1. NBA & GE HEALTHCARE BACKGROUND AND OVERVIEW

1.1. Collaboration Overview:

In June 2015, the NBA and GE Healthcare launched the NBA & GE Healthcare Orthopedics and Sports Medicine Collaboration, a strategic partnership aimed at engaging leading clinical researchers who have demonstrated excellence in orthopedics, sports medicine, radiology, and related disciplines. The NBA, GE Healthcare, and additional partners will provide funding for research that supports the mission of the collaboration.

1.2. Collaboration Mission:

The mission is to address high-priority clinical questions regarding the prevention, diagnosis, and treatment of acute and overuse injuries among NBA athletes, and to apply such findings to basketball players and the general population.

1.3. Collaboration Call For Proposals:

A series of Calls for Proposals (CFP) will be consecutively released by the NBA & GE Healthcare Orthopedics and Sports Medicine Collaboration, with each CFP strategically focused on a class of acute or overuse injuries affecting NBA athletes.

The first CFP was released in 2015 and focused on the natural history, diagnosis, treatment, and prevention of tendinopathy. The second was released in June 2016 and focused on prevention, assessment, treatment, and return-to-play strategies for acute myotendinous injuries. To learn more about these CFPs and awardees, and to register for notifications of upcoming CFP releases, please visit the NBA & GEHC collaboration CFP website.

2. NBA & GE HEALTHCARE PROGRAM GOVERNANCE

2.1. Overview:

This CFP is managed under the governance of the NBA & GE Healthcare collaboration.
The collaboration and CFPs are directed by a Steering Committee, Strategic Advisory Board, and panels of experts for scientific peer review of the submitted proposals.

2.2. Steering Committee:

A Steering Committee manages the collaboration’s overall partnership and has oversight of the other committees.

2.3. Strategic Advisory Board (“SAB”):

The SAB is comprised of clinicians, scientists, NBA team physicians, and player representatives. The SAB is led by Dr. John DiFiori, NBA Director of Sports Medicine.

2.4. Peer Review Panels:

Peer review panels will be composed of scientists and clinicians selected for their experience and subject matter expertise in the CFP topic. Panels will be assembled for each CFP, and the reviewers will be responsible for assessing the scientific merit of each application.

3. BONE STRESS INJURIES CALL FOR PROPOSALS

3.1. Overview:

Bone stress injuries (BSI) are common and debilitating in both athletes and other physically active populations. BSI occur as a result of repetitive submaximal loading rather than a single direct force. The clinical presentation of BSI can be of gradual or abrupt onset and can include both stress fractures and stress reactions. These injuries are typically confirmed by imaging, where a cortical defect may (stress fracture) or may not (stress reaction) be present. BSI in basketball can impair performance, limit playing time, and disrupt a career.

The purpose of this CFP is to fund studies that aim to advance understanding of prevention, diagnosis, treatment, and recovery of BSI in basketball players and other athletes. The NBA & GE Healthcare collaboration is interested in studies that advance established paradigms and studies that challenge such paradigms by proposing and testing new concepts and methods. Preclinical studies that have direct clinical relevance will be considered. There is, however, a strong preference for research that will directly impact clinical care in human populations; thus, studies that translate basic science or preclinical findings into clinical practice are most responsive to this CFP. Studies of abnormal (uninjured) bone growth are not responsive to this CFP.

3.2. Questions to be addressed in this CFP:

This CFP solicits research studies that will improve understanding of prevention, treatment, and recovery related to BSI, with a focus on two specific objectives.
Research Objective 1. Research that leads to advancements in imaging to improve prevention, diagnosis, and/or treatment of BSI.

Potential areas of focus include, but are not limited to, the following:
- Imaging to improve diagnosis of BSI
- Imaging to better inform return-to-play clinical decision-making
- Imaging to improve understanding of risk factors for BSI and re-injuries
- Improved imaging of the navicular bone
- Imaging techniques to improve our understanding of bone health
- Correlating imaging findings with athletes’ anatomy/morphology to inform the natural history of BSI
- Dynamic imaging techniques to examine the relationship between human movement and bone loading

Research Objective 2. Research that develops strategies to prevent and manage BSI.

Potential areas of focus include, but are not limited to, the following:
- Epidemiological determinants and characteristics of BSI in basketball
- Bone quality thresholds and biomechanical risk factors for BSI and/or re-injuries
- Quantifiable exposure factors associated with BSI (e.g., training exposures, recovery time between training exposures, and schedule density)
- Metabolic factors associated with BSI (e.g., diet and nutrition)
- Efficacy of primary prevention programs for BSI
- Interventions that are effective in managing BSI and optimizing return-to-play time while minimizing re-injury risk

3.3. Specific Areas of Research Interest:

Specific areas of research interest for this CFP include, but are not limited to, the following examples.

Research Objective 1. Studies that utilize imaging to:
- Characterize underlying pathobiological processes and natural history of BSI.
- Characterize the anatomy/morphology of athletes’ pre-injury bone health, and build models to predict bone failure.
- Improve imaging of the navicular bone under loaded and unloaded conditions.
- Examine the impact of human movement on bone stress and loading.
- Address individual variation in response to bone morphology and loading patterns (e.g., athlete-specific bone injury thresholds, underlying reasons for variation in athlete-specific bone injury thresholds, and movement-specific bone loading).
**Research Objective 2.** Studies aiming to prevent and/or manage BSI by:

- Identifying epidemiologic characteristics of BSI in basketball players and comparator athletes that have low bone loading.
- Identifying prevalence of prior history of BSI in elite basketball players.
- Characterizing risk factors for both initial BSI and re-injury in basketball.
- Developing screening programs to identify athletes at higher BSI risk.
- Characterizing the effect of bone loading factors associated with physical activity (e.g., density of training cycles).
- Detecting human movement factors (e.g., gait motion and landing strategies) that can be mediated or modified (e.g., taping, orthotics, footwear, and surfacing) to impact bone loading and bone injury thresholds.
- Developing wearable sensor systems to quantify loading of musculoskeletal tissues.
- Characterizing the role of metabolic factors in BSI.
- Determining primary prevention efficacy of BSI in athletes, including functional or dynamic screening, and metabolic interventions.
- Developing new or optimizing current prevention programs.
- Creating strategies to improve return-to-play decision-making for BSI.
- Identifying clinical variability associated with defining BSI, and testing the validity of a standardized operational BSI definition.

**4. AWARD MECHANISMS AND AMOUNTS**

**4.1. Overview:**

This CFP will award a total of $1,500,000 over a three-year period to support preclinical and clinical research addressing important unanswered questions regarding BSI prevention, diagnosis, treatment, and recovery relevant to elite basketball athletes. The maximum amount for an individual grant is $300,000, including direct and indirect costs, for the entire project period. Focused, impactful projects that require less than $300,000 in total support are encouraged.

**4.2. Duration of Funded Research Projects:**

The proposed research projects should not exceed three (3) years in duration. Research projects of shorter duration are encouraged.

**4.3. Overhead and Indirect Cost Limits:**

Any proposal in which the budget exceeds the maximum amount of $300,000 in total costs (direct and indirect) will not be considered. The maximum allowable indirect rate is 25%.
4.4. **Acceptable Use and Limitations of the Awarded Support:**

The awarded funds can be used to support the proposed research including:

- Salaries of investigators
- The cost of medical procedures that are required for the research endpoints and not part of standard of care
- Research-related subject costs including clinical supplies
- Consumables
- Necessary consortium expenses including costs of travel and communication between collaborating sites

Unallowable expenses that cannot be included in the budget are:

- Costs of travel to conferences or for educational meetings
- Capital equipment purchases

The total projected costs, including the direct and indirect costs of any subcontract or consortium costs, must be included in the total direct costs.

Applications must include a comprehensive budget with details provided for each year of the project, including all direct and indirect costs. The projected funding requirements for the entire research project must be included.

5. **APPLICATION PROCESS**

5.1. **Overview:**

This CFP, along with complete instructions and forms for applying, are available at the NBA & GEHC collaboration [Bone Stress Injury CFP website](#).

5.2. **Qualification Criteria:**

Qualified applications must meet the following criteria:

- Applications must be complete, including all of the materials specified in this CFP.
- The application must have projected costs that do not exceed the maximum amount of $300,000 and must be scheduled to complete in three (3) years or less.

5.3. **Application Review Process and Selection Criteria:**

Qualifying applications will undergo a two-stage review process. The first stage will consist of a confidential scientific peer review. All members of the peer review panel will be bound by a signed nondisclosure agreement, ensuring that information in the applications and evaluation process will not be disclosed outside of the collaboration.
This review will focus on the scientific merit of the proposed research. The applications will be scored on the following criteria, all of which will have equal importance:

- **Relevance and Impact:** Do the goals and aims of the proposed research address issues of relevance to future, current or former NBA players? Does the proposed research plan impact competitive athletes? If the research is successful, is it likely to benefit to the population at large? If the research is preclinical, is it directly translatable to clinical care of athletes? Does the proposed subject population adequately match the population of interest?

- **Innovation:** Does the research propose a novel approach to the topic, the use of unique methods, or the novel application of existing methods, treatments, or technology?

- **Research Strategy and Scientific Methods:** Is the research plan well designed? Are the proposed methods and statistical plan scientifically rigorous to yield research that will contribute to the advancement of scientific or clinical knowledge with a high likelihood of resulting in peer-reviewed publications? Is the scientific rationale supported by preliminary data or published research? Are appropriate control/comparison populations identified? Are the inclusion and exclusion criteria sufficiently defined and justified (if applicable)? Do the investigators acknowledge possible areas of difficulty in methodology or recruitment, and are alternate strategies proposed?

- **Personnel and Environment:** Is the research team (investigators, clinician staff, statisticians, etc.) appropriate to accomplish the proposed research? Does the research team have the skills, experience, and resources (including access to the required subject populations) to successfully conduct the proposed research within the projected timeframe? Are the levels of effort of the team members appropriate? Applications that are multi-institutional or involve collaborating research groups are encouraged.

Plans for the recruitment of the desired study population will be assessed by the reviewers. In particular, if planning to use collegiate, NBA, or other professional athletes, the research plan must clearly explain plans for recruitment and collaboration. Letters of support indicating intention to collaborate and details for recruitment of study populations are required.

In addition, the budget will be evaluated to determine if it conforms to the requirements and limitations of this CFP, and if it is appropriate for the proposed research plan. Unlike the above categories, the budget will be critiqued but not scored.
Reviewer scores and critiques will be used to identify the top-ranked proposals that will be discussed at a Scientific Review Meeting. Here, the peer review panel will discuss the scientific merit of qualifying applications and then anonymously evaluate each proposal using the aforementioned criteria.

Following the scientific peer review process, the qualifying applications will enter the second stage of the review process, a programmatic review. The programmatic review will be undertaken by representatives of the SAB and/or the Steering Committee. Selection of applications and funding recommendations will be based on the evaluations and scores from the scientific peer review panel meeting (Stage 1 review) as well as alignment to the goals and mission of the NBA & GE Healthcare collaboration. The following criteria will be used to evaluate the degree of alignment with the collaboration’s goals and mission:

- Consistency and applicability of the proposed research goals to address high-priority clinical questions regarding the prevention, diagnosis, and treatment of acute and overuse injuries among NBA athletes, and to apply such findings to basketball players and the general population.

- Probability of successful completion of the research.

- Overall composition of the research portfolio, with the goal of developing a balanced portfolio of research for this CFP, other CFPs, and directed research efforts of the NBA & GE Healthcare collaboration.

As a result of the programmatic review and the perspective of managing the entire research portfolio, all highly ranked or scored applications from the scientific peer review process are not guaranteed to be recommended for funding.

5.4. Number of Submissions:

There is no limitation on the number of submissions that a given investigator or institution can participate in or submit. Investigators are encouraged to submit applications for all research projects that align with the goals of this CFP.

5.5. Intellectual Property and Confidentiality:

GE Healthcare and the NBA intend to own any intellectual property developed as part of the proposed research. Complete intellectual property terms will be part of individual agreements negotiated with successful applicants.

Submitted applications will be confidential; however, the lay abstracts and statements of relevance for funded applications may be released to the public. Unfunded applications will remain confidential.
5.6. Compliance:

The applicant is responsible for ensuring that all aspects of the research are conducted in accordance with Good Clinical Practice (GCP) guidelines, when applicable, and in compliance with all local and federal regulations, including HIPAA. Local Ethics Committee (e.g., Institutional Review Board [IRB] or Institutional Animal Care and Use Committee [IACUC]) approval at the time of submission is not required.

5.7. Required Components for a Qualified Application:

The proposed research plan should be based on sound scientific rationale and be grounded in methods and concepts derived from a critical review of the peer-reviewed literature. Preliminary data that is relevant to the proposed research is not required, but if available, should be referenced and submitted as appropriate.

A complete application must include all eleven of the following components:

1. **Cover Letter**
   - Describe alignment of the proposed research with the NBA & GE Healthcare collaboration goals and mission, and relevance to this CFP.

2. **Technical Abstract (Not to exceed 500 Words)**
   - State the background and motivation for the proposed research, clearly addressing the scientific or clinical question to be addressed. State how the proposed research aligns with the goals of the CFP. State the hypothesis to be tested and the specific aims of the research. Describe the study design, including methods and population under investigation.

3. **Lay Abstract for General Distribution (Not to exceed 500 Words)**
   - Describe the objectives of the proposed research using language and terminology that will be understandable by lay readers, including those without a background in science or medicine. Do not simply duplicate the technical abstract. For funded applications, the Lay Abstract may be released to the public; therefore, any proprietary and confidential information should be excluded.

4. **Statement of Relevance to Elite Basketball Athletes (Not to exceed 250 Words)**
   - Although the proposed research project may not include NBA athletes, please articulate how the proposed research aims and methods are relevant to elite basketball players. Collaboration with NBA teams, team physicians and players is encouraged, where appropriate, but is not necessary for studies of other populations, such as NCAA, top international, youth basketball players, or other athletes. For funded applications, this Statement of Relevance may be released to the public; therefore, any proprietary and confidential information should be excluded.
5. **Statement of Relevance to Broader Population (Not to exceed 250 Words)**

Describe how the results of the proposed research will improve population health for athletes of other ages and abilities, including “weekend warriors” and retired or former players with musculoskeletal health issues. For funded applications, this Statement of Relevance may be released to the public; therefore, any proprietary and confidential information should be excluded.

6. **Research Plan (Not to exceed 5 pages)**

The research plan should clearly state the primary and any secondary aims of the research project, describe the population under study, and define a statistical plan to rigorously examine the stated aims. The applicants should clearly state any innovative treatments, methods, or analysis techniques. The research plan should include a well-defined statistical plan that supports all primary and secondary aims of the project, including a power analysis that reflects sample size estimates that support the study objectives.

For research plans that involve a clinical trial component, the application must include documented availability and access to subjects that will support the primary and secondary aims of the research plan. The investigators should describe goals for successful accrual of qualified subjects and if standards of care or other factors, such as basketball season schedules, will impact accrual or execution of the research plan. Alternative approaches for successful accrual should be considered and discussed. In addition, clinical trials should follow GCP guidelines for all aspects of the proposed research plans. The investigators should state the local EC/IRB of record for the trial and any other required regulatory approval processes. The investigators should commit to register any clinical studies in the National Institutes of Health (NIH) clinical trials registry, [www.clinicaltrials.gov](http://www.clinicaltrials.gov). If the research plan involves the use of investigational drugs/compounds or devices, the investigators should document availability and access to the drug/compound or device. The drug/compound or device should have quality commensurate with the appropriate Food and Drug Administration (FDA) standards (i.e., Quality System Regulation, Good Manufacturing Practices). The application should include a well-defined safety management plan, including reporting of adverse events.

7. **Timeline of Research Milestones (Not to exceed One Page)**

8. **Personnel Effort and Budget with Justification**

9. **Relevant Bibliography**

10. **Biosketch of Investigators (Not to exceed 5 Pages per Biosketch)**

Include appointments, publications, and qualifications that are most recent and relevant to the proposed research. Please include a personal statement, addressing the
significance of the CFP topic with the proposed research project. A biosketch in the NIH format is acceptable but not required.

11. Documentation of Institutional and Other Relevant Support

- Letter or letters of support from the sponsoring institution(s), confirming availability of laboratory space, equipment, and other required resources
- Letter or letters of support from all co-investigators and collaborators
- Signed and dated conflict of interest disclosure statement from all key personnel
- Demonstration of support from any entities that provide access to subjects (e.g., clinics, teams, leagues). If college or professional athletes are part of the study cohort, support for recruitment and collaboration should be clearly documented
- Demonstration of support from any companies or individuals providing support in the form of pre-market or post-market devices, drugs, or other resources

Note: Incomplete or non-conforming applications will not qualify for review or consideration.

5.8. Timeline for the Call For Proposals:

This CFP commences at 8:00am Eastern Standard Time ("EST") on January 23, 2017.

Completed applications and proposals must be received no later than 5:00pm Eastern Daylight Time (EDT) on April 17, 2017.

Scientific peer review and programmatic review is intended to be complete in June of 2017.

5.9. Instructions for Submitting Materials:

Instructions for submitting an application and all required materials are available at the NBA & GE Healthcare Collaboration Bone Stress Injury CFP website (https://gex.brightidea.com/BoneStressCFP2017). Only one proposal can be submitted for each online application. If multiple proposals are being submitted, the applicant must submit them separately by completing a new online application for each individual proposal.

Questions regarding the CFP website or how to submit a proposal should be directed to GE.geniuslink@ge.com.

Questions about the CFP should be directed to GE.NBA.Research@ge.com.

Questions to any member of the NBA or GE Healthcare will not be accepted.
5.10. Notification:

Successful applicants are intended to be notified in July 2017.

This CFP summarizes many of the proposed elements of a research project and represents a call for proposals. This is not an offer to contract. Full and final details shall be as set forth in any final agreement executed by the successful applicants. The NBA & GE Healthcare collaboration reserves the right to modify the review process at its discretion as well as the CFP prior to the CFP due date. Any modifications to the review process or this CFP will be notified through https://gex.brightidea.com/GENBACFP.