

SUMMARY STATEMENT

PROGRAM CONTACT:
LEONID TSAP
301-402-7747
tsapl@mail.nih.gov

(Privileged Communication)

Release Date: 03/24/2023
Revised Date:

Principal Investigator

DILLON, CHRISTOPHER R

Application Number: 1 R21 AG083686-01
Formerly: 1R21EB034788-01

Applicant Organization: BRIGHAM YOUNG UNIVERSITY

Review Group: IGIS
Imaging Guided Interventions and Surgery Study Section

Meeting Date: 02/23/2023
Council: MAY 2023
Requested Start: 07/01/2023

RFA/PA: PAR20-084
PCC: 1ATECLT

Project Title: Investigating the impact of subcutaneous fat properties on focused ultrasound thermal therapy outcomes
SRG Action: ++
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.

| Project Year | Direct Costs Requested |
|-----------------|---------------------------|
| 1 | 150,000 |
| 2 | 125,000 |
| 3 | 125,000 |
| TOTAL | 400,000 |

++NOTE TO APPLICANT: Members of the Scientific Review Group (SRG) were asked to identify those applications with the highest scientific merit, generally the top half. Written comments, criterion scores, and preliminary impact scores were submitted by the assigned reviewers prior to the SRG meeting. At the meeting, the more meritorious applications were discussed and given final impact scores; by concurrence of the full SRG, the remaining applications, including this application, were not discussed or scored. The reviewers' comments (largely unedited by NIH staff) and criterion scores for this application are provided below. Because applications deemed by the SRG to have the highest scientific merit generally are considered for funding first, it is highly unlikely that an application with an ND recommendation will be funded. Each applicant should read the written critiques carefully and, if there are questions about the review or future options for the project, discuss them with the Program Contact listed above.

DILLON, C

1R21AG083686-01 Dillon, Christopher

DESCRIPTION (provided by applicant): Soft tissue tumors cause pain, impair mobility, and, if malignant, metastasize to vital organs. While surgery and radiation can resolve tumors, recurrence and morbidities remain for many. Magnetic resonance-guided focused ultrasound (MRgFUS) is a promising treatment technology that may reduce morbidities related to tumor surgery, chemotherapy, and radiation. This is because MRgFUS non-invasively and precisely destroys tissue using non-ionizing radiation. However, patients whose tumors are infiltrated by fat do not receive the full benefits of MRgFUS because fatty tissues respond to MRgFUS in distinctive ways that impede effective treatment. This study proposes to reduce treatment times, preserve healthy tissue, and reduce tumor recurrence for fatty soft tissue tumors by measuring and then predicting fat behavior during MRgFUS. This work will enable a future simulation-based planning platform that can predict the response of fatty tissues for a given MRgFUS protocol. Surgeons can then use this platform to avoid collateral tissue damage, overly long treatments, and incomplete tumor ablations in fatty tissues. To achieve these goals, the study will execute the following Specific Aims. Specific Aim 1. Assess fat tissue properties as they change across MRgFUS-relevant temperatures. These properties include T1 and T2 MR relaxation times, acoustic speed of sound and attenuation coefficients, thermal conductivity, thermal diffusivity, specific heat capacity, and mechanical shear modulus. Correlations between these properties and their causal effects will be investigated. Specific Aim 2. Evaluate how well the tissue properties measured in Specific Aim 1 predict observed treatment outcomes in previously conducted MRgFUS treatments of desmoid soft tissue tumors. Predictions of acoustic focal location, intensity and temperature distribution will be derived by segmenting MR anatomic images and modeling acoustic and thermal processes. Prediction accuracy will be measured in comparison to identical parameters recorded during treatment. Completion of this study will improve outcomes for patients suffering from soft tissue tumors. Accurate models of fatty tissue properties will allow surgeons to preemptively predict and avoid treatment plans that cause long, incomplete MRgFUS treatments or that might ablate collateral healthy tissue.

PUBLIC HEALTH RELEVANCE: Soft tissue tumors cause pain, impair mobility, and, if malignant, metastasize to vital organs. Magnetic resonance-guided focused ultrasound (MRgFUS) might improve treatments of fatty soft tissue tumors so long as surgeons are able to predict and account for the variable response of fatty tissues to MRgFUS treatment. Our team has identified an opportunity to measure, predict, and account for variable fatty tissue responses to MRgFUS.

CRITIQUE 1

Significance: 2
Investigator(s): 2
Innovation: 2
Approach: 5
Environment: 2

Overall Impact: This is a new R21 application through the NIBIB Trailblazer Award for New and Early Stage Investigators, proposing to investigate the impact of subcutaneous fat properties on focused ultrasound thermal therapy outcomes. They suggest 3 problems introduced by fat in relation to MRI-guided focused ultrasound (MRgFUS) treatment: (1) inability to monitor temperature non-invasively using MRI, (2) FUS beam aberrations from fat interfaces/inhomogeneities, and (3) unexplained near field SC fat changes and tumor treatment variation. They propose two specific aims to study and potentially address these problems. In Aim 1, they will assess fat tissue properties (thermal, mechanical, acoustic, MR) across a range of relevant temperatures. In Aim 2, they will retrospectively analyze MRgFUS

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treatments in patients with desmoid tumors and perform simulations to resolve the contributions of fat properties in the treatment outcomes. This data will be used to develop a model for planning and performing MRgFUS treatments. In the end, they proposed developing a 'simulation-based treatment planning platform' to guide MRgFUS treatments in fatty tissues or targets surrounded by fat. The team and environment for the proposed work are excellent, although the PIs do not have prior publications or other shared work products. It remains unclear if an MR or other real-time monitoring approach may render the '3 problems' to be addressed in this project irrelevant. The approach would be strengthened by more detail on experimental replicates, the use of statistics, as well as accounting for in vivo and other biological variables. Model validation strategies are also not considered. Overall, this is a strong proposal that addresses a current clinical challenge in MRgFUS; however, the proposal would benefit from additional components and fine-tuning.

1. Significance:**Strengths**

- Improving the performance of MRgFUS in regions of fat and soft tissue inhomogeneity would be valuable.

Weaknesses

- The investigators do not propose an improved real-time monitoring strategy to gauge and monitor the effects of MRgFUS continuously and with some form of closed feedback loop control. Such components are key to the safety and effective use of MRgFUS in other applications.

2. Investigator(s):**Strengths**

- Strong experience team of investigators (CD, SA, DD) from BYU
- Collaboration with PG (Stanford), who has extensive experience with the InSightec MRgFUS body system and treatments of body tumors.

Weaknesses

- The investigative team has no evidence of productive collaboration.

3. Innovation:**Strengths**

- Expanding information about temperature-dependent fat properties at the level of acoustic, thermal, mechanical, and magnetic resonance is novel
- A computational model predicting and adjusting for fat-related variations during MRgFUS treatments would be a novel way to address the current clinical limitations

Weaknesses

- Other groups have resolved this issue with MR thermometry (PRFS) in fat using T1-based 2D-variable flip angle (VFA) thermometry with slice profile effect correction. PMID: 34061390. Such as system/approach could address most of the issues proposed for study in this project.

4. Approach:

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Strengths

- Aim 1: Use of fresh bovine and human tissues
- Aim 2: 80 treatments (60 patients) will be analyzed retrospectively to create the new models

Weaknesses

- Aim 1: there is no plan to explore different FUS parameters (e.g., frequency, duty cycle) that could reduce the impact of fat-related variations. A number of experimental replicates are not given. The rationale for the selected statistical approach is not given; for example, why is Bayesian vs. non-Bayesian in this case? There is no plan to assess fat properties in vivo where tissue perfusion, oxygenation, and other physiologic variables could impact ground truth measurements. No information or plan is given regarding the sex, age, or race of patients whose fat samples will be used.
- Aim 2: Given the models will be built retrospectively from patient treatments at one site (Stanford), it would be useful to validate the new model against treatments at another site.

5. Environment:**Strengths**

- The BYU, Utah, and Stanford environments have excellent resources for the proposed work

Weaknesses

- None noted

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

Inclusion Plans:

- Sex/Gender: Distribution not justified scientifically
- Race/Ethnicity: Distribution not justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion Based on Age: Distribution justified scientifically
- No information is given regarding the sex, age, or race of planned fat samples from patients.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans:

Acceptable

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Budget and Period of Support:

Recommend as Requested

CRITIQUE 2

Significance: 5

Investigator(s): 2

Innovation: 3

Approach: 6

Environment: 2

Overall Impact: This Trailblazer R21 application proposes to measure the temperature dependency of fat tissue acoustic, mechanical, and MR properties and integrate the measurements into computational modeling for treatment planning to improve the clinical MRgFUS treatment of soft tissue tumors. The proposed study is significant in that all applications of MRgFUS thermal ablation in the body involve traversing subcutaneous and abdominal fat of variable thickness. It is also innovative in that information on acoustic and mechanical properties of fat tissue changes with temperature is sparse in the literature. The investigators have the expertise and environmental support to perform the proposed study. There are several major weaknesses, including the prior research (Fig. 1) used to support this application lacks rigor, and the approach is not well-reasoned. Overall, the impact of this application is considered moderate.

1. Significance:**Strengths**

- MR-guided focused ultrasound (MRgFUS) has been used in the clinic for noninvasive, nonionizing, and localized thermal ablation treatment of soft tissue tumors. All applications of MRgFUS thermal ablation in the body, such as the treatment of uterine fibroids, involve traversing subcutaneous and abdominal fat of variable thickness. Because of the higher acoustic absorption of fatty tissues compared to non-fatty soft tissues, treating deep lesions has proved difficult in the clinic. Differences in acoustic impedance between fatty and non-fatty soft tissues cause reflection and refraction of ultrasound energy at tissue interfaces, which further influences the degree and location of heating at the target. Pre-focal fat not only limits thermal ablation for deep-seated lesions but also increases the risk of pre-focal tissue damage.
- This application proposes to measure the temperature dependency of fat tissue acoustic, mechanical, and MR properties and integrate the measurements into computational modeling for treatment planning to compensate for temperature-dependent fat property changes.
- Reports on how the acoustic and mechanical properties of fat tissue changes with temperature exist but are sparse in the literature.
- The pre-treatment modeling using well-characterized tissue properties can allow better prediction and optimization of the thermal changes during MRgFUS treatment.

Weaknesses

- The prior research that was used as the key support (Fig.1) lacks rigor. A phenomenon observed by interventional radiologists was used as a key supporter of the proposed project. Only MR images from three representative cases are presented. How often does this

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phenomenon occur? Is it always associated with decreases in tumor temperature? Is it a phenomenon observed by one or many radiologists?

- Acoustic and thermal parameters are needed for computational modeling. The significance of measuring fat tissue mechanical properties is not well reasoned. Characterizing MR properties of fat tissue is important, but its significance in this study is not clarified. How will the measured MR properties be used to improve MR thermometry in fat tissue?

2. Investigator(s):

Strengths

- The PI has the expertise needed to perform the proposed study.
- Dr. Ghanonuni (co-I) is an expert in performing MRgFUS clinical treatment.
- The team is strengthened by including a biostatistician.

Weaknesses

- None noted

3. Innovation:

Strengths

- The proposed measurements of temperature-dependent properties of fat are innovative.
- The integration of temperature-dependent thermal properties in MRgFUS computational modeling is new.

Weaknesses

- The approaches used for measuring the fat properties are established methods.
- It is stated that "there is currently no information available regarding temperature-dependent fat properties." This is an overstatement. For example, Baron et al. reported T1 and T2 temperature dependency of breast adipose tissue (DOI: 10.1002/nbm.3410).

4. Approach:

Strengths

- The proposed retrospective evaluation of the impact of the measured properties on clinical MRgFUS treatment provides validation of the measured properties and established modeling.

Weaknesses

- Tissue properties change rapidly outside the body unless maintained under physiologically normal conditions. The study proposes to place freshly excised fat tissue in water at room temperature, which is not close to the normal physiological condition.
- Fat tissue will be acquired from bovines and humans without considering the location where the tissue will be acquired. Fat tissue properties can be different in different anatomical locations.
- The experimental plan lacks consideration for how many samples will be needed.
- MR, thermal, and mechanical properties will be measured at different temperatures using different devices. How long will it take to finish all these measurements for every sample? How will the change in tissue properties over time be considered in the experimental plan?

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- All these measurements will be performed by using water circulators to heat up the fat. Before applying the measured properties to complex patient modeling, it is important to validate the acoustic and bioheat modeling for MRgFUS treatment with the ex vivo fat tissue.
- Aim 2 is going to segment MR data to tissue types, including skin, fat, muscle, tumor, and bone, and then perform a numerical simulation to incorporate temperature-dependent fat properties. However, the properties of all tissue types depend on temperature, not just fat.

5. Environment:

Strengths

- BYU has the resources needed to perform the proposed study.
- The collaboration with Stanford is critical to access patient MRgFUS clinical data.

Weaknesses

- None noted

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

Vertebrate Animals:

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans:

Acceptable

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3

Significance: 4

Investigator(s): 2

Innovation: 6

Approach: 6

Environment: 1

Overall Impact: This Trailblazer application from an experienced early-career investigator proposes to investigate the role of fatty tissue properties in outcomes of MR-guided focused ultrasound (MRgFUS), with the stated target of soft-tissue tumors. Improvements in MRgFUS procedures for fatty tissues, including treatment planning and temperature monitoring, would potentially be clinically significant, although the impact of the specific desmoid sarcoma clinical application is not convincingly argued. The

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general research direction of mitigating the effects of fatty tissue in the FUS propagation path is innovative and potentially important. However, the research plan's emphasis on the measurement of temperature-dependent acoustic and thermal properties is less innovative, and appears not to be sufficiently grounded in prior research from this field. The research strategy for the measurement of tissue-dependent properties has several weaknesses, including the use of water with tissue samples, unclear methodology, and lack of some relevant parameters from measurements. The incorporation of new results into treatment planning is not well developed, with unclear strategies for training statistical models, consideration of variations in tissue properties between individuals, and lack of clarity on what FUS parameters, such as sonication frequency, will be modeled. Overall, although the study addresses a potentially important problem, enthusiasm is diminished because of shortcomings in the planned approach, as well as modest innovation in some of the proposed work.

1. Significance:

Strengths

- Improved noninvasive treatments of solid tumors would be clinically significant for multiple disease states.
- MR-guided focused ultrasound (MRgFUS) is a powerful treatment approach with substantial room for improvement.
- Improved temperature monitoring and FUS treatment planning in fatty tissues are substantial unmet needs.

Weaknesses

- Unclear what the desired tumor targets are for the proposed approach, e.g., any tumors within soft tissue or mainly desmoid sarcomas?
- Unclear which tumors are argued to be "relatively common" in younger people and how common those may be.
- Although MRgFUS is stated to be "a promising therapeutic technology to displace traditional therapies for the control and elimination of desmoid and other soft tissue tumors," it's unclear what traditional therapies are meant and what their relevant disadvantages may be.
- Prior research on the measurement of fatty tissue properties has not been sufficiently considered in the research strategy.

2. Investigator(s):

Strengths

- The PI is an early-career investigator experienced in modeling and analysis of MR-guided focused ultrasound.
- Co-investigators and a Significant Contributor add strong support to MR-guided focused ultrasound research and clinical applications.
- The team includes a biostatistician.

Weaknesses

- The duties of consultant Christensen are stated as "guidance on the ultrasound aspects;" unclear if this will just include simulations or also measurements of temperature-dependent tissue properties.

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3. Innovation:

Strengths

- Better accounting for temperature-dependent properties of fat, though not a new idea for MRgFUS, would expand the potential of new FUS treatments for soft-tissue tumors and other applications.
- Resolution of FUS treatment difficulties associated with fatty tissue within the FUS propagation path is a novel and potentially important research direction.

Weaknesses

- The measurement of temperature-dependent tissue properties is a long-standing research area.
- Measurements of thermal properties would be performed using an off-the-shelf thermal property analyzer.
- The statement "there is currently no information available regarding temperature-dependent fat properties" is inaccurate, suggesting the applicant has not rigorously evaluated prior research in this field.

4. Approach:

Strengths

- Plans for the measurement of temperature-dependent MR and thermal tissue properties appear straightforward, using mainly established techniques.
- Retrospective evaluation of MRgFUS desmoid tumor treatments is ideal for testing the effects of modeled temperature-dependent fat properties.
- The hybrid angular spectrum method and Pennes bioheat model should be appropriate for most FUS simulations in inhomogeneous tissue.

Weaknesses

- Unclear how causality between tissue properties and MRgFUS effects will be established.
- For tissue property measurements, methodologic details like the size and orientation of the tissue samples are not described.
- Filling a sample container with water may damage and degrade tissue due to osmotic effects that disrupt cells and tissue structures.
- The technique for measurement of acoustic properties is unclear, e.g., when measuring insertion loss using a radiation-force balance, how reflections from tissue/water interfaces would be accounted for.
- No measurement of mass density or acoustic impedance is described.
- The choice of frequencies for acoustic property measurements is not clearly justified, and it's unclear why speed and attenuation are planned to be measured at different discrete frequency values.
- For simulations, unclear why constant-property tests would be done using literature values rather than values derived from the measurements of SA1.
- Unclear what is meant by the "temperature-dependent property model" and its k-fold cross-validation. How would this model be defined and trained?

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- Although tissue-dependent property measurements are likely to vary widely from one sample to the next, simulation studies, don't appear to analyze sensitivity to variations in these properties.
- The importance of some factors, such as scattering, would depend on the parameters of the MRgFUS treatments, e.g., sonication frequency, which is not specified.
- Sex as a biological variable is not explicitly addressed.

5. Environment:

Strengths

- Excellent biomedical research infrastructure and support system at BYU.
- Strong clinical environment for desmoid tumor treatments at Stanford, providing clinical data for this study.

Weaknesses

- None noted

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- Human tissue samples will be de-identified and collected from surgical procedures rather than specifically for the proposed research.
- Retrospective data from clinical MRgFUS studies will be de-identified appropriately.
- Exemption #4 applies so that Human Subjects Research will not be performed.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans:

Acceptable

- Data and methods sharing as supplementary material for journal articles are appropriate.
- Although multiple outputs are mentioned (tissue properties, models, and their parameters), it's not clear whether these will remain proprietary or under what conditions they will be disseminated.

Budget and Period of Support:

Recommend as Requested

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Footnotes for 1 R21 AG083686-01; PI Name: Dillon, Christopher R

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

Imaging Guided Interventions and Surgery Study Section Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group CENTER FOR SCIENTIFIC REVIEW

IGIS

02/23/2023 - 02/24/2023

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.

CHAIRPERSON(S)

GIBBS, SUMMER LYNNE, PHD
PROFESSOR
DEPARTMENT OF BIOMEDICAL ENGINEERING
OREGON HEALTH AND SCIENCE UNIVERSITY
PORTLAND, OR 97239

CRESSMAN, ERIK N, MD, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF INTERVENTIONAL RADIOLOGY
DUNN CENTER FOR RADIOLOGIC SCIENCES
UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER
HOUSTON, TX 77030

MEMBERS

AI, HUIWANG, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF CHEMISTRY AND MOLECULAR
PHYSIOLOGY AND BIOPHYSICS
UNIVERSITY OF VIRGINIA
CHARLOTTESVILLE, VA 22908

FOWLER, AMY, MD, PHD *
ASSISTANT PROFESSOR
DEPARTMENT OF RADIOLOGY
SECTION OF BREAST IMAGING
UNIVERSITY OF WISCONSIN – MADISON
MADISON, WI 53792

APPLEGATE, BRIAN E, PHD
PROFESSOR
DEPARTMENT OF HEAD AND NECK SURGERY AND
BIOMEDICAL ENGINEERING
KECK SCHOOL OF MEDICINE
UNIVERSITY OF SOUTHERN CALIFORNIA
LOS ANGELES, CA 90033

GOLDBERGER, JEFFREY J, MD *
CHIEF
DIVISION OF CARDIOVASCULAR
MILLER SCHOOL OF MEDICINE
UNIVERSITY OF MIAMI
MIAMI, FL 33136

BAYER, CAROLYN LOUISE, PHD *
ASSISTANT PROFESSOR
DEPARTMENT OF BIOMEDICAL ENGINEERING
BIOMEDICAL FUNCTIONAL IMAGING LABORATORY
TULANE UNIVERSITY
NEW ORLEANS, LA 70118

GRISWOLD, MARK, PHD
PROFESSOR
DEPARTMENT OF RADIOLOGY
CASE WESTERN RESERVE UNIVERSITY
CLEVELAND, OH 44106

CASTILLO, EDWARD JR, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF BIOMEDICAL ENGINEERING
UNIVERSITY OF TEXAS AT AUSTIN
AUSTIN, TX 78712

HARIRI, LIDA P, BS, MD, PHD *
ASSOCIATE PROFESSOR
DEPARTMENT OF PATHOLOGY
MASSACHUSETTS GENERAL HOSPITAL
HARVARD MEDICAL SCHOOL
BOSTON, MA 02114

CHEN, HONG, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF BIOMEDICAL ENGINEERING
WASHINGTON UNIVERSITY
ST. LOUIS, MO 63130

JUCHEM, CHRISTOPH, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF BIOMEDICAL ENGINEERING
AND RADIOLOGY
COLUMBIA UNIVERSITY
NEW YORK, NY 10027

KELLY, JAMES, PHD *
ASSISTANT PROFESSOR
DEPARTMENT OF RADIOLOGY
WEILL CORNELL MEDICINE
NEW YORK, NY 10065

KHOKHLOVA, TATIANA, PHD
ASSOCIATE PROFESSOR
DIVISION OF GASTROENTEROLOGY
SCHOOL OF MEDICINE
UNIVERSITY OF WASHINGTON
SEATTLE, WA 98195

MAST, T DOUGLAS, PHD
PROFESSOR
DEPARTMENT OF BIOMEDICAL ENGINEERING
COLLEGE OF ENGINEERING AND APPLIED SCIENCE
UNIVERSITY OF CINCINNATI
CINCINNATI, OH 45267

NGWA, WILFRED, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF RADIATION ONCOLOGY AND MOLECULAR
RADIATION SCIENCES
JOHNS HOPKINS UNIVERSITY
BALTIMORE, MD 21218

NIETHAMMER, MARC, PHD
PROFESSOR
DEPARTMENT OF COMPUTER SCIENCE
COLLEGE OF ARTS AND SCIENCES
UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
CHAPEL HILL, NC 27599

PAYNE, ALLISON, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF RADIOLOGY AND IMAGING SCIENCES
SCHOOL OF MEDICINE
UNIVERSITY OF UTAH
SALT LAKE CITY, UT 84109

PRAKASH, PUNIT, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF ELECTRICAL AND COMPUTER
ENGINEERING
KANSAS STATE UNIVERSITY
MANHATTAN, KS 66506

SAWYER, TRAVIS WILLIAM, PHD *
ASSISTANT PROFESSOR
DEPARTMENT OF OPTICAL SCIENCES
UNIVERSITY OF ARIZONA
TUCSON, AZ 85721

SIMPSON, AMBER, PHD
CANADA RESEARCH CHAIR
ASSOCIATE PROFESSOR
DEPARTMENT OF BIOMEDICAL AND MOLECULAR SCIENCES
SCHOOL OF COMPUTING
QUEEN'S UNIVERSITY
KINGSTON, ON K7L4L5
CANADA

WOODWORTH, GRAEME F, MD
PROFESSOR AND CHAIR
DEPARTMENT OF NEUROSURGERY
UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE
BALTIMORE, MD 21201

XU, ZHEN, PHD
PROFESSOR
DEPARTMENT OF BIOMEDICAL ENGINEERING
UNIVERSITY OF MICHIGAN
ANN ARBOR, MI 48109

ZOU, HONGYAN, MD, PHD
PROFESSOR
DEPARTMENTS OF NEUROSCIENCE AND NEUROSURGERY
ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI
NEW YORK, NY 10029

SCIENTIFIC REVIEW OFFICER

JONES, ELLA FUNG, PHD
SCIENTIFIC REVIEW OFFICER
CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

EXTRAMURAL SUPPORT ASSISTANT

STANSBURY, JACQUELINE M
LEAD EXTRAMURAL SUPPORT ASSISTANT
CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

OTHER REVIEW STAFF

CHENG, YUANNA, MD, PHD
SCIENTIFIC REVIEW OFFICER
CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

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.