how cancer associated fibroblasts affect tumor cell invasion, which has been proved in other systems.

4. Training Potential:

Strengths

- Proposed research training plan has the potential to provide the applicant with supervised experiences that will develop his research skills.
- Training plan has listed 4 goals to train Mr. Truong in the area of research: for microfabrication and biomarker, cancer biology and invasion, cell imaging and biostatistics and in leadership area of educational outreach.

Weaknesses

- None noted.

5. Institutional Environment & Commitment to Training:

Strengths

- The environment in Arizona State University is adequate for the proposed studies.

Weaknesses

- None noted.

Protections for Human Subjects:

Not Applicable (No Human Subjects)

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable

Training in the Responsible Conduct of Research:

Comments on Format (Required):

- The RCR training has three phases: Online course, seminar, and by PI to ensure the high ethical standard in each research lab which are acceptable.

Comments on Subject Matter (Required):

- The Arizona State University hosts seminars discussing bioethics, research misconduct, and research integrity.

Comments on Faculty Participation (Required):

- PI serves as a role model.

Comments on Duration (Required):

- No particular duration stated in application.

Comments on Frequency (Required):

- No frequency stated in application.

Select Agents:

Not Applicable (No Select Agents)

Resource Sharing Plans:

Not Applicable (No Relevant Resources)

Budget and Period of Support:

Recommend as Requested

Additional Comments to Applicant:

- Only one of three reference letters directly relates to this funding mechanism.

Critique 3

Fellowship Applicant: 2

Sponsors, Collaborators, and Consultants: 2

Research Training Plan: 2

Training Potential: 2

Institutional Environment & Commitment to Training: 2

Overall Impact/Merit: The application seeks to train a great candidate in the area of tumor immunology. The well-written application seeks to develop a tumor stroma microfluidic platform to better study these interactions in vitro. The successful completion of this research will be impactful as the widely used 2-D in vitro platform has too many limitations but is used as it is convenient and can be easy to establish. This platform will be used to test the role of fibroblasts in breast cancer, to study if the combination of doxorubicin and a CXCR4 inhibitor show enhanced effectiveness, and as means of drug delivery. Enhanced models to study the interaction of tumor cells with the stroma, if easily adoptable, can have a high impact on cancer research providing a more relevant in vitro test to test potential therapeutics. The experiments are well outlined and potential pitfalls and alternative approaches are addressed. Preliminary data supports the feasibility of the project. The sponsor has extensive experience training graduate students and the training environment appears to be quite good. If funded, this application will have a strong impact on training the applicant.

1. Fellowship Applicant:

Strengths

- The applicant has previous research experience that has led to four peer reviewed publication.
- Strong letters of support.
- Good grades and test scores.

Weaknesses

- None noted.

2. Sponsors, Collaborators, and Consultants:

Strengths

- The sponsors have the proper expertise and experience to mentor the applicant.

- The sponsors form a strong team to guide the applicant through the different stages of the project.
- Both have strong prior experience mentoring students.

Weaknesses

- None noted.

3. Research Training Plan:

Strengths

- Well written research plan.
- Research plan addresses potential pitfalls and includes alternative approaches.
- Preliminary data included supports the feasibility of the project.
- Well populated lab with other graduate students and post docs should enhance the applicant's training.

Weaknesses

- None noted.

4. Training Potential:

Strengths

- This is an interesting project with strong training potential.

Weaknesses

- None noted.

5. Institutional Environment & Commitment to Training:

Strengths

- This is a very good training environment.

Weaknesses

- None noted.

Protections for Human Subjects:

Not Applicable (No Human Subjects)

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research:

Acceptable

Comments on Format (Required):

- online CITI course, seminars, and PI's enforcing ethical behavior in their labs

Comments on Subject Matter (Required):

- bioethics and research misconduct

Comments on Faculty Participation (Required):

- enforcing in their own lab

Comments on Duration (Required):

- not mentioned

Comments on Frequency (Required):

- not mentioned

Select Agents:

Not Applicable (No Select Agents)

Resource Sharing Plans:

Unacceptable

- Not delineated.

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:

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

ADMINISTRATIVE NOTE:

During the review of this application, reviewers and/or NIH staff noted that one or more biosketches did not comply with the required format (NOT-OD-15-032). An electronic notification has been sent to the contact Program Director/Principal Investigator and Signing Official for this application, to ensure that future applications use the correct biosketch format. NIH has the authority to withdraw such applications from review or consideration for funding.

Footnotes for 1 F31 EB023784-01; PI Name: Truong, Danh

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
Center for Scientific Review Special Emphasis Panel

CENTER FOR SCIENTIFIC REVIEW
Fellowships: Oncological Sciences
ZRG1 F09B-B (20)
06/27/2016 - 06/28/2016

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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.