



**U.S. House of Representatives
Committee on Energy and Commerce
Ranking Member Frank Pallone, Jr.
Democratic Staff Report**

**The National Football League's Attempt to Influence Funding
Decisions at the National Institutes of Health**

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I. EXECUTIVE SUMMARY

This report serves as an update on the Democratic Committee staff investigation of claims that the National Football League (NFL) attempted to influence decisions on brain injury research at the National Institutes of Health (NIH). The review has included requests for information from the National Institute of Neurological Disorders and Stroke (NINDS) at NIH, the Foundation for the NIH (FNIH), and the NFL, briefings with staff from NIH, FNIH, and the NFL, as well as a review of relevant documents and communications.

Democratic Committee staff received evidence to support the allegations that the NFL inappropriately attempted to influence the selection of NIH research applicants funded by the NFL's \$30 million donation to NIH. As NIH's Policy Manual makes clear, donors to the NIH cannot influence the agency's grant decision-making process. This policy protects the NIH's peer review process, which forms the cornerstone of the NIH research mission and ensures that applications submitted to the NIH are evaluated by scientific experts in a manner free of inappropriate influence or bias.¹ Despite the NFL's attempts to influence the selection of research applicants, the integrity of the peer review process was preserved and funding decisions were made solely based on the merit of the research applications.

This report concludes with findings on the need to clarify the roles of donors, FNIH, and NIH as to future donations to NIH research and to limit inappropriate efforts by donors to influence NIH funding decisions. The investigation found that:

1. The NFL improperly attempted to influence the grant selection process at NIH.
2. The NFL's Head, Neck and Spine Committee members played an inappropriate role in attempting to influence the outcome of the grant selection process.
3. The NFL's rationalization that the Boston University study did not match their request for a longitudinal study is unfounded.
4. FNIH did not adequately fulfill its role of serving as an intermediary between NIH and the NFL.
5. NIH leadership maintained the integrity of the science and the grant review process.
6. The NFL did not carry out its commitment to respect the science and prioritize health and safety.

The Democratic Committee staff offers several recommendations to address the investigation's findings:

1. FNIH must establish clearer guidelines regarding donor communications with NIH.
2. FNIH must come to a mutual understanding with donors at the beginning of the process regarding their degree of influence over the research they are funding and

¹ National Institutes of Health, *NIH Peer Review: Grants and Cooperative Agreements* (2013) (online at grants.nih.gov/grants/peerreview22713webv2.pdf).

remind donors that NIH policy prohibits them from exerting influence at any point in the grant decision-making process.

3. FNIH should provide donors with the clear, unambiguous language from the NIH Policy Manual, which states that a donor may not dictate terms that include “any delegation of NIH’s inherently governmental responsibilities or decision-making,” or “participation in peer review or otherwise exert real or potential influence in grant or contract decision-making.”
4. NIH and FNIH should jointly develop a process to address concerns about donors acting improperly.
5. The NFL, FNIH, and NIH should amend their current agreements to ensure that each party has a clear understanding of its role for the remainder of this partnership.

II. BACKGROUND

A. The Democratic Committee Staff Investigation

On December 22, 2015, ESPN published an article alleging that the National Football League (NFL) had backed out of funding a National Institutes of Health (NIH) study because of the League's objections to NIH's selected grantee.² In 2012, the NFL committed to an "unrestricted" \$30 million gift to Foundation for the National Institutes of Health (FNIH), for sports-related research funded by NIH, and in 2015, NIH selected a grant led by Boston University (BU) researcher Dr. Robert Stern to receive \$16 million of that funding.³

As an expert on neurodegenerative diseases and the director of clinical research at the BU Chronic Traumatic Encephalopathy (CTE) Center, Dr. Stern has been vocal about the connection between football and brain damage. In October 2014, Dr. Stern filed a 61-page declaration opposing the NFL's settlement of a class action lawsuit brought by its players, claiming that the settlement would deny many deserving players of adequate compensation.⁴ Dr. Stern primarily objected to the settlement's high threshold for determining cognitive impairment, because it would deprive former players with documented cognitive deficits of compensation, and he also opposed the lack of compensation for individuals suffering from significant changes in mood and behavior who did not yet display cognitive impairment or dementia.⁵

Over the next two months, ESPN wrote a series of articles further investigating the NFL's communications with NIH and FNIH about its concerns with Dr. Stern.⁶ The ESPN articles explored participation by members of the NFL's Head, Neck and Spine Committee (HNS Committee) in funding decisions, noting that some of the committee's members had also applied for the NIH grant in question.⁷ The ESPN investigation found that, "[a]fter the NIH concluded that the NFL's complaints were unfounded, the NFL reversed a commitment to fund the project."⁸

² *NFL Backs Away from Funding BU Brain Study, NIH to Fund it Instead*, ESPN (Dec. 22, 2015).

³ *Id.*

⁴ *Id.*

⁵ *In re: National Football League Players' Concussion Injury Litigation*, Declaration of Robert A. Stern, Ph. D. (filed Oct. 6, 2014) (Case No. 2:12-md-02323-AB).

⁶ *NFL Health Officials Confronted NIH About Researcher Selection*, ESPN (Jan. 21, 2016); *NFL Donations to Brain Research Benefit League-Linked Doctors, Raise Worries about Influence on Science*, ESPN (Feb. 4, 2016).

⁷ *NFL Donations to Brain Research Benefit League-Linked Doctors, Raise Worries about Influence on Science*, ESPN (Feb. 4, 2016).

⁸ *Id.*

Following the publication of the December 2015 article, Democratic members of the Committee on Energy and Commerce sent letters to NIH and FNIH initiating an investigation into whether the NFL had acted inappropriately in attempting to exercise influence over the NIH study.⁹ The members sought to ensure that grant applications submitted to NIH are evaluated in a fair manner free of inappropriate influence or bias. On March 23, 2016, the Democratic members sent a letter to the NFL, asking the League to provide responses clarifying its role in the controversy.¹⁰ Additionally, the NFL was asked to provide information about the role of its HNS Committee, an informal group of medical experts and advisors who help guide the NFL's health and safety policies, as well as play an important role in how the NFL allocates its funding for biomedical research.

B. NIH Policy and Procedures

NIH publishes a Policy Manual that establishes policies and procedures regarding the acceptance, acknowledgement, and administration of gifts.¹¹ NIH policy explicitly prohibits employees from requesting or suggesting donations to NIH or any of its Institutes or Centers.

Gifts to NIH are classified into two categories: conditional and unconditional.¹² Conditional gifts are those for which a donor imposes some condition or restriction on the gift's use or imposes a condition that must be met in order to obtain the gift. An unconditional gift is one where the donor imposes no condition or restriction on the gift's use and no conditions to be met in order to obtain it.¹³ A gift to support a specific activity conducted by a particular office (e.g. the Office of Research on Women's Health), or a gift to support certain categories of expenditure – such as personnel, equipment, or supplies – would qualify as “conditional” gifts.¹⁴

The Policy Manual also outlines acceptable and unacceptable terms for gifts.¹⁵ Terms that are generally acceptable include, among others: (1) a grant directed to support a specific institute, lab, or project; (2) an agreement to collaborate with other scientific institutions; (3) the provision of financial reports to the donor at appropriate intervals; (4) scientific reports to the

⁹ Letter from Ranking Member Frank Pallone, Jr., et al., Committee on Energy and Commerce, to Dr. Francis Collins, Director, National Institutes of Health (Jan. 7, 2016); Letter from Ranking Member Frank Pallone, Jr., et al., Committee on Energy and Commerce, to Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health (Jan. 7, 2016).

¹⁰ Letter from Ranking Member Frank Pallone, Jr. et al., Committee on Energy and Commerce, to Roger Goodell, Commissioner, National Football League (Mar. 23, 2016).

¹¹ NIH Policy Manual, *1135- Gifts Administration* (Oct. 5, 2011) (online at oma1.od.nih.gov/manualchapters/management/1135).

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

donor that the NIH institute or center is also prepared to publicly share; (5) participation by the donor in public scientific meetings or conferences; and (6) audits by the donor, as arranged between the parties.¹⁶ However, according to the Policy Manual, a donor may not dictate terms that include any delegation of NIH's inherently governmental responsibilities or decision-making, or participation in peer review or otherwise exert real or potential influence in grant or contract decision-making.¹⁷

C. Organizational Overview of FNIH

Congress established FNIH, a non-profit 501(c)(3) charitable organization, in 1990 to support the mission of NIH by advancing collaboration with private sector partners.¹⁸ A major part of FNIH's role in promoting groundbreaking science and biomedical research is to direct funding from public and private donors to projects initiated by NIH.¹⁹ FNIH effectively acts as a conduit between the NIH and private donors, which include businesses, universities, and nonprofit organizations. In contrast to NIH, FNIH is statutorily authorized to "solicit and accept gifts, grants, and other donations" to further NIH research.²⁰

Central to achieving the goal of supporting NIH's mission and research efforts is FNIH's ability to form public-private partnerships. Recent initiatives that FNIH has helped manage include the Alzheimer's Disease Neuroimaging Initiative (ADNI) beginning in 2004, and the Grand Challenges in Global Health (GCGH) initiative launched by the Bill & Melinda Gates Foundation in 2003.²¹ The ADNI partnership has made contributions to the study of Alzheimer's disease, including developing new methods for the early detection of the disease and standardized methods for clinical tests.²² The Gates Foundation's GCGH initiative resulted in 20 projects managed by FNIH from 2005 to 2015 that focused on improving vaccine development and storage, genetic and biological mosquito control strategies, and other novel public health innovations.²³

D. Role of the NFL's Head, Neck and Spine Committee

¹⁶ *Id.*

¹⁷ *Id.* (emphasis added).

¹⁸ National Institutes of Health Amendments of 1990, Pub. Law 101-613.

¹⁹ Foundation for the National Institutes of Health, *About Us* (online at www.fnih.org/about) (accessed May 10, 2016).

²⁰ 42 U.S.C. § 290b(c)(1).

²¹ Foundation for the National Institutes of Health, *Major Completed Programs* (online at www.fnih.org/what-we-do/major-completed-programs/#a-programs) (accessed May 7, 2016).

²² Alzheimer's Disease Neuroimaging Initiative (online at www.adni-info.org/Scientists/ADNIOverview.html) (accessed May 11, 2016).

²³ Foundation for the National Institutes of Health, *Grand Challenges in Global Health* (online at fnih.org/what-we-do/major-completed-programs/grand-challenges-in-global-health) (accessed May 7, 2016).

The NFL first convened the Mild Traumatic Brain Injury Committee (MTBI Committee) in 1994 to shape the League's concussion policies.²⁴ The MTBI Committee was chaired by Dr. Elliot Pellman, a rheumatologist who described concussions as "an occupational risk" of the sport.²⁵ In 1999, Dr. Pellman stated that head injuries in football had not increased and tended to be relatively minor, based on four years of head injury data.²⁶ The MTBI Committee, led by Dr. Pellman from 1994 to 2007, consistently downplayed the health risks posed by concussions.²⁷ Under Dr. Pellman's leadership, the MTBI Committee questioned the return to play guidelines for players who had been concussed, argued that NFL players are less susceptible to brain injury than the general population, and disputed reputable research that showed the detrimental effects of repeat concussions.²⁸ Allegations regarding the MTBI Committee's role in ignoring, minimizing, and suppressing information concerning the link between repetitive head trauma and brain damage were central to the NFL players' lawsuit against the NFL.²⁹

Dr. Pellman stepped down as head of the MTBI Committee in 2007 amid questions about his credentials and research methods, yet he stayed on as a member of the committee until it was disbanded in 2010.³⁰

Following the disbandment of the MTBI Committee, the League founded the Head, Neck and Spine Committee to study and advise team medical staffs and the League on head, neck, and spine injuries.³¹ The HNS Committee is composed of independent experts who are selected by the Committee's chairs, Dr. Richard Ellenbogen and Dr. Hunter Batjer.³² All but one member of the Committee serve in a voluntary capacity, though they do receive reimbursement for travel and expenses associated with attendance at Committee meetings or events, as well as free Super Bowl tickets.³³

²⁴ *New questions about NFL doctor*, ESPN (Aug. 18, 2013).

²⁵ *Timeline: The NFL's Concussion Crisis*, Frontline (Oct. 8, 2013); *The Worst Case*, Sports Illustrated (Dec. 19, 1994).

²⁶ *Heads Up*, Chicago Tribune (Dec. 24, 1999).

²⁷ *Timeline: The NFL's Concussion Crisis*, Frontline (Oct. 8, 2013).

²⁸ *Id.*

²⁹ *In re: National Football League Players' Concussion Injury Litigation*, Slip Opinion (3d Cir. Apr. 18, 2016) (online at www2.ca3.uscourts.gov/opinarch/152206p.pdf).

³⁰ *N.F.L. Doctor Quits Amid Research Doubt*, New York Times (March 1, 2007); *NFL Concussions Fast Facts*, CNN (Mar. 15, 2016).

³¹ National Football League, *NFL Names New Co-Chairs of Head, Neck & Spine Medical Committee* (Mar. 16, 2010).

³² National Football League, *Health committees plan help to guide NFL's safety plans* (Aug. 2, 2013); *N.F.L. Picks New Chairmen for Panel on Concussions*, New York Times (Mar. 16, 2010).

³³ Letter from Roger Goodell, Commissioner, National Football League, to Ranking Member Frank Pallone, Jr., et al., Committee on Energy and Commerce (Apr. 25, 2016).

In a letter to the Committee, the NFL stated that the medical advisors' opinions and comments on scientific and medical issues are their own and are not reviewed in advance by the League.³⁴ However, the NFL made clear that the League relies heavily on its HNS advisors when deciding on research priorities.³⁵

According to the NFL, Dr. Pellman does not serve on the HNS Committee, but he is currently a medical administrator for the NFL.³⁶ He has been involved in instituting recent safety programs.³⁷ The NFL's Vice President for Communications recently stated that Dr. Pellman "performs administrative functions for the committees which are responsible for the implementation of the league's protocols" and "is not a member of any league medical committee and neither sets policy nor provides medical advice on any issue."³⁸

III. TIMELINE OF EVENTS

A. The Agreements Between the NFL, FNIH, and NIH

In June 2012, the National Football League (NFL) and the Foundation for the National Institutes of Health (FNIH) began conversations about a partnership to support research relevant to the health of NFL players.³⁹ Dr. Pellman organized a meeting at NFL headquarters to bring together the NFL and its advisors with National Institutes of Health (NIH) and FNIH staff.⁴⁰ Dr. Pellman indicated the NFL was interested in committing \$30 million to FNIH over the course of three or more years to support agreed upon research programs.⁴¹

In September 2012, FNIH announced that the NFL had pledged \$30 million in support of research on "serious medical conditions prominent in athletes" that are also relevant to the general population.⁴² The program was designated the Sports and Health Research Program

³⁴ *Id.*

³⁵ Briefing by Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Energy and Commerce Democratic Committee Staff (Apr. 14, 2016).

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Lions' DeAndre Levy: Why does NFL employ doc who denies CTE link?*, ESPN (Mar. 15, 2016).

³⁹ E-mail from Dr. Elliot Pellman, NFL, to Dr. Andrea Baruchin and Dr. Stephanie James, FNIH (June 14, 2012) (on file with Committee Staff).

⁴⁰ *Id.*

⁴¹ E-mail from Dr. Stephanie James, FNIH, to Dr. Kathy Hudson and Dr. Amy Patterson, NIH (June 29, 2012) (on file with Committee Staff).

⁴² Foundation for the National Institutes of Health, *NFL Commits \$30 Million Donation to the FNIH to Support Medical Research* (Sept. 5, 2012).

(SHRP) and involved interparty agreements between NIH, the NFL, and FNIH.⁴³ The parties executed two agreements: a Letter of Agreement (LOA) between the NFL and FNIH and a Memorandum of Understanding (MOU) between FNIH and NIH. Both agreements made clear that NIH retained responsibility and control over the scientific aspects of the program, including the review and awarding of scientific grants.⁴⁴

In early September 2012, the NFL and FNIH signed the LOA detailing the funding arrangement for the SHRP.⁴⁵ The LOA outlined possible areas of research, including “Chronic traumatic encephalopathy: accurate diagnosis and risk factors,” “Concussion: assessing brain injury and risk of disability,” and “Understanding the potential relationship between traumatic brain injury and late life neurodegenerative disorders, especially Alzheimer’s disease.”⁴⁶ The primary programmatic contact for the NFL was Dr. Elliot J. Pellman, listed as the League’s Medical Director.⁴⁷

The LOA allowed the NFL a certain degree of involvement in the administrative process. For example, the LOA provided that the NFL was allowed to appoint two representatives to a Stakeholder Board, which provides a forum where donors can engage with outside parties to develop the highest priority areas of research for consideration by NIH.⁴⁸ Additionally, FNIH agreed to share each research plan under the SHRP with the NFL; after all three parties signed each research plan, the plan was then incorporated into the LOA. Finally, the agreement stated that “[u]pon agreement by DONOR, FNIH, and NIH on the Research Plan, FNIH will transfer DONOR funds to NIH.”⁴⁹

The LOA made clear that NIH has exclusive control over certain areas. It states, “DONOR [NFL] acknowledges and agrees that NIH will have responsibility for and control over the scientific and administrative aspects of the Research Plans it manages under the Program, including but not limited to holding workshops, developing and posting calls for applications, reviewing applications, determining grantees, awarding grants, overseeing the grants, including

⁴³ Master Letter of Agreement, Sports and Health Research Program, The National Football League and the Foundation for the National Institutes of Health, Inc. (Sept. 4, 2012); Memorandum of Understanding between The Foundation for the National Institutes of Health, Inc., and The National Institutes of Health Office of the Director For the Sports and Health Research Program (Sept. 4, 2012).

⁴⁴ *Id.*

⁴⁵ Master Letter of Agreement, Sports and Health Research Program, The National Football League and the Foundation for the National Institutes of Health, Inc. (Sept. 1, 2012).

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

the scientific and financial progress of the grantees, monitoring data sharing plans, and publication of research results related to the Program.”⁵⁰

The LOA established that payments from the NFL to FNIH would be structured in installments.⁵¹ The first installment consisted of a \$3 million payment immediately following the execution of the LOA, followed by \$2 million within ten business days of the first meeting of the Stakeholder Board. Further installments were to be provided according to the budget and payment schedule set forth in each executed Research Plan.⁵²

The LOA established that the NFL was obligated to provide funding once a Research Plan had been approved and signed. As the LOA clearly states, “upon agreement by DONOR [NFL], FNIH and NIH on the Research Plan, FNIH will transfer DONOR funds to NIH.”⁵³ The NFL retained the right to terminate the LOA at will, but the LOA provided that “termination of this Agreement will not terminate or otherwise relieve any of NFL’s obligations for payment of any installments that are set forth in any executed Research Plan(s).”⁵⁴

On September 4, 2012, NIH and FNIH entered into the MOU regarding the SHRP. According to the MOU, FNIH is “responsible for all interactions with Donor(s) throughout the life of the Program [SHRP].”⁵⁵ The MOU also stated that “FNIH will use reasonable efforts to facilitate resolution of any Donor related issues that arise with respect to the applicable project.”⁵⁶ The MOU also obligates NIH to provide drafts of public communications and promotional materials, including news releases, to FNIH and the Donor, no later than ten business days prior to their public availability or dissemination. The MOU requires NIH to “acknowledge FNIH and the Donor(s) support for the Program in all Communications.” Communications regarding the Program “will not be released until NIH, Donor(s) and FNIH have provided prior written consent to such release.”⁵⁷

The MOU used similar language to the LOA to describe NIH’s role in the grant process: “Upon mutual agreement among NIH, FNIH and the Donor(s) on the Research Plan, NIH and the applicable NIH Institutes and Centers will manage the programmatic, logistical, and administrative aspects necessary to initiate projects funded by the Program, including ... developing and posting calls for applications, reviewing applications, determining grantees,

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ Memorandum of Understanding between The Foundation for the National Institutes of Health, Inc., and The National Institutes of Health Office of the Director For the Sports and Health Research Program (Sept. 4, 2012).

⁵⁶ *Id.*

⁵⁷ *Id.*

awarding grants, overseeing the grants, including the scientific and financial progress of the grantees.”⁵⁸

On September 5, 2012, the NFL issued a press release entitled “National Football League Grants \$30 million in Unrestricted Funding to the Foundation for the National Institutes of Health for Medical Research.”⁵⁹ The release explicitly described the gift as “unrestricted” and stated, “[d]issemination of funding from this grant will be governed by federal law and policy applicable to NIH-funded research.”

B. The Execution of the Research Plans

Over the course of the following year, NIH successfully executed four research plans under the terms of the LOA and MOU. The first research plan involved a chronic traumatic encephalopathy (CTE) Neuropathology Workshop, held in December 2012 with scientists, advocates, clinicians, and government employees.⁶⁰ The workshop was specifically designed to guide the development of future research plans to fund CTE neuropathology research. Three additional research plans were funded, including, a program to study the neuropathology of CTE and the delayed effects of traumatic brain injury (TBI), an initiative to fund pilot projects for sports-related TBI research, and a workshop on brain-trauma-related neurodegeneration.⁶¹ All four research plans proceeded smoothly.⁶²

The fifth research plan recommended a longitudinal study in high-risk adults to collect, validate, and analyze biomarker data to characterize CTE in individuals with a history of repetitive head impacts.⁶³ The proposal’s research objectives included characterizing the clinical syndrome of CTE and its progression over a three- to five-year period, tracking the progression of CTE using neuroimaging, and developing consensus criteria for the diagnosis, staging, and ways to measure the progression of CTE.

The fifth research plan listed anticipated costs at just over \$17.5 million and stated, “NFL is requested to provide a total of \$16,325,242.”⁶⁴ The research plan outlined a schedule of payments, with the first payment of \$1.44 million due to FNIH on or before April 1, 2015. The

⁵⁸ *Id.*

⁵⁹ National Football League, *National Football League Grants \$30 million in Unrestricted Funding to the Foundation for the National Institutes of Health for Medical Research* (Sept. 5, 2012).

⁶⁰ SHRP Research Plan Schedule No. 1 (Nov. 30, 2012).

⁶¹ SHRP Research Plan Schedule No. 2 (Mar. 12, 2013); SHRP Research Plan Schedule No. 3 (Mar. 12, 2013); SHRP Research Plan Schedule No. 4 (June 13, 2013).

⁶² Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016).

⁶³ SHRP Research Plan Schedule No. 5 (July 24, 2014).

⁶⁴ *Id.*

payment schedule provided for annual payments of \$2.48 million from 2016 through 2021.⁶⁵ According to the research plan, grant applications were expected to be due by December 31, 2014, and a decision regarding the grant's awardee would be made by the National Institute of Neurological Disorders and Stroke (NINDS) Council in May 2015.⁶⁶ The research plan was executed and approved by representatives from the NFL, NIH, and FNIH by July 24, 2014.

C. The NFL Attempts to Influence Grant Decision-Making

1. The NFL Raises Concerns Regarding the NIH Grantee

NIH began accepting grant applications for this fifth research plan on September 30, 2014, seeking “a multicenter and multidisciplinary longitudinal study of individuals with a ‘probable’ or ‘possible’ diagnosis of [CTE] using brain imaging and other biomarkers.”⁶⁷ The NINDS Council met as scheduled in May 2015 to review grant applications and recommend a recipient.⁶⁸ After an evaluative peer review process that culminated in scores being assigned to the various proposals, the NINDS Council recommended funding the BU group led by Dr. Stern, which had the highest ranked proposal.

Following the Council meeting, NIH began its standard process to issue the Notice of Grant Award (NGA) by the end of June.⁶⁹ But on June 17, 2015, before that process was complete, Dr. Pellman sent an e-mail on behalf of the NFL to Dr. Maria Freire, the President and Executive Director of FNIH, to raise questions about the grant to the BU group.⁷⁰ Dr. Pellman voiced concern about the award, stating:

I received some information that Walter [Koroshetz] and the NINDS is close to signing off on awarding Boston University the monies for the third and final stage of the NFL grant for the longitudinal study. There are many of us who have significant concerns re BU and their ability to be unbiased and collaborative. Betsy Nabel (now NFL Chief Medical Officer), Richard Ellenbogen, Russell Lonser and others are included in that

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ National Institute of Neurological Disorders and Stroke, National Institutes of Health, *RFA: Detect, Define and Measure the Progression of Chronic Traumatic Encephalopathy*, RFA-NS-14-012 (July 29, 2014) (online at grants.nih.gov/grants/guide/rfa-files/RFA-NS-14-012.html).

⁶⁸ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Feb. 10, 2016).

⁶⁹ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Democratic Committee Staff (Apr. 29, 2016).

⁷⁰ E-mail from Dr. Elliot Pellman, NFL, to Dr. Maria Freire, FNIH (June 17, 2015) (on file with Committee Staff).

concerned group...I'm hoping that you could communicate our concerns and slow down the process until we all have a chance to speak to figure this out.⁷¹

Dr. Freire then forwarded the e-mail to Dr. Walter Koroshetz, Director of NINDS, to which Dr. Koroshetz replied:

Yes we knew this was coming. Lots of history here. But our process was not tainted and all above board. The grant will go to a multisite group around the country. NINDS will manage it. The data will be believable and unbiased.

Trouble is of course is that the group is led by the people who first broke the science open and NFL owners and leadership think of them as the creators of the problem.

I think we need to go to Betsy Nabel first and get her on board (Betsy is their chief medical officer). We spoke this week.⁷²

Although the Boston University (BU) researchers had been notified about their grant award by this time, their receipt of the grant was not public knowledge.⁷³ Dr. Koroshetz explained that NIH does not discuss grants that have not yet been funded.⁷⁴ Additionally, FNIH does not customarily learn of the grant recipient until the information becomes public.⁷⁵ Dr. Freire informed Committee staff that this was the first instance in her experience of a donor learning of the grant recipient before it was made public.

In briefings with Committee staff, Dr. Koroshetz, Dr. Freire, and Jeff Miller, the NFL's Executive Vice President of Health and Safety, all indicated that they had heard that members of the BU group had shared that they would be receiving the grant.⁷⁶ Dr. Stern confirmed to

⁷¹ *Id.*

⁷² E-mail from Dr. Walter Koroshetz, NIH, to Dr. Maria Freire, FNIH (June 18, 2015) (on file with Committee staff).

⁷³ Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016).

⁷⁴ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Feb. 10, 2016).

⁷⁵ Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016).

⁷⁶ Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016); Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Feb. 10, 2016); Briefing by Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Energy and Commerce Democratic Committee Staff (Apr. 14, 2016).

Committee staff that he informed Jeff Pash, the NFL's Executive Vice President and General Counsel, that BU had been selected for the grant.⁷⁷

Dr. Elizabeth Nabel, the NFL's Chief Medical Officer, e-mailed Dr. Koroshetz the day after Dr. Pellman e-mailed Dr. Koroshetz to express her own concerns.⁷⁸ She stated, “[a]pparently a Dr. Stern, who may also be with this group, has filed independent testimony in the NFL/Players Association settlement. I hope this group is able to approach their research in an unbiased manner.”⁷⁹ In a separate email, she attached Dr. Stern's affidavit in the 2014 class action case against the NFL.⁸⁰

Dr. Nabel also questioned the peer review process that led to the selection of Dr. Stern's grant proposal.⁸¹ Dr. Nabel expressed concern that members of the BU-led group and members of the review board had co-authored articles together. She wrote, “I am taking a neutral stance here, but I believe the concern is that members of the study section had published within the past two years with Dr. McKee or Dr. Cantu, who the grant applicant believes will receive the [Notice of Grant Award.]”⁸²

Additionally, according to Jeff Miller, the NFL was concerned that BU's study did not reflect the consensus they believed had been reached prior to signing the fifth research plan.⁸³ Miller told Committee staff that the NFL sought a “Framingham-style” longitudinal study to

⁷⁷ Briefing by Dr. Robert Stern, Director of Clinical Research, Chronic Traumatic Encephalopathy Center, Boston University, to Energy and Commerce Democratic Committee Staff (Apr. 28, 2016).

⁷⁸ E-mail from Dr. Elizabeth Nabel, NFL, to Dr. Walter Koroshetz, NIH (June 23, 2015) (on file with Committee Staff).

⁷⁹ *Id.*

⁸⁰ E-mail from Dr. Elizabeth Nabel, NFL, to Dr. Walter Koroshetz, NIH (June 23, 2015) (on file with Committee Staff); *In re: National Football League Players' Concussion Injury Litigation*, Declaration of Robert A. Stern, Ph. D. (filed Oct. 6, 2014) (Case No. 2:12-md-02323-AB).

⁸¹ E-mail from Dr. Walter Koroshetz, NIH, to Dr. Maria Freire, FNIH (June 26, 2015) (on file with Committee Staff).

⁸² E-mail from Dr. Elizabeth Nabel, NFL, to Dr. Walter Koroshetz, NIH (June 23, 2015) (on file with Committee Staff). Dr. McKee and Dr. Cantu are both professors at the Boston University School of Medicine. Dr. McKee is the Director of the Neuropathology Core at BU's Alzheimer's disease and CTE Center; Dr. Cantu is the co-director of the CTE Center. Neither individual is listed as a primary investigator on Dr. Stern's grant. National Institutes of Health, *Notice of Award: Chronic Traumatic Encephalopathy, Detection, Diagnosis, Cure, and Risk Factors* (Dec. 12, 2015) (Grant Number 1U01NS093334-01).

⁸³ Briefing by Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Energy and Commerce Democratic Committee Staff (Apr. 14, 2016).

examine the long-term effects of concussions.⁸⁴ According to Miller, once Dr. Stern's grant had been selected, members of the HNS Committee advised the NFL that his study would not accomplish what the NFL sought in a longitudinal study and did not fit into the areas they wanted to research. Miller further indicated the sentiment among HNS Committee members that BU did not do longitudinal studies and that their expertise was limited to neuropathology. Neither Dr. Koroshetz nor Dr. Freire mentioned that the NFL had raised this issue contemporaneously in connection with their other concerns regarding the award of the grant to BU.⁸⁵ Dr. Koroshetz noted that a long-term study was discussed in 2012 during the development of the SHRP; however, both NIH and the NFL agreed then that such a study was not feasible under the time and funding constraints.⁸⁶

2. *The NFL, NIH, and FNIH Attempt to Resolve the NFL's Concerns*

FNIH arranged for representatives of the NFL, NIH, and FNIH to hold a conference call on June 29, 2015, to discuss the NFL's concerns with the grant.⁸⁷ For the NFL, participants included Jeff Miller and three members of the NFL's HNS Committee: Dr. Richard Ellenbogen, Dr. Mitchel Berger, and Dr. Hunt Batjer.⁸⁸ Dr. Freire and Dr. Koroshetz each participated on the call, along with additional staff from FNIH and NIH. On the call, the HNS members raised concerns about bias in NIH's peer review process and Dr. Stern's affidavit in favor of former NFL players.⁸⁹ They also raised issue about balance related to money going to only one

⁸⁴ *Id.* The Framingham Heart Study is a large-scale, longitudinal multigenerational study of cardiovascular disease (CVD) that has contributed significantly to our understanding of the factors that contribute to CVD. The objective of the study was to identify common factors that contribute to CVD by following its development over a long period of time in a large group of participants who had not yet developed any symptoms of the disease. Framingham Heart Study (online at www.framinghamheartstudy.org/about-fhs/history.php).

⁸⁵ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Democratic Committee Staff (Apr. 29, 2016); Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016).

⁸⁶ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Democratic Committee Staff (Apr. 29, 2016).

⁸⁷ E-mail from Felicia Gray, FNIH, to Julie Wolf-Rodda, Maria Freire, and Stephanie James, FNIH; Jeff Miller, NFL; and Walter Koroshetz, NIH (June 29, 2015) (on file with Committee staff).

⁸⁸ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Feb. 10, 2016); *NFL Donation to Brain Research Benefit League-Linked Doctors, Raise Worries about Influence on Science*, ESPN (Feb. 4, 2016); E-mail from Kevin Klock, FNIH, to Energy and Commerce Committee Staff (Jan. 29, 2016).

institution, given that funding under prior research grants had been divided across multiple institutions.⁹⁰

Although Dr. Ellenbogen participated as a representative of the NFL on this call, he had also been an applicant for the \$16 million grant.⁹¹ His application, in conjunction with Dr. Kevin Guskiewicz at the University of North Carolina (UNC) and Dr. Mike McCrea at the Medical College of Wisconsin, had not been selected.⁹² Drs. Ellenbogen, Guskiewicz, and McCrea are all members of the NFL's HNS Committee.

On the conference call, Dr. Koroshetz proposed a potential compromise solution.⁹³ He suggested the possibility that two studies could be funded, thereby increasing the number of research sites, subjects, and primary investigators.⁹⁴ NIH had employed a similar approach on the second research plan, splitting the grant money between two institutions to explore the neuropathology of CTE.⁹⁵ Dr. Koroshetz suggested that the two studies might address the NFL's concerns.⁹⁶ Dr. Koroshetz raised the possibility of revisiting the application that had been awarded the second highest score at the May Council meeting. Later, with the permission of the investigators, it was revealed that this was the UNC-led study with Drs. Guskiewicz and McCrea as principal investigators, and Dr. Ellenbogen as a co-investigator.⁹⁷

⁸⁹ Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016); Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 19, 2016).

⁹⁰ Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016).

⁹¹ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Feb. 10, 2016); *NFL Donations to Brain Research Benefit League-Linked Doctors, Raise Worries about Influence on Science*, ESPN (Feb. 4, 2016).

⁹² *NFL Donations to Brain Research Benefit League-Linked Doctors, Raise Worries about Influence on Science*, ESPN (Feb. 4, 2016).

⁹³ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Feb. 10, 2016).

⁹⁴ Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016).

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016); Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Feb. 10, 2016);

According to Dr. Koroshetz, Dr. Ellenbogen called him again separately soon after the June 29, 2015, conference call to reiterate his opposition to awarding the grant to Dr. Stern.⁹⁸ At that time, Dr. Ellenbogen told Dr. Koroshetz that he could not recommend that the NFL fund the BU study, because he believed that Dr. Stern had a conflict of interest and that the grant application process had been tainted by bias.⁹⁹

On July 10, Dr. Koroshetz e-mailed Dr. Nabel to clarify NIH's conflict of interest (COI) rules.¹⁰⁰ According to NIH regulations, co-authorship of a review article, position paper professional group or conference report is not an automatic basis for a COI complaint.¹⁰¹ Dr. Koroshetz concluded that "based on co-authorships and NIH definition of COI, there are zero conflicts of interest between the members of the peer review panel and the investigators on the MPI [Multiple Principal Investigators] grant from Stern, Cummings, Reiman and Shenton."¹⁰²

According to an e-mail from Dr. Freire to Dr. Nabel dated August 12, 2015, Dr. Koroshetz agreed to formally bring the proposal to fund two sites to the NIH Council meeting in September 2015.¹⁰³ However, Dr. Freire expressed concern that NIH would likely be unable to fund an entire second grant without an additional funding commitment from the NFL.¹⁰⁴

Briefing by Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Energy and Commerce Democratic Committee Staff (Apr. 14, 2016).

⁹⁸ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Feb. 10, 2016).

⁹⁹ *Id.*

¹⁰⁰ E-mail from Dr. Walter Koroshetz, NIH, to Dr. Elizabeth Nabel, NFL (July 10, 2015) (on file with Committee Staff).

¹⁰¹ *Id.*

¹⁰² *Id.* Additionally, Dr. Koroshetz stated that at some point before the September Council Meeting, he informed Dr. Freire that the Stern affidavit did not represent a conflict of interest under NIH conflict-of-interest rules. Because the affidavit represented a personal opinion, it was not required to be submitted for consideration as a potential disqualifying conflict of interest as part of the grant application. Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Feb. 10, 2016); Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016).

¹⁰³ E-mail from Dr. Maria Freire, FNIH, to Dr. Elizabeth Nabel, NFL (Aug. 12, 2015) (on file with Committee staff).

¹⁰⁴ *Id.*

According to Dr. Freire, the NFL did not commit to additional funding at this time and wanted to wait until after the September Council meeting to assess that issue.¹⁰⁵

At the September Council meeting, the Council recommended funding only the BU proposal.¹⁰⁶ According to Dr. Koroshetz, Council members concluded in closed session that: 1) the peer review process that had selected the CTE grant to the BU researchers was entirely appropriate; 2) there had been no conflicts of interest that would compromise researchers' objectivity; and 3) none of the other grant proposals had adequate scores to justify funding an additional group of researchers.¹⁰⁷ The Council members also concluded that the CTE study was vitally important to public health and safety interests, and if necessary, NINDS should fund it in its entirety using NINDS funds.¹⁰⁸

3. Attempts by NIH and FNIH to Get Clarity on the NFL's Funding Commitment

After the September Council decision, NIH awaited the NFL's decision on funding the CTE grant.¹⁰⁹ Dr. Koroshetz informed Dr. Freire of the NINDS's decision, and made multiple unsuccessful attempts to get a clear answer from FNIH on the NFL's funding commitment throughout the fall of 2015. Additionally, according to Dr. Koroshetz, NIH staff made Dr. Freire aware of the date that the NGA was going to be released, because NIH needed to know whether the NFL and the SHRP should be acknowledged in the public release, as called for in the FNIH-NIH MOU.¹¹⁰ Dr. Koroshetz stated that he did not receive a response from Dr. Freire as to whether the NFL would fund the study.

When questioned whether he ever asked the NFL directly if they planned to fund the study, Dr. Koroshetz responded that he had not.¹¹¹ Due to strict NIH rules prohibiting NIH

¹⁰⁵ Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016).

¹⁰⁶ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 19, 2016)

¹⁰⁷ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 19, 2016); Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Feb. 10, 2016).

¹⁰⁸ *Id.*

¹⁰⁹ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Feb. 10, 2016).

¹¹⁰ *Id.*

¹¹¹ *Id.*

employees from soliciting private donations, Dr. Koroshetz did not feel that it was appropriate to pursue the issue directly with the NFL.¹¹²

It does not appear that Dr. Freire ever made clear to the NFL that it had an obligation to fund the CTE study, or directly requested that the NFL begin transferring funds according to the schedule laid out in the Research Plan.¹¹³ However, Dr. Freire did inquire whether the NFL planned to fund the study. On October 19, Dr. Freire e-mailed Jeff Miller:

We are keen to find a path forward and to ensure that all parties are satisfied with the outcome. As you know, the CTE grant was predicated on the availability of funds from our agreement with NFL. Clearly, it would be best if NINDS could count on the entire support from NFL for the CTE project, as originally agreed. If that is not possible, I hope you would consider partial funding, with the balance to go to other meritorious research supported by NINDS.¹¹⁴

In response, Jeff Miller replied:

Didn't you represent, as did Dr. Koroshetz, that the CTE grant would be supported by NIH dollars? That's what was stated to the group the other day.¹¹⁵

Dr. Freire replied with the following:

The RFA for the CTE study was predicated on the agreement with NFL. When the concerns arose with NFL on the grantee, Walter went back to his Advisory Council to seek approval for a second study to be funded, as you know. Council rejected that option. However, they determined that this was a very important study and that, if need be, NINDS should fund it in its entirety.

NINDS is prepared to do this. As I have said, and I know you can appreciate, this puts NINDS in a difficult budgetary situation because this is very large grant- a cost that was not expected to be paid by taxpayers' dollars. The normal NIH budget process for RFAs begins years in advance to ensure appropriate balance on other aspects of the Institute's research portfolio. Since this grant not was [sic] expected to be sourced from the NINDS budget, supporting the CTE study with taxpayer dollars means that NINDS will be unable to fund other meritorious research for several years.

¹¹² *Id.*

¹¹³ Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016).

¹¹⁴ E-mail from Dr. Maria Freire, FNIH, to Jeff Miller, NFL (Oct. 19, 2015) (on file with Committee staff).

¹¹⁵ E-mail from Jeff Miller, NFL, to Dr. Maria Freire, FNIH (Oct. 19, 2015) (on file with Committee staff).

As I mentioned on the phone to you, we think it is important for NFL to contribute to this study. If funding the full study is completely off the table, it would be good if you could support, for example, the first year of the study or longer. Stephanie also indicated [sic] to the group during our last conversation that by doing so, NFL would allow the study to begin before Congress determines the FY 2016 budget, which could take some time in the current environment.

Frankly, this would also be an important statement about NFL's commitment to research and will help dampen criticism, while reserving the greater portion of your funding commitment for another research project. We understand that this is a very awkward situation all around, but some level of compromise would be the best possible solution.¹¹⁶

Miller responded:

We have not made any determination on the use of the FNIH funds at this point. Obviously, this is a complex area, but we are driving to some conclusions which I hope to share with you in the next week or two.

Dr. Koroshetz's representation on the funding of the project was quite clear, but as you and I discussed, we are seriously considering the idea toward the end of your note.¹¹⁷

In a briefing with Committee staff, Jeff Miller explained that the NFL was operating under the assumption that the September Council meeting decision meant that NIH would fund the study on their own.¹¹⁸ When questioned about Dr. Freire's October 19, 2015, e-mails, Miller stated that the e-mail communications were a "major surprise," and that he was unsure why FNIH was coming back to the NFL requesting funding for the CTE study. He believed it had already been settled that NINDS would fund the study.¹¹⁹

It appears that after the October 19, 2015 emails, the communications between Dr. Freire and Jeff Miller shifted to focusing on the NFL funding the first year of the CTE study. On November 6, 2015, Dr. Freire emailed Jeff Miller to state that "the total cost for Year 1 funding for the BU CTE project is \$2.58 million (\$2,577,483 to be exact)."¹²⁰ On December 1, 2015, Dr. Freire emailed Jeff Miller the following: "Jeff, NINDS needs to announce the grant for the CTE

¹¹⁶ E-mail from Dr. Maria Freire, FNIH, to Jeff Miller, NFL (Oct. 19, 2015) (on file with Committee staff).

¹¹⁷ E-mail from Jeff Miller, NFL, to Dr. Maria Freire, FNIH (Oct. 20, 2015) (on file with Committee staff).

¹¹⁸ Briefing by Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Energy and Commerce Democratic Committee Staff (Apr. 14, 2016).

¹¹⁹ *Id.*

¹²⁰ E-mail from Dr. Maria Freire, FNIH, to Jeff Miller, NFL (Nov. 6, 2015) (on file with Committee staff).

study. They are working on the press release now. Please let me know as soon as possible if you have reached a decision about funding part of the BU study.”¹²¹

The NFL did consider Dr. Freire’s request to provide additional funding to support the first year of the study.¹²² Jeff Miller consulted with Jeff Pash, the NFL’s Executive Vice President and General Counsel, as well as Dr. Nabel, Dr. Ellenbogen, and Dr. Russell Lonser.¹²³ Ultimately, Miller decided to offer two million dollars in funding to cover the first year of the study: \$1 million reprogrammed from the original \$16 million and an additional \$1 million in new money from the NFL.¹²⁴

4. Continuing Attempts by the NFL to Direct Funding to Other Priorities

Throughout this same period of time following the September Council meeting through the NGA in December, the NFL and its advisors continued to explore other research initiatives that the NFL could fund with the \$16 million that had previously been committed to the CTE study.

Dr. Lonser – a member of the HNS Committee who had previously been Chief of the Surgical Neurology Branch at NINDS – reached out to Dr. Leighton Chan at NIH’s Clinical Center to inquire about expanding an ongoing intramural study involving patients with traumatic brain injury recruited into a protocol at the NIH Clinical Center involving the Washington Hospital Center and other sites, to incorporate athletes.¹²⁵ Dr. Chan then reached out to Dr. Koroshetz sometime in October to discuss the idea that Dr. Lonser was proposing, which would direct the NFL funds to the NIH intramural campus, and would involve the researchers from the second highest scored grant proposal from the CTE study.¹²⁶ The investigators associated with

¹²¹ E-mail from Dr. Maria Freire, FNIH, to Jeff Miller, NFL (Dec. 1, 2015) (on file with Committee staff).

¹²² Briefing by Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Energy and Commerce Democratic Committee Staff (Apr. 14, 2016).

¹²³ E-mail from Kenneth Edmonds, NFL, to Energy and Commerce Committee Staff (May 3, 2016).

¹²⁴ Briefing by Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Energy and Commerce Democratic Committee Staff (Apr. 14, 2016); Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Feb. 10, 2016).

¹²⁵ Briefing by Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Energy and Commerce Democratic Committee Staff (Apr. 14, 2016); Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Democratic Committee Staff (Apr. 29, 2016).

¹²⁶ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff

the grant proposal included Drs. Ellenbogen, McCrea, and Guskiewicz. Dr. Koroshetz informed Dr. Chan about the Council's decision in September to fund only the BU grant, and stated that the intramural proposal would have to be elevated to Dr. Francis Collins, the NIH Director, for his consideration.¹²⁷

In December, Dr. Freire met with Dr. Collins and others to discuss the options and make final funding decisions.¹²⁸ Dr. Collins rejected the concept of Dr. Chan's intramural program funding such a study outside of the regular NIH process of peer review. NIH decided to use its own money to fund the BU study in its entirety, and decided to issue a new request for applications (RFA) to use the \$16 million from the NFL. The agency also declined the additional funding from the NFL for the first year of the CTE study.¹²⁹ Dr. Koroshetz explained that NIH leadership felt it was best to reserve the full remaining NFL contribution for a future study.¹³⁰

5. The Future of the NFL Funding to FNIH

On February 12, 2016, Dr. Koroshetz and Dr. Kathy Hudson, NIH's Deputy Director for Science, Outreach and Policy, wrote to the NFL to lay out a potential path forward on a new RFA.¹³¹ They wrote:

We are writing to apprise you, as partners in the Sports and Health Research program, of NIH's plans moving forward with concussion research. Scientifically, the next logical step is to extend this research into youth populations (pre-college ages). ...If the NFL is

(Feb. 10, 2016); Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Democratic Committee Staff (Apr. 29, 2016).

¹²⁷ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Democratic Committee Staff (Apr. 29, 2016).

¹²⁸ Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Democratic Committee Staff (Jan. 28, 2016).

¹²⁹ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 19, 2016).

¹³⁰ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Feb. 10, 2016).

¹³¹ Letter from Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, and Dr. Kathy Hudson, Deputy Director for Science, Outreach and Policy, National Institutes of Health, to Jeff Miller, Executive Vice President of Health and Safety, National Football League (Feb. 12, 2016).

interested in this research plan once it is developed, then we would welcome the organization as partners in this important endeavor.¹³²

Jeff Miller responded to assert the NFL's request for a prospective, longitudinal study on the long-term effects of concussion.¹³³ His response did not commit the NFL to funding the RFA for the youth study:

From the formation of the Sports and Health Research Program (“SHRP”), the NFL and the NIH have expressed a shared interest in two primary areas of scientific inquiry: 1. Improved understanding of the neuropathology around Chronic Traumatic Encephalopathy (“CTE”); and 2. A prospective longitudinal study to examine the long-term implications of closed head brain injury. These goals were set in October 2012 at a meeting where leaders from the NIH, FNIH and NFL participated. ...

The second of these goals, a prospective longitudinal study on the long-term effects of concussion, was the subject of a SHRP-funded and NIH-led public workshop in Bethesda, Maryland in July 2013. At that meeting, national experts, including senior representatives of the NIH, FNIH, as well as members of the NFL's Head, Neck and Spine Committee, reached consensus on the need to fund a prospective longitudinal study with the remainder of the NFL's contribution to the SHRP.

As the NIH pursues its plans for concussion research, we hope you will consider the conclusions reached at the most recent workshop on the importance of a longitudinal study.¹³⁴

In response, Dr. Koroshetz and Dr. Hudson replied:

We were puzzled by your comments asking us to consider funding a longitudinal study. Informed by the July 2013 SHRP-funded public workshop on Brain Trauma-Related Neurodegeneration that included national experts from the NIH and the NFL's Head, Neck and Spine Committee, the NIH drafted a proposal for a prospective longitudinal study of “high risk individuals with symptoms and medical history suggestive of CTE.” NFL, FNIH and NIH agreed to pursue this longitudinal study in July, 2014 in the attached Research Plan for a “longitudinal study in high risk adults.”

As you know, in December 2015, NINDS did award a grant to a consortium led by Boston University in response to the attached Funding Opportunity Announcement

¹³² *Id.*

¹³³ Letter from Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, Dr. Kathy Hudson, Deputy Director for Science, Outreach and Policy, National Institutes of Health, and Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health (Mar. 11, 2016).

¹³⁴ *Id.*

Detect, Define and Measure the Progression of Chronic Traumatic Encephalopathy for a “multicenter and multidisciplinary longitudinal study of individuals with a “probable” or “possible” diagnosis of chronic traumatic encephalopathy (CTE).” The award of this longitudinal study was a direct result of the July 2013 workshop. We eagerly await the results and do not have any plans to support an additional longitudinal study for CTE at this time.¹³⁵

In a phone call with Democratic Committee staff, Dr. Koroshetz stated that he did not understand the NFL’s rationale in its March 11 letter or why the NFL suggested that NIH conduct another longitudinal study.¹³⁶ Dr. Koroshetz stated that NIH will continue to make research decisions based on the science, and then offer up potential funding opportunities to FNIH and the NFL.

IV. FINDINGS

A. The NFL improperly attempted to influence the grant selection process at NIH.

As a donor providing funding for objective scientific research to the National Institutes of Health (NIH), the National Football League (NFL) acted improperly in attempting to influence the outcome of NIH’s internal process for selecting grantees. The terms of the letter of agreement (LOA) and the five individual research plans make clear that NIH retained authority with respect to reviewing grant applications, awarding grants, and overseeing those grants. When NFL officials executed Research Plan 5—the longitudinal study designed to help develop methods of diagnosing chronic traumatic encephalopathy (CTE) in living individuals—they committed the League to funding the grant application deemed most meritorious by NIH. The terms of their agreements made clear that the NFL did not reserve the right to weigh in on the grant selection process. Such a provision would be contrary to NIH policy, which makes clear that a donor may not dictate terms that include any delegation of NIH’s inherently governmental responsibilities, decision-making, or participation in peer review or otherwise exert real or potential influence in grant or contract decision-making.¹³⁷

Accordingly, the NFL should not have intervened in the process once it had signed the research plan. It was improper for any members of the NFL’s staff, as well as members of its Head, Neck and Spine Committee (HNS Committee), to opine on the merits of Dr. Stern’s grant and attempt to circumvent the peer review process. Additionally, Dr. Ellenbogen, as co-chair of the HNS Committee, should not have participated in conversations with NIH and the Foundation

¹³⁵ Letter from Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, and Dr. Kathy Hudson, Deputy Director for Science, Outreach and Policy, National Institutes of Health, to Jeff Miller, Executive Vice President of Health and Safety, National Football League (Apr. 28, 2016).

¹³⁶ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Democratic Committee Staff (Apr. 29, 2016).

¹³⁷ NIH Policy Manual, *1135- Gifts Administration* (Oct. 5, 2011).

for the National Institutes of Health (NIH) about the NFL's concerns. Although he did not violate any specific NIH rule we are aware of, Dr. Ellenbogen's participation in these discussions contravenes the spirit of the NIH conflict of interest rules, which are designed to ensure that individuals who have a financial interest in the outcome of a grant award are not involved in the decision-making process to award such a grant.¹³⁸

Jeff Miller expressed that the NFL leadership believed the League acted properly in voicing its concerns to NIH.¹³⁹ He noted that Dr. Nabel and Dr. Ellenbogen felt concerns about the process were raised in the most appropriate way, and this back-and-forth over the grants process was hardly unusual.

Dr. Koroshetz disagreed with these assertions.¹⁴⁰ He expressed that the stipulations in funding agreements have consistently expressed that the NIH scientific process is out of bounds for donors. Dr. Koroshetz was aware of no other instance where a donor raised objections to a grantee prior to the issuance of a notice of grant award (NGA).¹⁴¹

The NFL's characterization of the appropriateness of its actions suggests a lack of understanding of the importance of the NIH's independent peer review process. The process forms the cornerstone of the NIH research mission and ensures that applications submitted to NIH are evaluated by scientific experts in a manner free of inappropriate influences or bias. The NIH Policy Manual clearly and explicitly prohibits donor involvement in the grant selection process for this reason.¹⁴²

Additionally, once the September Council recommendation was finalized and the objections the NFL had raised were conclusively addressed, the NFL should have committed to funding the CTE study in full. Jeff Miller attributed this outcome to his understanding that at September Council, the National Institute of Neurological Disorders and Stroke (NINDS) decided to fund the study on its own and in full.¹⁴³ However, Dr. Freire's multiple requests to Jeff Miller that the NFL fund the full \$16 million, and her explanations that the failure to do so would negatively impact NINDS, suggest otherwise. Although Dr. Freire could have been clearer about the NFL's obligation to fund the full amount, Miller should also have sought a better understanding of what was expected of the NFL after the September Council decision.

¹³⁸ See, e.g., National Institutes of Health, *NIH Conflict of Interest Rules: Information for Reviewers of NIH Applications and R&D Contract Proposals* (Mar. 18, 2015).

¹³⁹ Briefing by Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Energy and Commerce Democratic Committee Staff (Apr. 14, 2016).

¹⁴⁰ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Democratic Committee Staff (Apr. 29, 2016).

¹⁴¹ *Id.*

¹⁴² NIH Policy Manual, *1135- Gifts Administration* (Oct. 5, 2011).

¹⁴³ Briefing by Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Energy and Commerce Democratic Committee Staff (Apr. 14, 2016).

B. The NFL’s Head, Neck and Spine Committee members played an inappropriate role in attempting to influence the outcome of the grant selection process.

The NFL repeatedly emphasized the “independent” nature of the HNS Committee members, and suggested that the actions of those members did not reflect the official positions of the League.¹⁴⁴ The uncertainty surrounding whether scientists were reaching out as representatives of the NFL or as independent researchers led to unnecessary confusion in the relationship between NIH, FNIH, and the NFL.

Despite their expertise as researchers and physicians, members of the HNS Committee cannot approach the NFL-FNIH-NIH partnership claiming to be impartial observers. They are under the same obligations as paid NFL staff when it comes to observing guidelines for donors to FNIH.

Dr. Ellenbogen is a primary example of the conflicts of interest between his role as a researcher and his role as an NFL advisor. He had been part of a group that applied for the \$16 million grant. After his group was not selected, Dr. Ellenbogen became one of the NFL’s primary advocates in expressing concerns surrounding the process with the BU grant selection. He not only participated on a conference call with NIH and FNIH on behalf of the NFL; he also reached out to Dr. Koroshetz separately to share that he would be unable to recommend to the NFL owners that they fund the Boston University (BU) study.¹⁴⁵ This series of events raises significant questions about Dr. Ellenbogen’s own bias. It is clear that he should not have been communicating directly with Dr. Koroshetz or any other NIH staff about the grant selection process.

Dr. Lonser’s role similarly raises concerns about the lack of clarity in the roles of HNS members as NFL advisors. Dr. Lonser initiated the conversations between the NFL and Dr. Chan at NIH’s Clinical Center to explore using the NFL funding in other ways. As with Dr. Ellenbogen, it was inappropriate for Dr. Lonser to be communicating directly with NIH staff in this manner. Attempts by the NFL HNS Committee advisors to influence how funding is allocated by NINDS are inappropriate, whether intramurally or extramurally, and in direct contravention of NIH policy prohibiting donor involvement in the grant decision-making process.

¹⁴⁴ Briefing by Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Energy and Commerce Democratic Committee Staff (Apr. 14, 2016); Letter from Roger Goodell, Commissioner, National Football League, to Ranking Member Frank Pallone, Jr., et al., Committee on Energy and Commerce (Apr. 25, 2016).

¹⁴⁵ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Committee Staff (Feb. 10, 2016).

Jeff Miller emphasized that the HNS Committee is “very informal” and that committee members do not need permission to advocate on the NFL’s behalf.¹⁴⁶ According to Miller, the HNS Committee members had suggested to the NFL leadership that they raise concerns with the BU grant, and Miller stated that the NFL leadership completely defer to the HNS Committee members on what is appropriate. Miller acknowledged that there were multiple communications between NIH and HNS Committee members to which he was not a party.¹⁴⁷

While this informal structure may be valuable for the NFL’s internal processes, such informality is inappropriate in outreach to NIH and FNIH. If they had questions or concerns about the NIH grant process, the HNS Committee members should have channeled that outreach exclusively through FNIH.

C. The NFL’s rationalization that the Boston University study did not match their request for a longitudinal study is unfounded.

There is no merit to the NFL’s claims that the BU grant did not match what had been agreed upon in the desired longitudinal study, and this appears to be a post-hoc rationalization for declining to fund the CTE study. In briefings with Committee staff, Jeff Miller expressed that the NFL had consistently been interested in a prospective, longitudinal “Framingham-style” study, and the BU proposal did not satisfy that request.¹⁴⁸ While it is true that at the earliest stage of the relationship between the NFL and NIH in 2012, an expansive longitudinal study was proposed to examine the risk factors for developing CTE, it quickly became clear that the cost and time frame of such a study proved prohibitive.¹⁴⁹ The study would have to be at least 20 years long, and Dr. Berger – a member of the HNS Committee – estimated it could cost up to \$140 million, according to Dr. Koroshetz.¹⁵⁰

In 2014, NIH, FNIH, and the NFL agreed upon Research Plan 5, which acknowledged that a longer study would be valuable but decided that a shorter study was merited in the meantime.¹⁵¹ The NFL raised no objections at that time and understood the limits of the plan.¹⁵² The research plan stated:

¹⁴⁶ Briefing by Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Energy and Commerce Democratic Committee Staff (Apr. 14, 2016).

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Democratic Committee Staff (Apr. 29, 2016).

¹⁵⁰ *Id.*

¹⁵¹ SHRP Research Plan Schedule No. 5 (July 14, 2014).

¹⁵² Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016); Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and

Although a large, natural history longitudinal study of youth athletes over many years would be a powerful approach to identify the population incidence and prevalence of neurological deficits caused by brain trauma, it would require several decades to complete the study. Given the urgency of the problem, an alternative approach is to focus on high risk individuals with symptoms and medical history suggestive of CTE. In such individuals, it may be possible to detect progression over the 3-5 year time span of this study. Therefore, this initiative aims to support a 7-year longitudinal, hypothesis-driven study to detect, define and monitor the progression of CTE in high-risk middle-aged adults, along with appropriate control studies.¹⁵³

Dr. Stern's grant application reflected the language from Research Plan 5.¹⁵⁴ The application stated, "we propose a multidisciplinary, multicenter, longitudinal study of former athletes with high exposure to repetitive head impacts (120 former NFL players with and without symptoms) or medium exposure to repetitive head impact (60 former college football players with and without symptoms) and a control group of 60 asymptomatic same-age men without any history of repetitive head impact exposure or traumatic brain injury."¹⁵⁵ The BU study was closely aligned with what the NFL had agreed to under Research Plan 5 in 2014. There is no evidence to support the NFL's claims that the BU study did not match what NIH and the NFL mutually agreed upon throughout the course of the Sports and Health Research Program (SHRP).

Additionally, information received from NIH and FNIH is inconsistent with Jeff Miller's assertion that the NFL raised concerns about the longitudinal nature of the BU study as early as the June 2015 conference call. Dr. Freire noted that the NFL's concerns on the conference call centered on the peer review process, Dr. Stern's affidavit, and issues of balance related to money going to only one institution.¹⁵⁶ Dr. Koroshetz confirmed that the NFL did not raise concerns about the nature of the longitudinal study through the discussions of the BU grant in 2015.¹⁵⁷

Stroke, National Institutes of Health, to Energy and Commerce Democratic Committee Staff (Apr. 29, 2016).

¹⁵³ SHRP Research Plan Schedule No. 5 (July 14, 2014).

¹⁵⁴ National Institutes of Health, *Notice of Award: Chronic Traumatic Encephalopathy, Detection, Diagnosis, Cure, and Risk Factors* (Dec. 12, 2015) (Grant Number 1U01NS093334-01).

¹⁵⁵ *Id.*

¹⁵⁶ Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016).

¹⁵⁷ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Democratic Committee Staff (Apr. 29, 2016).

It was not until the March 2016 letter from Jeff Miller to Dr. Koroshetz and Dr. Hudson that NIH became aware of the NFL's concerns surrounding a longitudinal study.¹⁵⁸

D. FNIH did not adequately fulfill its role of serving as an intermediary between NIH and the NFL.

FNIH was created to serve as intermediary between NIH and potential donors, both to preserve the independence of the scientific process and to conduct fundraising and solicitation from private donors which NIH employees are not permitted to do. Because NIH employees are strictly prohibited from soliciting funding from private donors, it was up to FNIH to make sure all parties were clear in their expectations and understanding regarding the execution of the funding agreements. FNIH failed to effectively fulfill this role. This resulted in a private donor circumventing appropriate protocols of communication, attempting to influence NIH's selection of grant recipients, and ultimately violating its obligation to provide funding for that grant.

FNIH should have made clear to the NFL from the outset that it was inappropriate for the NFL to act on non-public information prior to the NGA and raise concerns regarding the selection of a grantee with NINDS. This series of misunderstandings and disputes might have been avoided had FNIH reminded the NFL of its obligation to fund the study under the LOA and Research Plan 5, and reminded the NFL that the agreement made clear that NIH retained responsibility and control over the review and awarding of scientific grants.

Similarly, after the September Council recommendation, FNIH should have been clearer with the NFL about their obligation to fund the study. FNIH should also have been more proactive and responsive to NINDS' repeated efforts to ascertain whether the NFL would be funding the entirety of the \$16 million after the September Council meeting.

Finally, FNIH should have made absolutely clear to both the NFL and NIH that they were the NFL's exclusive point of contact for questions about funding decisions. It should have been clear to the NFL – and to its medical advisors on the HNS Committee – that they should not contact NIH directly to discuss pending grant decisions. Dr. Freire agreed that additional clarity is needed in defining the donor and advisor relationship.¹⁵⁹ It must be clear that donor representatives who are scientists are still donors.

E. NIH leadership maintained the integrity of the science and the grant review process.

¹⁵⁸ Letter from Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, Dr. Kathy Hudson, Deputy Director for Science, Outreach and Policy, National Institutes of Health, and Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health (Mar. 11, 2016).

¹⁵⁹ Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health, to Energy and Commerce Committee Staff (Jan. 28, 2016).

The NINDS staff, led by Dr. Koroshetz, ensured that the scientific process – not funding decisions – dictated their approach to the CTE study. Under pressure from an influential private donor, NIH leadership maintained the integrity of the process and thus ensured that the best applicants received the grant. The Committee staff’s review of documents and correspondence show that NIH officials relied on the established procedures for awarding research grants. This resulted in the most highly meritorious applicants receiving the grant, while the proposals of lower scoring applicants who applied through this program were not funded.

Nonetheless, NIH may have gone too far in attempting to accommodate the NFL. While it might have been appropriate for NIH to investigate the allegations of conflicts of interest to ensure the integrity of its own scientific process, once NIH completed its internal review and determined the allegations were unfounded, the issue should have been considered resolved. Attempts by NIH to find a mutually agreeable solution involving a second research site signaled a willingness to have the NFL more involved in the grant selection process. It also may have encouraged the NFL to conduct further direct outreach to NIH staff, as evidenced by HNS Committee advisors’ inappropriate overtures directly to NIH intramural staff regarding potential funding opportunities.

Additionally, NIH staff should not have communicated directly with the NFL or HNS Committee members without FNIH’s participation. In recognition of these miscommunications, NIH has requested that the NFL and its advisors include FNIH in all future discussions. In a letter to Jeff Miller in February 2016, Drs. Koroshetz and Hudson wrote, “Moving forward, we would request that if NFL or its advisors would like to discuss research collaborations with NIH employees, such discussions should include FNIH and the NIH Office of the Director.”¹⁶⁰ NIH expressed that including all parties is the best course moving forward given all the issues raised by the BU grant process.¹⁶¹

F. The NFL did not carry out its commitment to respect the science and prioritize health and safety.

Despite their stated intention to “let the science go where the science goes” in answering critical safety questions, the NFL’s actions in this case indicated otherwise.¹⁶² The behavior of the NFL leadership and their medical advisors is inconsistent with their public commitment to “support science and medicine and allow them to make those decisions...[and] try to see what

¹⁶⁰ Letter from Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, and Dr. Kathy Hudson, Deputy Director for Science, Outreach and Policy, National Institutes of Health, to Jeff Miller, Executive Vice President of Health and Safety, National Football League (Feb. 12, 2016).

¹⁶¹ Briefing by Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, to Energy and Commerce Democratic Committee Staff (Apr. 29, 2016).

¹⁶² *NFL exec: Research shows a link between football and CTE*, NBC Sports (Mar. 15, 2016).

we can do to support that and advance that.”¹⁶³ NIH stood by the conclusion of its review committee that Dr. Stern’s involvement in no way biased the BU group’s proposal to study CTE in living individuals. Respect for the process should have dictated the NFL’s acceptance of this conclusion.

The NFL’s interactions with NIH and approach to funding the BU study fit a long-standing pattern of attempts to influence the scientific understanding of the consequences of repeated head trauma. These efforts date back to the formation of the NFL’s now-discredited MTBI Committee, which attempted to control the scientific narrative around concussions in the 1990s.¹⁶⁴

In this instance, our investigation has shown that while the NFL had been publicly proclaiming its role as funder and accelerator of important research, it was privately attempting to influence that research. The NFL attempted to use its “unrestricted gift” as leverage to steer funding away from one of its critics. The League, its players, and the public have a vested interest in advancing our knowledge of the relationship between degenerative diseases and sports-related head trauma.

V. RECOMMENDATIONS

In light of these findings, we issue the following recommendations:

- **FNIH must establish clearer guidelines regarding donor communications with NIH.**

The Foundation for the National Institutes of Health (FNIH) must make clear to donors that they cannot communicate with the National Institutes of Health (NIH) regarding pending grant or contract decisions. There should be no instance where any individual with ties to the donor organization – whether in a formal or informal capacity – communicates directly with NIH about a pending grant or contract decision until after the public announcement of the award, except to allow for the coordination of the public announcement of a grant decision, as provided in the FNIH-NIH memorandum of understanding (MOU). If a donor has legitimate questions about the integrity of the peer review process prior to the notice of grant award (NGA), these concerns may be raised with FNIH. FNIH can then refer the matter to NIH for NIH to determine the appropriate course of action for investigation and resolution. However, it is inappropriate for the donor to go directly to NIH with these concerns and attempt to influence grant funding decisions.

The National Football League’s (NFL) position of having both paid staff and unpaid advisors may be unique to this case. But FNIH should make abundantly clear – and both the NFL and NIH should understand – that neither the NFL’s staff nor their scientific advisors may communicate with NIH staff regarding pending grant or contract decisions.

¹⁶³ *Roger Goodell sidesteps CTE questions after NFL official’s acknowledgement to Congress*, Washington Post (March 23, 2016).

¹⁶⁴ *Doctor Yes*, ESPN (April 15, 2009).

In order to avoid future instances in which private donors commit substantial amounts of money to particular topics of research and then seek to influence the direction of that research, FNIH must establish clearer guidelines regarding donor communication with NIH. The guidelines should be part of the initial agreement between FNIH and the donor.

- **FNIH must come to a mutual understanding with donors at the beginning of the process regarding their degree of influence over the research they are funding and remind donors that NIH policy prohibits them from exerting influence at any point in the grant decision-making process.**

While it is undoubtedly important for FNIH to strike a balance between facilitating the wishes of private donors and ensuring independent research, donors must be made explicitly aware of the degree of influence over the research they are funding and the limits of that influence. Donors should be made aware that the purpose of this prohibition is to protect the integrity of NIH's independent peer review process, a cornerstone of the NIH research mission that operates to ensure that applications submitted to NIH are evaluated by scientific experts in a manner free of inappropriate influences or bias.

Donors may be able to participate in workshops, stakeholder boards, or other similar events surrounding dispensation of their donated funds. However, donors must understand the limits to that participation.

- **FNIH should provide donors with the clear, unambiguous language from the NIH Policy Manual, which states that a donor may not dictate terms that include “any delegation of NIH’s inherently governmental responsibilities or decision-making,” or “participation in peer review or otherwise exert real or potential influence in grant or contract decision-making.”**

Although the agreements in this case did make clear that NIH had responsibility and control over the grant making process, language incorporating the NIH Policy Manual language (with a citation to the Policy Manual) would provide additional clarity regarding the limits of donor involvement and the rationale for such limits.

FNIH should ensure that all donors have a clear understanding of the boundaries set by the NIH Policy Manual. The relevant sections of the Policy Manual should be made available to each donor at the outset of the donation agreement.

- **NIH and FNIH should jointly develop a process to address concerns about donors acting improperly.**

If a donor improperly contacts NIH staff, there must be a process whereby NIH can refer the donor's request back to FNIH. It should then be exclusively handled by FNIH staff. If any further questions from the donor arise, they may be referred through FNIH to NIH staff. There should not, however, be joint communications between NIH, FNIH, and the donor about “NIH's inherently governmental responsibilities, decision-making, or participation in peer review.”

FNIH must also communicate to the donor why such outreach directly to NIH was improper, citing the prohibition on NIH employees from requesting or suggesting donations to NIH or any of its Institutes or Centers.

- **The NFL, FNIH, and NIH should amend their current contracts to ensure that each party has a clear understanding of its role for the remainder of this partnership.**

The NFL has stated on numerous occasions that it remains committed to funding the full \$30 million that it originally committed to NIH.¹⁶⁵ Given that the schedule of payments associated with Research Plan 5 is no longer applicable, it is unclear when the remaining funds will be transferred to FNIH for disbursement to NIH.

Given the recent history, the NFL, FNIH, and NIH should revisit the language under the letter of agreement (LOA) and MOU to ensure each party has clear guidelines on its appropriate role for the remainder of the partnership. A recommitment to these agreements would help restore trust and eliminate any perception that the NFL is continuing to attempt to influence the scientific process, or any perception that the NFL is not committed to funding the full \$30 million donation that it announced it would be making.

¹⁶⁵ Briefing by Jeff Miller, Executive Vice President of Health and Safety, National Football League, to Energy and Commerce Democratic Committee Staff (Apr. 14, 2016).



NATIONAL FOOTBALL LEAGUE

September 1, 2012

Charles A. Sanders, MD
Chairman
Foundation for the National Institutes of Health
9650 Rockville Pike
Bethesda, MD 20814

Dear Dr. Sanders,

This master letter of agreement ("Agreement") sets forth the terms under which the National Football League (hereinafter "DONOR") will provide funding in support of research on serious medical conditions prominent in athletes and relevant to the general population (hereinafter "Sports and Health Research Program" or the "Program"). The Program will be conducted by or with institutes and centers at the National Institutes of Health (hereinafter "NIH"), through a public-private partnership coordinated by the Foundation for the National Institutes of Health, Inc. (hereinafter "FNIH"), a 501(c)(3) nonprofit organization. DONOR is providing funding with the understanding that the funds are to be used for scientific purposes. If permitted under applicable law and/or regulations, funding for the Program by DONOR will be treated as a charitable contribution to the maximum extent allowable under applicable law or regulation.

The purpose of FNIH pursuant to 42 U.S.C. 290b is to support the NIH in its mission and advance collaboration among universities, industry, and other non-profit organizations. Consistent with that purpose, FNIH is coordinating fundraising and partnership activities to support the Program.

The goal of the Program is to accelerate the pace of discovery through a public-private partnership to support the most innovative and promising science in areas of mutual interest. The areas of research to be funded by the Program might include, but are not limited to:

- 1) Chronic traumatic encephalopathy: accurate diagnosis and risk factors;
- 2) Concussion: assessing brain injury and risk of disability;
- 3) Understanding the potential relationship between traumatic brain injury and late life neurodegenerative disorders, especially Alzheimer's disease;
- 4) Chronic degenerative joint disease as a result of athletic injuries;
- 5) The transition from acute to chronic pain;
- 6) Sudden cardiac death in young athletes;
- 7) Heat and hydration-related illness and injury;
- 8) Use and dependency risks of pharmaceuticals, particularly NSAID agents;

- 9) Health effects of commonly used performance enhancing substances, including human growth hormones;
- 10) Assessment of third party research proposals; and/or
- 11) Other research that DONOR may request and that FNIH, through its customary process, determines to be of scientific and/or clinical merit.

Details of specific research areas to be funded by DONOR, including specific goals, milestones and budgets, will be set forth on numbered research descriptions agreed to by the parties after the date hereof and subsequently attached to this Agreement as a schedule (each, a "Research Plan" and, together, the "Research Plans"). Each such Research Plan shall be in the form attached hereto as Exhibit A and shall, upon execution, be incorporated by reference herein.

DONOR desires to support the Program by providing funding to FNIH as set forth below, pursuant to the following terms and conditions:

1. **Funding:**

- a. *Payments:* DONOR agrees and shall remit payment to FNIH for funding for the Program in the amount of \$30,000,000 (the "Grant"), payable to FNIH according to the following schedule:

Installment 1: *\$5 million to be paid as follows: \$3 million on the date of the last signature on this Agreement, and \$2 million within ten business days of the first meeting of the Stakeholder Board described in paragraph 3 of the Agreement ("Donor Involvement").*

Further installments: *To be provided according to the budget and payment schedule set forth in each executed Research Plan; provided that DONOR shall not be required to fund in excess of \$10,000,000 in any Program Year (as defined below). Upon request of NIH or FNIH, the NFL will provide commercially reasonable assurances of its ability to fund any remaining amount of the Grant.*

- b. *Use of funds:* FNIH shall use the funds provided by DONOR solely for the purpose of funding Program overhead and Research Plan costs, including without limitation the direct research costs associated with each Research Plan, the indirect costs of the institutions supporting the research (such indirect costs are agreed upon between eligible research institutions and the U.S. Government), and the costs of FNIH. FNIH shall retain (i) one percent (1%) of each installment of the Grant paid to support its operating cost recovery; (ii) a sufficient portion of each installment to cover direct costs incurred for performing its services in connection with the Program and any Research Plans funded through the Program; and (iii) all interest earned on unused portions of each installment to cover costs incurred in connection with FNIH's administration of the funds.

- c. *Time and place of payment:* Grant installment payments will be made according to the schedule set forth in Section 1(a) and delivered by DONOR to:

Stephanie James, PhD (prior to Nov. 1, 2012)
Acting Executive Director
Foundation for the National Institutes of Health
9650 Rockville Pike
Bethesda, MD 20814

Maria Freire, PhD (as of Nov. 1, 2012)
President
Foundation for the National Institutes of Health
9650 Rockville Pike
Bethesda, MD 20814

or sent via electronic transfer to:

SunTrust Bank
1 Park Place
Atlanta, GA 30303



For the account of the Foundation for NIH

2. **Content and Administration:** For NIH-managed activities, FNIH will provide funds to the NIH for use in funding the Program and Research Plans conducted under its auspices. DONOR acknowledges and agrees that NIH will have responsibility for and control over the scientific and administrative aspects of the Research Plans it manages under the Program, including but not limited to holding workshops, developing and posting calls for applications, reviewing applications, determining grantees, awarding grants, overseeing the grants, including the scientific and financial progress of the grantees, monitoring data sharing plans, and publication of research results related to the Program. Should the case arise that it is deemed more appropriate and expedient for FNIH to directly manage activities under the Program, management details will be articulated in the Research Plan.
3. **DONOR Involvement:** To encourage and facilitate private collaborators' involvement in the Program, FNIH will establish and convene a Stakeholder Board ("SB"). The SB provides an independent forum where donors can engage scientifically with each other and with NIH scientific leadership, patient advocacy organizations, sports organizations, and scientists to share information and updates, express viewpoints, address challenges, share expertise, and develop common perspectives on related issues. DONOR will be invited to appoint two representatives to the SB. The SB will help to develop the highest priority areas of research for consideration by NIH.

DONOR, NIH, and FNIH will discuss, propose, and determine prioritized areas of mutual interest for research related to serious medical conditions prominent in athletes and relevant to the general population. NIH will develop a Research Plan for each area of mutual interest for which

funding is available from DONOR. The Research Plan, a form of which is attached hereto as Exhibit A, may include a description of the work that needs to be accomplished, proposals for scientific workshops or other public meetings as appropriate, proposed topics for NIH Funding Opportunity Announcements (FOAs), a timeline and a budget necessary to accomplish the Research Plan. FNIH will share the Research Plan with DONOR; both NIH and FNIH may be involved in related discussions with DONOR. Upon agreement by DONOR, FNIH and NIH on the Research Plan, FNIH will transfer DONOR funds to NIH. NIH intends to initiate implementation of the Research Plan following its typical funding process. This includes issuing FOAs for research proposals, evaluation by NIH peer review, and making funding determinations based on scientific excellence and program need.

4. **Research Results:** Dissemination of results arising from research funded by DONOR will be governed by the Federal law and policy applicable to NIH-funded research. In accordance with NIH policy current at the time of this Agreement, NIH funding recipients will be urged to disseminate the results of research funded by DONOR in order to optimize the value of the science to the research community and the public. DONOR will have no early or special access to scientific study data.
5. **Scientific Reporting:** Reports on scientific progress of Research Plans described in amendments to this Agreement, including attainment of specific goals and milestones, will be provided to DONOR according to a reporting schedule specified in the Research Plan(s).
6. **Financial Reporting:** Reports on the expenditure of funds provided by DONOR will be provided to DONOR according to a reporting schedule specified in the Research Plan(s). For purpose of verifying FNIH's reporting obligations under this Agreement, upon fifteen (15) days prior written notice, the NFL and its duly authorized representatives at its expense, may, during FNIH's reasonable business hours, inspect and audit all records related to the expenditure of funds with respect to any Research Plan at any time within three (3) years after the conclusion of each Research Plan. FNIH covenants that it will fully cooperate with the inspection, audit or examination and will not unreasonably cause or permit any interference with the NFL or its representatives during any inspection, audit or examination.
7. **DONOR Recognition:** As a partner in the Program, DONOR will be acknowledged for its support of the NIH and the FNIH. The parties agree that public print and electronic communications and promotional materials, including news releases, that are generated by DONOR, FNIH or NIH and incorporate the name of the Program ("Communications") shall include one of the following partner-recognition language, or such other language that shall be approved by the DONOR, in a manner and location mutually agreed to by the parties:
 - "Sponsored by the National Football League";
 - "Funded by the National Football League"; or
 - "Made possible by the Foundation for the National Institutes of Health, Inc. through a gift from the National Football League".

FNIH will work with DONOR and NIH to appropriately acknowledge DONOR in FNIH and NIH generated Communications and on the Foundation's web site, www.fnih.org or any successor website. FNIH agrees to share drafts of such Communications with DONOR and NIH for review,

comment and approval at least ten business (10) days prior to their public availability or dissemination; *provided* that silence or a failure by DONOR to respond within such ten business (10) day period shall not be deemed an approval. It is understood that DONOR agrees to share drafts of all Communications that it generates with FNIH and NIH for review, comment and approval at least ten business (10) days prior to public availability or dissemination; *provided* that silence or a failure by FNIH or NIH to respond within such ten business (10) day period shall not be deemed an approval. DONOR agrees that Communications will not be released until DONOR, FNIH, and NIH have provided written consent to such release (email sufficient); NIH agreement will be obtained via FNIH.

8. **Responsible Personnel:** The primary *programmatic* contact at DONOR will be:

NAME: Elliot J Pellman MD
TITLE: Medical Director
National Football League



The primary *business* contact at DONOR will be:

NAME: Matthew Morgado
TITLE: League Counsel
National Football League



The primary contact at FNIH will be:

Julie Wolf-Rodda
Director of Partnership Development
Foundation for NIH
9650 Rockville Pike
Bethesda, MD 20814



Other relevant FNIH contacts are:

Stephanie James, PhD, Acting Executive Director, [REDACTED]
Maria Freire, PhD, President as of Nov. 1, 2012, [REDACTED]
Julie Tune, Chief Financial Officer, [REDACTED]
Kimberly O'Sullivan, Communications Officer, [REDACTED]
Andrea Baruchin, PhD, Director, NIH Relations, [REDACTED]

9. **Term:**

- a. This Agreement shall be effective as of September 1, 2012 and will terminate on August 31, 2017 (the "Term"), unless renewed by the parties or terminated earlier according to the terms hereof.
 - b. The NFL shall have the right to terminate this Agreement for any reason or for no reason upon providing FNIH thirty (30) days' advance written notice. For the avoidance of doubt, termination of this Agreement will not terminate or otherwise relieve any of NFL's obligations for payment of any installments that are set forth in any executed Research Plan(s).
 - c. As used herein, "Program Year" shall be the period beginning on September 1 of any year and ending on August 31 of the following year.
10. **Disposition of Unused Funds:** Should the Program terminate prematurely, FNIH shall, at DONOR's election, either (i) return to DONOR all uncommitted funds or (ii) upon DONOR's consent and at the discretion of the FNIH Board of Directors, redirect all uncommitted funds to another FNIH Program or purpose. Uncommitted funds shall not be deemed to include FNIH's costs, including without limitation the 1% operating cost recovery fee as provided for in Section 1(b) above, any direct costs as yet not covered, nor the interest earned on said payment, nor any funds that have been paid to NIH as provided for in Section 2 above.
11. **Disclosures:** DONOR's participation as a contributor to the Program may be disclosed at any time by FNIH, including but not limited to instances where such disclosure is in accordance with legal and regulatory requirement; *provided, however*, that FNIH shall not use DONOR's corporate logos or trademarks without the prior written consent of DONOR.
12. **No Relation to DONOR's Business:** DONOR's funding of the Program is not in any way conditioned upon any present or future business relationship between DONOR and FNIH.
13. **Use of NFL and FNIH Marks:**
- a. For the avoidance of doubt, FNIH shall not have the right to use the NFL Marks (as defined below) for any purpose whatsoever without the prior written approval of the NFL in each instance (such consent to be granted or withheld in the NFL's sole discretion). For the purposes of this Agreement, "NFL Marks" means the names, symbols, emblems, designs, and colors of the NFL and its professional football member clubs (the "Member Clubs"), including, without limitation, the terms "National Football League", "NFL", "National Football Conference", "American Football Conference", "NFC", "AFC", "Super Bowl", "Pro Bowl", the NFL Shield design, as well as the full team names, nicknames, helmet designs, uniform designs, logos and slogans of the Member Clubs. FNIH acknowledges and agrees that NFL represents and warrants that all right, title and interest in and to the NFL Marks belongs to the NFL, its Member Clubs, NFL Ventures, Inc., NFL Ventures, L.P. or any of its direct or indirect subsidiaries, NFL Charities and the NFL Youth Football Fund (collectively, the "NFL Entities"). FNIH agrees that the NFL represents and warrants that the NFL Marks possess a special, unique and extraordinary character that makes difficult the assessment of the monetary damages that would be sustained by their unauthorized use. Notwithstanding anything to the contrary herein, FNIH recognizes that irreparable injury may be caused by

the unauthorized use of any of the NFL Marks, in which case injunctive and other equitable relief from a court of competent jurisdiction may be appropriate in the event of such unauthorized use, and that such remedy would not be exclusive of other legal remedies.

- b. For the avoidance of doubt, neither the NFL, its professional football member clubs, NFL Ventures, Inc., NFL Ventures, L.P., or any of its direct or indirect subsidiaries, NFL Charities and the NFL Youth Football Fund (collectively "NFL Entities"), nor any of their affiliates shall have the right to use FNIH Marks (as defined below) for any purpose whatsoever without the prior written approval of the FNIH in each instance (such consent to be granted or withheld in the FNIH's sole discretion). "FNIH Marks" means the name and logo of the Foundation and its programs. NFL acknowledges and agrees that the FNIH represents and warrants that all right, title and interest in and to the FNIH Marks belongs to the FNIH. NFL agrees that the FNIH represents and warrants that the FNIH Marks possess a special, unique and extraordinary character that makes difficult the assessment of the monetary damages that would be sustained by their unauthorized use. Notwithstanding anything to the contrary herein, NFL recognizes that irreparable injury may be caused by the unauthorized use of any of the FNIH Marks, in which case injunctive and other equitable relief from a court of competent jurisdiction may be appropriate in the event of such unauthorized use, and that such remedy would not be exclusive of other legal remedies.
- c. For the avoidance of doubt, nothing in this agreement authorizes NIH to use NFL or FNIH Marks, nor provides authority to FNIH or NFL to use NIH Marks. If the Parties wish to use NIH marks, they must enter into a separate license agreement with NIH.
- d. FNIH acknowledges that, as between FNIH and the NFL, NFL exclusively owns or has the right to license the NFL Marks and all copyrights, trademarks and other proprietary rights in and to the NFL Marks. FNIH further acknowledges and agrees that, as between FNIH and the NFL, during and after the term that this Agreement is in effect, the NFL shall own worldwide in perpetuity: (i) all materials provided to FNIH by the NFL in connection with this Agreement, and (ii) all derivative works ("Derivative Works") based on any of the NFL Marks or Artwork owned and/or controlled by the NFL Entities that incorporate graphic depictions of the NFL Marks and all copyrights and other proprietary rights in such Derivative Works.

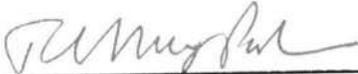
14. **Governing Law; Arbitration:** This Agreement shall be deemed made and prepared and shall be governed, construed and interpreted in accordance with the laws of the state of New York, as if the Agreement were a contract wholly entered into and wholly performed within the State of New York and without regard to principles of conflict of laws thereof which may require the application of the law of another jurisdiction. To the fullest extent allowed by law, any controversy, claim or dispute arising out of or relating to this Agreement or concerning the respective rights or obligations of the parties hereto, including the breach thereof, shall be settled and determined by binding arbitration in New York, New York before a panel of three (3) arbitrators administered by the American Arbitration Association in accordance with the Commercial Arbitration rules, including the Optional Rules for Emergency Measures of Protection. One arbitrator shall be chosen by each of the parties within ten (10) days of the submission of a dispute to the American Arbitration Association under this Agreement and the two arbitrators shall within ten (10) days of their appointment choose a neutral third arbitrator in accordance with the rules of the American Arbitration Association referenced above and then in effect, who shall act as the chairperson of the panel. In any such arbitration proceeding, the

parties agree to provide all discovery deemed necessary by the arbitrator within ninety (90) days following the appointment of all the arbitrators. Prior to the commencement of the hearings, each of the arbitrators shall provide an oath or undertaking of impartiality. The arbitrators are bound to determine any dispute in accordance with the substantive laws of the State of New York. The arbitrators are not authorized by the parties or this Agreement to and may not make an award in equity. The decision and award made by the arbitrators shall be final, binding and conclusive on all parties hereto for all purposes, and shall be a reasoned opinion in writing and rendered no later than thirty (30) days after completion of the hearing, and judgment may be entered thereon in any court having jurisdiction thereof. Either party may apply to the arbitrator seeking equitable, interim or provisional or emergency relief until the arbitration award is rendered or the dispute is otherwise resolved. The prevailing party shall be entitled to an award of reasonable attorneys' fees, expert fees and arbitration costs and expenses.

15. **Miscellaneous:** This Agreement shall supersede any previous understandings or agreement solely between the parties hereto, written or otherwise with respect to the subject matter herein. This Agreement may only be amended by a written instrument signed by both parties. This Agreement, and any subsequent amendment(s), may be executed in counterparts and the counterparts, together, shall constitute a single agreement. A facsimile transmission or an email copy of this signed Agreement bearing a signature on behalf of a party shall be legal and binding on such party.

FNIH and DONOR shall indicate acceptance of this Agreement and certification that these funds will be used in support of the indicated research by having an authorized representative of FNIH and DONOR sign the duplicate originals of this Agreement.

THE NATIONAL FOOTBALL LEAGUE

By: 
Name: Jeffrey Pash
Title: Executive Vice President
Date: September 1, 2012

FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH, INC.

By: 
Name: Charles A. Sanders, MD
Title: Chairman
Date: Sept. 4, 2012
Tax ID No: 52-1986675

EXHIBIT A

[FORM OF] RESEARCH PLAN – SCHEDULE NO. []

This **RESEARCH PLAN – SCHEDULE NO. []** (hereinafter referred to as the "Research Plan"), dated as of ____ __, 20__ describes research that will be initiated and carried out by the National Institutes of Health ("NIH") and made possible by the Foundation for the National Institutes of Health, Inc., ("FNIH") through a gift from the National Football League ("NFL").

WHEREAS, the NFL and FNIH have entered into that certain Master Letter of Agreement, dated as of ____, 2012 (as amended, supplemented or otherwise modified from time to time, the "Agreement"; capitalized terms used and not otherwise defined herein shall have the meaning set forth in the Agreement); and

WHEREAS, the Agreement contemplates that the parties will agree to certain Research Plans as part of the Program, which Research Plans shall set forth certain details and specifications necessary to accomplish research in the scientific areas provided.

NOW, THEREFORE, the NFL, FNIH and NIH hereby agree as follows:

1. **AREA OF RESEARCH:**
2. **DESCRIPTION OF WORK EXPECTED TO BE ACCOMPLISHED:**
3. **TIMELINE:**
4. **REPORTING SCHEDULE:**
5. **USE OF FUNDS:**
6. **PAYMENT TERMS:**
7. **KEY FNIH AND NIH PERSONNEL:**
8. **INCORPORATION BY REFERENCE:** The terms and conditions of this Research Plan are hereby incorporated by reference and made a part of the Agreement.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK; SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have executed this Research Plan, effective as of the date first written above.

THE NATIONAL FOOTBALL LEAGUE

By: _____
Name: _____
Title: _____
Date: _____

FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH, INC.

By: _____
Name: Charles A. Sanders, MD
Title: Chairman
Date: _____
Tax ID No: 52-1986675

THE NATIONAL INSTITUTES OF HEALTH (Appropriate Institutes or Centers)

By: _____
Name: _____
Title: _____
Date: _____

**Memorandum of Understanding
Between
The Foundation for the National Institutes of Health, Inc.
and
The National Institutes of Health Office of the Director
For
The Sports and Health Research Program**

This Memorandum of Understanding (“MOU”) is entered into by and between The Office of the Director (“OD”) at the National Institutes of Health (“NIH”), an agency of the United States Government, and the Foundation for the National Institutes of Health, Inc. (“FNIH”), a Maryland 501(c)(3) not-for-profit corporation, effective as of the date when signed by the last Party to this MOU. The OD and FNIH are referred to herein individually as a “Party” and collectively as the “Parties.”

WHEREAS, NIH is the largest funder of biomedical research in the world; committed to seeking fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability;

WHEREAS, many sports leagues and associations and others (“Donors”) are committed to safeguarding the health of current and retired players;

WHEREAS, a number of serious medical conditions that are common in the general population are especially prominent in athletes;

WHEREAS, the NIH and entities interested in research on injuries and illnesses acquired through sports and other activities can together accelerate the pace of discovery through a public-private partnership to support the most innovative and promising science in areas of mutual interest (such efforts being collectively referred to as the “Sports and Health Research Program” or the “Program”);

WHEREAS, the FNIH was established by Section 499 of the Public Health Service Act, 42 U.S.C. §290b, exclusively to support the NIH in its mission and to advance collaboration with biomedical researchers from universities, industry, and non-profit organizations and is incorporated as a 501(c)(3) non-profit corporation;

WHEREAS, FNIH desires to assist the NIH in its efforts by raising funds from Donors to accomplish the Program;

NOW, THEREFORE, the Parties agree as follows:

A. NIH Activities

MOU Reference No. 1124

Project Title – Sports and Health Research Program

1. As research areas relevant to the Program are identified, NIH will develop research concepts on topics of mutual interest to share with FNIH and Donor(s).
2. Upon mutual agreement among NIH, FNIH and the applicable Donor(s) that a particular research concept should be developed under the Program, NIH and appropriate individual NIH Institutes and Centers will develop a mutually agreed upon detailed research plan with a timeline, budget, and specific milestones to accomplish the research ("Research Plan").
3. Upon mutual agreement among NIH, FNIH and the Donor(s) on the Research Plan, NIH and the applicable NIH Institutes and Centers will manage the programmatic, logistical, and administrative aspects necessary to initiate projects funded by the Program, including holding workshops, developing and posting calls for applications, reviewing applications, determining grantees, awarding grants, overseeing the grants, including the scientific and financial progress of the grantees, and monitoring data sharing plans.
4. NIH will use the Donor(s) funding to implement the Research Plan.
5. NIH and the applicable NIH Institutes and Centers will report on scientific progress of the Research Plan to FNIH according to the reporting schedule specified in the Research Plan.
6. NIH and the applicable NIH Institutes and Centers will provide to FNIH financial reports, indicating how funds provided by FNIH have been spent to implement Research Plans initiated under the Program, according to a reporting schedule specified in the Research Plans.
7. Dissemination of results arising from research funded by Donor(s) will be governed by Federal law and policy applicable to NIH-funded research. In accordance with current NIH policy, NIH funding recipients will be urged to disseminate the results of research funded by Donor(s), in order to optimize the value of the science to the research community and the public. Specific data sharing plans may be developed for individual projects.
8. The NIH and applicable NIH Institutes and Centers are responsible for any costs they incur as a result of administering the Program or otherwise in furtherance of the Program that are not detailed in the budget set forth in the Research Plan. FNIH shall not be obligated to provide NIH with any additional funds beyond the donated funds that FNIH has raised for the Program, less FNIH overhead cost recovery and direct costs associated with carrying out its responsibilities as described in Section (B) and Section (C)(2) below.
9. Should the NIH and applicable NIH Institutes and Centers generate public print and electronic communications and promotional materials including news releases that incorporate the name of the Program ("Communications"), the NIH and applicable NIH Institutes and Centers will provide drafts of such Communications including any Communications involving references to FNIH and the Donor(s), to FNIH within a reasonable period, and in any event no later than ten (10) business days prior to their public availability or dissemination, and will endeavor in good faith to incorporate suggestions by

FNIH and the Donor(s) as appropriate. NIH will acknowledge FNIH and the Donor(s) support for the Program in all Communications. Such Communications will include the standard FNIH descriptive paragraph and other language as mutually agreed upon by the NIH, FNIH and Donor(s) (Attachment 1). Communications regarding the Program will not be released until NIH, Donor(s), and FNIH have provided prior written consent to such release (email sufficient). This paragraph 9 is applicable only to Communications incorporating the name of the Program and does not apply to grant, contract, or other communications initiated by NIH during the usual course of business.

10. The NIH and applicable NIH Institutes and Centers will provide comments and edits on Communications regarding the Program that are developed by Donor(s) and FNIH. Letters of Agreement between FNIH and Donor(s) will provide that Communications regarding the Program developed by Donor(s) will be submitted to NIH for review and approval prior to release.
11. Appropriate NIH representatives will participate as reasonably requested on or with a Stakeholder Board convened by the FNIH to facilitate discussion of the Program and Research Plans and the provision of periodic progress reports to FNIH and its Donor(s).
12. NIH contacts for the Program are:

Kathy Hudson, Ph.D.
Deputy Director for Science, Outreach, and Policy



Ken Frushour
Director, Office of Budget
National Institute of Neurological Diseases and Stroke
NIH



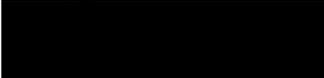
John Burklow
Associate Director, Communications & Public Liaison



B. FNIH Activities

1. FNIH will solicit, receive, manage, steward, and acknowledge private donations and sponsorships for support of the Program (the "Donations") and will hold such Donations until disbursed in accordance with Section (B)(2) below.
2. In coordination with the NIH, FNIH will use the Donations it has received under Section (B)(1) to support the Program either directly or through contributions to the NIH OD Conditional Gift Fund or Conditional Gift Funds of appropriate Institutes and Centers. The FNIH will hold payments from the Donor(s) and disburse funds according to the schedule specified in the Research Plan mutually agreed upon with NIH, FNIH and the applicable Donor(s).
3. FNIH is responsible for all interactions with Donor(s) throughout the life of the Program, including providing Donor(s) with required scientific progress and financial reports, facilitating the review of Communications described in paragraphs A(9) and A(10) above and ensuring that all Letters of Agreement with Donor(s) have language indicating that Communications generated by Donors will be submitted to FNIH and NIH for review, comment, and approval, and responding to Donor(s)' other reasonable requests for information regarding the Program. In addition, FNIH will use reasonable efforts to facilitate resolution of any Donor related issues that arise with respect to the applicable project. FNIH will convene a Stakeholder Board to provide an independent, open forum for the Program, where Donor(s) can engage scientifically with each other, and with NIH scientific leadership, patient advocacy organizations, sports organizations, and scientists to share information and updates, express viewpoints, address challenges, share expertise, and develop common perspectives on issues relating to the Program.
4. FNIH contacts for the Program are:

Stephanie James, Ph.D. (prior to Nov. 1, 2012)
Acting Executive Director



Maria Freire, Ph.D. (after Nov. 1, 2012)
President



Julie Wolf-Rodda
Director, Partnership Development



Julie Tune

Chief Financial Officer
[REDACTED]

Kimberly O'Sullivan
Communications Manager
[REDACTED]

C. General Provisions

1. It is understood and acknowledged by the Parties that NIH employees are prohibited from soliciting gifts; all such activities will be undertaken only by the FNIH, pursuant to its statutory authority.
2. FNIH will retain an overhead cost recovery for NIH-managed projects of one percent (1%) of all Donations, plus direct costs incurred for performing its services in connection with the Program and the related research activities, and all interest earned on such Donations for expenses in soliciting, collecting, administering, and accounting for the Donations and in carrying out the activities described herein.
3. Should the NIH or any Donor(s) request FNIH to perform other related tasks not currently specified in this MOU, such as FNIH direct funding of Program grants, FNIH will consult with NIH, or the applicable NIH Institutes or Centers, and with applicable Donor(s) regarding the costs associated with these tasks. If mutually agreed upon by FNIH and the applicable NIH Institutes or Centers and the applicable Donor(s), FNIH also may undertake those tasks and shall be reimbursed for its costs for such additional tasks from the funds received under Section (B)(1).
4. The Parties may revise or modify this MOU by written amendment hereto, provided such revisions and/or modifications are mutually agreed upon and that any such amendment is signed by each Party hereto.
5. Either Party may terminate this MOU upon thirty (30) days prior written notice.
6. Upon completion of the Program, or in the event this MOU is terminated before completion of the Program, FNIH will retain control of any undisbursed Donations received under Section (B)(1).
7. This MOU contains the entire agreement of the Parties with respect to the subject matter hereof and supersedes all prior and/or contemporaneous agreements or understanding, written or oral, with respect to the subject matter of this MOU.
8. This MOU shall be construed and interpreted in accordance with the laws of the State of Maryland and Federal Law. In case of a conflict, Federal Law will prevail.

MOU Reference No. 1124

Project Title – Sports and Health Research Program

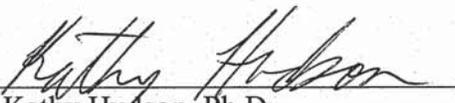
9. This MOU may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall constitute a single document.

SIGNATURES BEGIN ON NEXT PAGE

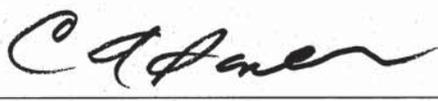
SIGNATURES

In Witness Whereof, the Parties have executed this MOU, effective on the latest date of the signatures of the Parties below.

Approved and Accepted for the National Institutes of Health

Signature:  Date: 9/04/12
Kathy Hudson, Ph.D.
Deputy Director for Science, Outreach, and Policy

Approved and Accepted for the Foundation for the National Institutes of Health, Inc.

Signature:  Date: 9/4/12
Charles A. Sanders, M.D.
Chairman

Attachment 1

Established by the United States Congress to support the mission of the NIH—improving health through scientific discovery in the search for cures—the Foundation for the NIH is a leader in identifying and addressing complex scientific and health issues. The Foundation is a non-profit, 501(c)(3) charitable organization that raises private-sector funds for a broad portfolio of unique programs that complement and enhance NIH priorities and activities. For additional information about the Foundation for the NIH see <http://www.fnih.org/>.

Made possible by the Foundation for the National Institutes of Health, Inc., through a gift from Donor(s).

CTE Neuropathology Workshop RESEARCH PLAN – SCHEDULE NO. 1

This RESEARCH PLAN – SCHEDULE NO. 1 (hereinafter referred to as the “Research Plan”), dated as of 11 30 2012 describes research that will be initiated and carried out by the National Institutes of Health (“NIH”) and made possible by the Foundation for the National Institutes of Health, Inc., (“FNIH”) through a gift from the National Football League (“NFL”).

WHEREAS, the NFL and FNIH have entered into that certain Master Letter of Agreement, dated as of September 1, 2012 (as amended, supplemented or otherwise modified from time to time, the “Agreement”; capitalized terms used and not otherwise defined herein shall have the meaning set forth in the Agreement); and

WHEREAS, the Agreement contemplates that the parties will agree to certain Research Plans as part of the Program, which Research Plans shall set forth certain details and specifications necessary to accomplish research in the scientific areas provided.

NOW, THEREFORE, the NFL, FNIH and NIH hereby agree as follows:

1. **AREA OF RESEARCH:** Chronic Traumatic Encephalopathy (CTE) Neuropathology Workshop
Chronic traumatic encephalopathy (CTE) is a progressive neurodegenerative disease that is due to repetitive trauma to the brain. The evidence that a series of extraordinary concussive insults can lead to widespread neurodegeneration (dementia pugilistica) in severely affected individuals is fairly well established. However, efforts to understand the relevant risk factors, i.e., number and severity of concussive events, as well as the earliest signs of CTE, and the spectrum of clinical signs and symptoms, have been hampered by limited understanding of the neuropathological signature of the stages of the disease and a lack of objective, diagnostic criteria for CTE in vivo. These limitations also impede estimations of the prevalence of CTE in persons with history of repetitive concussion. A more comprehensive study of post-mortem brains in persons with a history of repetitive concussion is needed to validate diagnostic criteria for the various stage of CTE and to explore the prevalence of CTE pathology in at-risk populations. Pathologic- neuroimaging correlation in post mortem brains offers the possibility of establishing imaging criteria that could be applied to clinical studies in at-risk individuals. Ideally, this will lead to the development of imaging and other biomarkers to guide clinical diagnosis and treatment trials.
2. **DESCRIPTION OF WORK EXPECTED TO BE ACCOMPLISHED:**
This research plan entails funding of a scientific planning workshop scheduled on December 5 and 6, 2012. Approximately 40-50 scientists, advocates, clinicians, and government employees with brain injury research interests will meet over two days to discuss and identify scientific opportunities to advance understanding of CTE neuropathology and strategize about the how to maximize impact of a funding initiative on this topic. The goals of this workshop are to:
 - gather input on the key research questions
 - brainstorm possible scientific approaches to answer the key questions
 - identify resources, including brain banks and at-risk populations, necessary to attain the research goals.

In particular, participants will be asked to discuss:

- What are the earliest neuropathological features of CTE and what are the neuropathological stages of the disorder?
- What are the criteria for making a post-mortem diagnosis of CTE and how specific are they for the various stages of the disorder?
- What is the optimal means to validate a set of pathologic criteria for the stages of CTE?
- What can we learn about the causal biologic processes that give rise to onset and spread of CTE pathology by examination of brains of persons with history of repetitive head injury?
- How do we provide access to qualified investigators to the brain bank and overcome concerns about patient privacy and data sharing?
- What brain/biospecimen banks and other resources are available for CTE neuropathology studies?
- How do we overcome issues related to obtaining valuable post mortem brains for CTE research, i.e., obtaining informed consent in emotionally charged situations, engaging pathologists, dieners and ongoing brain banking efforts
- What neuroimaging tools and biomarkers show promise for diagnosing CTE in affected individuals? How can these be used to correlate post-mortem pathology?
- What are the best means of engaging at-risk groups in the TBI research effort?
- How do we get the necessary history and clinical information to make it possible to correlate neuropathology and symptoms?

These discussions will guide how future research plans are developed to fund CTE Neuropathology research.

3. **TIMELINE:**

Workshop planning will occur from the date of this agreement through early December. The workshop will be held in Bethesda, MD on December 5 and 6, 2012. The workshop output will guide next steps for funding of CTE – Neuropathology projects. As such, a Research Plan for a CTE – Neuropathology Funding Strategy will be provided on or before December 31, 2012 for review by the SHRP Stakeholder Board. The exact Funding Opportunity Announcement (FOA) will be developed and released after approval of a CTE Neuropathology Research Framework.

4. **REPORTING SCHEDULE:**

The outcomes of the workshop will be compiled and made public on the NINDS website within a month.

5. **USE OF FUNDS:**

A budget of no more than \$35,000, outlined below, is anticipated to cover meeting and attendee travel expenses for the workshop. Of that amount, any remaining funds will be retained at NINDS for related projects or expenses and/or funding grants awarded through a resulting FOA.

Budget:

Travel, lodging, ground transportation M&E for 20 @ \$1500	\$30,000
Other potential meeting expenses	5,000
FNIH direct costs (15 hrs staff time @ \$135/hr)	<u>2,025</u>
TOTAL	\$37,025

6. **PAYMENT TERMS:**

From funds already received by FNIH from the NFL, a lump sum of \$35,000 to be transferred from FNIH to NINDS within two weeks of this agreement.

7. **KEY FNIH AND NIH PERSONNEL:**

FNIH – Andrea Baruchin, Director NIH Relations; Julie Wolf-Rodda, Director of Partnership Development

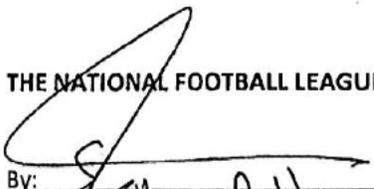
NIH/NINDS – Walter Koroshetz, Deputy Director; Ramona Hicks, Program Manager; Rebecca Frederick, AAAS Science Policy Fellow

8. **INCORPORATION BY REFERENCE:** The terms and conditions of this Research Plan are hereby incorporated by reference and made a part of the Agreement.

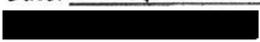
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IN WITNESS WHEREOF, the parties have executed this Research Plan, effective as of the date first written above.

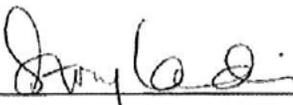
THE NATIONAL FOOTBALL LEAGUE

By: 
Name: Stephen Pellman M.D.
Title: Medical Director
Date: 11/7/2012

FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH, INC.

By: 
Name: Charles A. Sanders, MD
Title: Chairman
Date: 11-30-2012


THE NATIONAL INSTITUTES OF HEALTH (NINDS)

By: 
Name: Stony Landis
Title: Director, NINDS
Date: 11/8/12

**Collaborative Research on Chronic Traumatic Encephalopathy and Delayed
Effects of Traumatic Brain Injury: Neuropathology and Neuroimaging
Correlation**

RESEARCH PLAN – SCHEDULE NO. 2

This RESEARCH PLAN – SCHEDULE NO. 2 (hereinafter referred to as the "Research Plan"), dated as of March 13 2013, describes research that will be initiated and carried out by the National Institutes of Health ("NIH") and made possible by the Foundation for the National Institutes of Health, Inc., ("FNIH") through a gift from the National Football League ("NFL").

WHEREAS, the NFL and FNIH have entered into that certain Master Letter of Agreement, dated as of September 1, 2012 (as amended, supplemented or otherwise modified from time to time, the "Agreement"; capitalized terms used and not otherwise defined herein shall have the meaning set forth in the Agreement); and

WHEREAS, the Agreement contemplates that the parties will agree to certain Research Plans as part of the Program, which Research Plans shall set forth certain details and specifications necessary to accomplish research in the scientific areas provided.

NOW, THEREFORE, the NFL, FNIH and NIH hereby agree as follows:

1. **AREA OF RESEARCH:** This initiative will provide a competitive opportunity for a multicenter team to: 1) more fully characterize the neuropathology associated with chronic traumatic encephalopathy (CTE) and delayed effects of traumatic brain injury (TBI) through systematic, rigorous, and collaborative studies of post-mortem biospecimens; 2) validate the neuropathological criteria for a post-mortem diagnosis of CTE and delayed post-traumatic neurodegenerative diseases through independent and blinded analyses; 3) provide a better understanding of the incidence and prevalence of CTE, and 4) identify neuroimaging signatures of the neuropathology as a foundation for the development of diagnostic tools in the future. Specific research areas of interest include:
 - a. Similarities and differences between the neuropathology of CTE and the delayed effects of TBI.
 - b. Validation studies for the post-mortem diagnosis of CTE and the delayed effects of TBI.
 - c. Identification of a neuroimaging signature on post-mortem brain specimens that correlates with the histological data.
 - d. Development of a brain donor program that leverages the resources available through the NIH Neurobiobank to enable studies aimed at a better understanding of the incidence and prevalence of CTE; correlating clinical signs, symptoms, and risk factors for CTE with neuropathology.
 - e. Hypothesis-driven projects to elucidate the biologic basis of CTE and the delayed effects of TBI.

2. **DESCRIPTION OF WORK EXPECTED TO BE ACCOMPLISHED:** This research plan entails funding one of the grant applications received by NIH in response to a Request for Applications (RFA) for research on chronic traumatic encephalopathy and delayed effects of traumatic brain injury emphasizing the correlation between neuropathology and neuroimaging. The U01 Cooperative Agreement is the recommended funding mechanism for this effort because it allows for

significant NIH Program staff involvement, which will be required to monitor the progress, benchmarks and timelines established for this multicenter initiative. This initiative will support a multicenter, systematic and comprehensive investigation of the neuropathology of CTE and the delayed effects of TBI using post-mortem biospecimens, and histological and neuroimaging tools as a foundation for future studies to develop *in vivo* diagnostics. The principal criteria for success of the initiative will be the following:

- a. Collaborative research on post-mortem brain tissue to clarify and expand our understanding of the neuropathology associated with CTE and the delayed effects of TBI.
- b. Establishment of a brain-donor program to link high quality behavioral information with neuropathology.
- c. Coordinated neuroimaging and neuropathology research on post-mortem brain tissue as a foundation for developing diagnostic tools on live subjects.

3. **TIMELINE:** It is expected that an RFA will be issued in March 2013 with a grant application due date of June 1, 2013 and review in late summer of 2013 for a NINDS Council funding decision in October 2013. Research support will be for 4 years.

4. **REPORTING SCHEDULE:** The FNIH will provide annual financial and scientific progress report to the NFL on this initiative.

5. **USE OF FUNDS:** The anticipated cost of this initiative is as follows.

Oct-13	2,500,000	for research grant(s)
Oct-14	2,500,000	for research grant(s)
Oct-15	2,500,000	for research grant(s)
Oct-16	2,500,000	for research grant(s)

FNIH direct costs: 106,452 (includes travel 4 FNIH staff to NYC 1/year, 1 SB meeting in DC & events staff costs/year, travel for 2 Principal Investigators to 1 SB meeting in DC/year, FNIH staff time)

Subtotal:	10,106,452
FNIH admin @1%	<u>101,065</u>
TOTAL	<u>10,207,517</u>

6. **PAYMENT TERMS:**

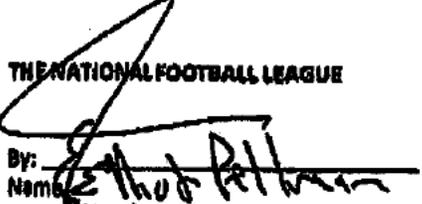
- Payment 0 - \$2,551,880 from funds already transferred to FNIH
- Payment 1 - \$2,551,879 due to FNIH by June 1, 2014 (for year 2)
- Payment 2 - \$2,551,879 due to FNIH by June 1, 2015 (for year 3)
- Payment 3 - \$2,551,879 due to FNIH by June 1, 2016 (for year 4)

7. **KEY FNIH AND NIH PERSONNEL:**

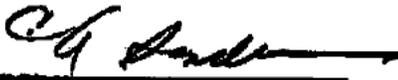
- a. FNIH – Andrea Baruchin, Director NIH Relations; Julie Wolf-Rodda, Director of Partnership Development, Stephanie James, Director of Science
- b. NIH/NINDS – Walter Koroshetz, Deputy Director; Ramona Hicks, Program Manager; Rebecca Frederick, AAAS Science Policy Fellow

IN WITNESS WHEREOF, the parties have executed this Research Plan, effective as of the date first written above.

THE NATIONAL FOOTBALL LEAGUE

By: 
Name: Tom Kelly
Title: MD
Date: 2/19/2013

FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH, INC.

By: 
Name: Charles A. Sanders, MD
Title: Chairman
Date: 3-12-2013

THE NATIONAL INSTITUTES OF HEALTH (NINDS)

By: 
Name: Director NINDS
Title: Director NINDS
Date: 2/22/2013

**Pilot Projects on Sports-Related Brain and Spinal Cord Injury Research (R03,
R21)
RESEARCH PLAN – SCHEDULE NO. 3**

This **RESEARCH PLAN – SCHEDULE NO. 3** (hereinafter referred to as the "Research Plan"), dated as of March 17 2013, describes research that will be initiated and carried out by the National Institutes of Health ("NIH") and made possible by the Foundation for the National Institutes of Health, Inc., ("FNIH") through a gift from the National Football League ("NFL").

WHEREAS, the NFL and FNIH have entered into that certain Master Letter of Agreement, dated as of September 1, 2012 (as amended, supplemented or otherwise modified from time to time, the "Agreement"; capitalized terms used and not otherwise defined herein shall have the meaning set forth in the Agreement); and

WHEREAS, the Agreement contemplates that the parties will agree to certain Research Plans as part of the Program, which Research Plans shall set forth certain details and specifications necessary to accomplish research in the scientific areas provided.

NOW, THEREFORE, the NFL, FNIH and NIH hereby agree as follows:

1. **AREA OF RESEARCH:** This initiative will fund pilot projects for sports-related traumatic brain injury (TBI) and spinal cord injury (SCI) research. The scope will comprise a wide range of research topics, including mechanical and biological mechanisms of injury and recovery, development of diagnostics and biomarkers, and interventions for minimizing injury and improving outcomes. This initiative will support both preclinical and clinical studies to collect high quality preliminary data on sports-related TBI and SCI on such topics as:
 - a. the mechanical and biological mechanisms of injury and recovery
 - b. genetic and environmental risk factors
 - c. development of diagnostics and biomarkers
 - d. assessment of short- and long-term behavioral deficits
 - e. development of tools and equipment for prevention
 - f. characterization and validation of animal models
 - g. interventions for minimizing injury and improving outcomes

Outcomes indicating progress toward the goal of this initiative include:

- a. Development of models, tools, diagnostics, therapies to attenuate injury and/or promote recovery that will be useful in subsequent research
- b. Peer-reviewed publications on mechanisms of sports-related neurotrauma injury and recovery, diagnostic tools, incidence, prevalence, risk factors, etc.
- c. Success rate of pilot studies at obtaining future R01 or other funding mechanism grants
- d. Foundational data for more consistent, evidence-based guidelines for concussion and SCI diagnosis, treatment, return to play and recovery.

Discussion is underway with other NIH Institutes and Centers regarding potential expansion of research topics for support under this initiative.

2. **DESCRIPTION OF WORK EXPECTED TO BE ACCOMPLISHED:** This research plan entails funding of grant applications received by NIH in response to a Request for Applications (RFA) for research on TBI and SCI. For this initiative, R03 (Small Research Grants with total direct costs up to \$100,000 and time period no longer than 2 years) and R21 (developmental/exploratory grants with total direct costs up to \$275,000 and time no more than 2 years) are appropriate mechanisms. The grant applications will be reviewed through the regular NIH review process administered by the NIH Center for Scientific Review (<http://public.csr.nih.gov/Pages/default.aspx>) as there are no unusual requirements for the review and a broad range of scientific expertise may be required.
3. **TIMELINE:** It is expected that a Request for Applications (RFA) will be issued in March 2013 with a grant application due date of June 1, 2013 and review in late summer of 2013 for a NINDS Council funding decision in October 2013. Research support for each grant will be for 2 years. One receipt date for applications will enable side-by-side comparison of the applications. Meritorious applications that are unfunded can be resubmitted to the NIH parent R03 or R21 mechanism that covers a broader range of research, or can be paid by relevant NIH Institutes and Centers depending upon the focus of the research and the availability of funds. It is anticipated that the RFA may be renewed, with revisions as needed, for an additional funding cycle upon agreement by NFL, NIH and FNIH. A separate Research Plan will be submitted to the NFL for the RFA renewal.
4. **REPORTING SCHEDULE:** The FNIH will provide annual financial and scientific progress report to the NFL on this initiative.
5. **USE OF FUNDS:** The anticipated cost of this initiative is as follows.
- | | |
|--------------------|-----------------------------------|
| October 2013 | 1,000,000 for research grant(s) |
| October 2014 | 1,000,000 for research grant(s) |
| FNIH direct costs: | 17,114 (includes FNIH staff time) |
| Subtotal | 2,017,114 |
| FNIH admin @1% | 20,171 |
| TOTAL | 2,037,285 |
6. **PAYMENT TERMS:**
 Payment 0: \$1,018,643 from funds already transferred to FNIH
 Payment 2: \$1,018,642 due to FNIH by June 1, 2014 (for year 2)
7. **KEY FNIH AND NIH PERSONNEL:**
- FNIH – Andrea Baruchin, Director NIH Relations; Julie Wolf-Rodda, Director of Partnership Development, Stephanie James, Director of Science
 - NIH/NINDS – Walter Koroshetz, Deputy Director; Ramona Hicks, Program Manager; Rebecca Frederick, AAAS Science Policy Fellow
8. **INCORPORATION BY REFERENCE:** The terms and conditions of this Research Plan are hereby incorporated by reference and made a part of the Agreement.

IN WITNESS WHEREOF, the parties have executed this Research Plan, effective as of the date first written above.

THE NATIONAL FOOTBALL LEAGUE

By: [Signature]
Name: [Signature]
Title: [Signature]
Date: 2/18/2013

FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH, INC.

By: [Signature]
Name: Charles A. Sanders, MD
Title: Chairman
Date: 3-12-2013
[Redacted]

THE NATIONAL INSTITUTES OF HEALTH (NINDS)

By: [Signature]
Name: Director, NINDS
Title: [Signature]
Date: 2/22/13

RESEARCH PLAN – SCHEDULE NO. [4]

This **RESEARCH PLAN – SCHEDULE NO. [4]** (hereinafter referred to as the "Research Plan"), dated as of June 7 2013, describes research that will be initiated and carried out under the Sports and Health Research Program and made possible by the Foundation for the National Institutes of Health, Inc., ("FNIH") through a gift from the National Football League ("NFL").

WHEREAS, the NFL and FNIH have entered into that certain Master Letter of Agreement, dated as of September 1, 2012 (as amended, supplemented or otherwise modified from time to time, the "Agreement"; capitalized terms used and not otherwise defined herein shall have the meaning set forth in the Agreement); and

WHEREAS, the Agreement contemplates that the parties will agree to certain Research Plans as part of the Program, which Research Plans shall set forth certain details and specifications necessary to accomplish research in the scientific areas provided.

NOW, THEREFORE, the NFL, FNIH and NIH hereby agree as follows:

1. **AREA OF RESEARCH:** Workshop on 'Brain-trauma-related neurodegeneration: strategies to define, detect and predict'
Chronic traumatic encephalopathy (CTE) is a progressive neurodegenerative disease that has been observed to occur in athletes with lengthy exposure to subconcussive impacts to the brain. However, the causative link between brain trauma and CTE, as well as the prevalence of CTE and other long-term effects of neurotrauma within the broader population, remain unknown. A more comprehensive, prospective observational study could help to understand the links between brain trauma exposure and other risk factors and functional, cognitive and psychological outcomes.
2. **DESCRIPTION OF WORK EXPECTED TO BE ACCOMPLISHED:**
This research plan entails funding of a scientific planning workshop scheduled for July 22 and 23, 2013. Approximately 70 epidemiologists, sports medicine doctors, pediatric neurologists, neuropsychologists and other scientific experts will meet over one and a half days to discuss and identify scientific opportunities to advance understanding of traumatic brain injury (TBI)-related neurodegeneration. The goals of this workshop are to:
 - gather input on the key research questions
 - brainstorm possible scientific approaches to answer the key questions
 - identify tools and resources necessary to attain the research goals

In particular, participants will be asked to discuss:

 - What is known about the natural history of TBI-related neurodegeneration?
 - What is the capability for diagnosing earlier stages of TBI-related neurodegeneration and TBI-related dementia?
 - How does this neurodegeneration progress over time and are there risk factors that can lead to prediction of cognitive decline?
 - What has been learned from past observational studies that can be applied to the design of a longitudinal study on TBI-related neurodegeneration?
 - What are the tools and resources required to answer the research question?

- What would an ideal study entail?

The deliverable from the workshop will be a summary report of discussions, including considerations for design of a prospective observational study, which will guide future decisions about support for a new funding opportunity.

3. **TIMELINE:**

Planning and preparation will be ongoing through the date of the workshop, which will be held in Bethesda, MD on July 22 and 23, 2013. Any future funding opportunity arising from these discussions will be the subject of a separate SHRP Research Plan.

4. **REPORTING SCHEDULE:**

The outcomes of the workshop will be compiled and made public on the NINDS website within 45 days.

5. **USE OF FUNDS:**

A budget of no more than \$67,500 is proposed to cover meeting and attendee travel expenses for the workshop.

Budget:

Travel, lodging, ground transportation M&E for 32 @ \$1250	\$40,000
Other potential meeting expenses	\$14,100
FNIH direct costs (76 hrs. staff time @ \$135/hr. and 45.5 hrs. staff time @ \$51.30/hr.)	\$12,595
TOTAL	\$67,423

6. **PAYMENT TERMS:**

FNIH will support the workshop from funds already received from the NFL. FNIH requests to apply previously approved funds remaining from Research Plan #1 (\$15,615.79) toward the expected expenses for this workshop. These funds will offset the budget for Research Plan #4, so that \$51,807.21 in new funds are anticipated to be required.

7. **KEY FNIH AND NIH PERSONNEL:**

FNIH – Stephanie James, Director of Science Division; Julie Wolf-Rodda, Director of Development

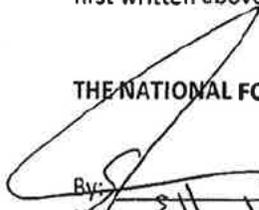
NIH/NINDS – Walter Koroshetz, Deputy Director; Ramona Hicks, Program Manager; Rebecca Frederick, AAAS Science Policy Fellow

8. **INCORPORATION BY REFERENCE:** The terms and conditions of this Research Plan are hereby incorporated by reference and made a part of the Agreement.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK; SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have executed this Research Plan, effective as of the date first written above.

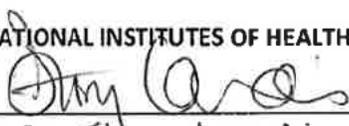
THE NATIONAL FOOTBALL LEAGUE

By: 
Name: Ed O'Connell
Title: VP of Football
Date: 6/7/13

FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH, INC.

By: 
Name: Charles A. Sanders, MD
Title: Chairman
Date: 6-10-2013


THE NATIONAL INSTITUTES OF HEALTH (NINDS)

By: 
Name: D. Story Landis
Title: Director, NINDS
Date: 6/13/2013

RESEARCH PLAN – SCHEDULE NO. 5

This **RESEARCH PLAN – SCHEDULE NO. 5** (hereinafter referred to as the “Research Plan”), dated as of July 14, 2014, describes research that will be initiated and carried out by the National Institutes of Health (“NIH”) and made possible by the Foundation for the National Institutes of Health, Inc., (“FNIH”) through a gift from the National Football League (“NFL”).

WHEREAS, the NFL and FNIH have entered into that certain Master Letter of Agreement, dated as of September 1, 2012 (as amended, supplemented or otherwise modified from time to time, the “Agreement”; capitalized terms used and not otherwise defined herein shall have the meaning set forth in the Agreement); and

WHEREAS, the Agreement contemplates that the Parties will agree to certain Research Plans as part of the Program, which Research Plans shall set forth certain details and specifications necessary to accomplish research in the scientific areas provided.

NOW, THEREFORE, the NFL, FNIH and NIH hereby agree as follows:

1. AREA OF RESEARCH: Longitudinal Study to Detect Early Stages and Progression of Chronic Traumatic Encephalopathy, Workshop to Plan a Longitudinal Study on Youth and Sports Health, Semiannual Stakeholders Meetings

The long-term neurological consequences of sports and other activities that expose players to repetitive impacts to the head are currently a major public health concern with a limited scientific knowledge base. While first identified in boxers and referred to as “dementia pugilistica,” this condition has also been observed in non-boxers exposed to varying degrees of repetitive neurotrauma and is now referred to as chronic traumatic encephalopathy (CTE). However, the clinical manifestations of these progressive neurodegenerative changes are not well-characterized, and diagnostic tools and criteria are lacking. A multidisciplinary approach to detect, define and clinically characterize the progression of CTE is needed to support development of effective treatments.

2. DESCRIPTION OF WORK EXPECTED TO BE ACCOMPLISHED:

NIH longitudinal study in high-risk adults: This research plan will provide funding for a grant application received by NIH in response to a Request For Application (RFA) to support a longitudinal study to collect, validate and analyze biomarker data [e.g., MRI and PET images, genetics, cognitive tests, cerebral spinal fluid (CSF) and blood biomarkers] to characterize CTE in individuals with a history of repetitive head impacts. A fuller understanding of the neurodegeneration of CTE and diagnostic methods to detect and monitor it at the earliest stages possible, when intervention may be most effective, will provide a foundation for the prevention and treatment of CTE in the future.

Although a large, natural history longitudinal study of young athletes over many years would be a powerful approach to identify the population incidence and prevalence of neurological deficits caused by brain trauma, it would require several decades to complete the study. Given the urgency of the problem, an alternative approach is to focus on high risk individuals with symptoms and medical history suggestive of CTE. In such individuals it may be possible to detect progression over the 3-5 year time span of this study. Therefore, this initiative aims to support a 7-year longitudinal,

hypothesis-driven study to detect, define and monitor the progression of CTE in high-risk middle-aged adults, along with appropriate control studies.

The research objectives are:

- 1) To characterize the clinical syndrome of CTE and its progression over a 3-5 year period in affected individuals with varying severities of illness.
- 2) To track the progression of CTE using neuroimaging and other biomarkers over a 3-5 year period.
- 3) To develop consensus criteria for the diagnosis, staging and ways to measure the progression of CTE to inform future therapeutic trials.

The study team should include the expertise necessary to recruit and follow a relevant study cohort containing individuals with varying severity of neurologic dysfunction likely due to CTE and an appropriate control group. In addition, the multidisciplinary team should be able to collect and analyze high quality data such as MRI and PET, genetics, cognitive tests, CSF and blood biomarkers to detect and define CTE. The study must include relevant TBI Common Data Elements and comply with the data sharing policies of the Federal Inter-Agency Traumatic Brain Injury Research (FITBIR) Informatics System.

Research areas of interest include but are not limited to:

- Advanced imaging studies, including high field MRI scans, tau-radioligand and/or metabolic PET studies aimed at defining the regional distribution and other characteristic features of CTE in high-risk, symptomatic individuals with “possible” or “probable” CTE.
- A qualitative and quantitative assessment of the progression of the neurodegeneration in symptomatic, individuals considered to be at high risk for CTE over a 3-5 year period
- Development and/or validation of clinical tools to make a “possible” and “probable” diagnosis of CTE and to develop sensitive and specific biomarkers to track the progression over time that may inform future therapeutic trials.
- Clinical studies to advance knowledge about the pathophysiological mechanisms of CTE and its progression.
- Identification of risk factors for CTE.
- Investigation of the temporal correspondence between the neurodegenerative changes and the clinical signs and symptoms of CTE.

Coordination and planning workshop: As aforementioned, the extension of such a study to young athletes would lead to better understanding of the prevalence of brain trauma-related neurological deficits. This plan will also provide funding for a scientific workshop to coordinate among all related major studies, and identify needs and opportunities to extend research in the field of traumatic-brain injury (TBI) and its long-term effects across the age span. The one-day workshop, to be scheduled no earlier than October 2014 (timing to be agreed upon by NFL, NIH and FNIH), is expected to include up to 40 scientific experts, of whom 30 will require travel support.

The deliverable from the workshop will be a summary report of discussions, and recommendations for additional research.

Semiannual stakeholders meetings: Representatives from NFL, National Collegiate Athletic Association (NCAA), Department of Defense (DoD) and NIH agree that it would be useful to hold semiannual meetings to discuss programs of mutual interest, review results and undertake joint planning, and have tasked FNIH with organizing these meetings. This plan includes funding for one meeting to be held annually in New York and one in the Washington, DC, area. Meetings in the DC area will include provision for NIH grantees under SHRP, or other invited guests, to attend and present their work.

3. TIMELINE:

The workshop is tentatively scheduled for the Fall of 2014 (October 2014) in Bethesda, MD. Planning and preparation will be ongoing through the date of the workshop.

It is expected that the RFA will be issued in the third quarter of 2014 (July-September), with grant applications due to NIH by December 31, 2014. It is anticipated that NIH will review the applications in the first quarter of 2015 (January-March), and be submitted to the NINDS Council for funding decision in May 2015. The research support for the accepted application will be seven years, June 1, 2015-May 31, 2022.

4. REPORTING SCHEDULE:

FNIH will provide annual financial and scientific progress reports to the NFL on the NIH longitudinal study as part of its overall annual reporting on the Sports and Health Research Program.

The outcomes of the workshop will be compiled and made public on the NINDS website approximately 45 days after the workshop.

5. USE OF FUNDS:

The anticipated cost of this research plan is \$17,574,136. Of this, NFL is requested to provide a total of \$16,325,242. FNIH intends to provide \$1,248,894 out of funds remaining from previous payments.

The breakdown for the budget is:

NIH Longitudinal Study: \$16,590,000, with NIH grant payments according to the following schedule (all funds to be used for research grants):

June 2015:	\$2,370,000
June 2016:	\$2,370,000
June 2017:	\$2,370,000
June 2018:	\$2,370,000
June 2019:	\$2,370,000
June 2020:	\$2,370,000
June 2021:	\$2,370,000

Coordination and Planning Workshop: \$48,070

Travel, lodging, ground transportation and incidentals for 30 participants @ \$1,200	\$36,000
Other meeting logistic expenses	\$12,070

FNIH Direct Costs: \$772,814 FNIH staff time and stakeholders meetings
(includes travel for 3 FNIH staff to NYC 1/year, 1 stakeholders meeting in DC/year, venue costs and travel for principal investigators to DC stakeholders meeting, FNIH staff time, through 2022)

Subtotal – Direct Costs **\$17,410,884**

FNIH Operating Cost Recovery **\$163,252**
(1% of \$16,325,242 requested)

Total Costs **\$17,574,136**

6. PAYMENT TERMS: The following payment schedule (for payments from the NFL) will enable the grants and activities outlined in section 5, above.

Payment 1 – \$1,442,520 due to FNIH on or before April 1, 2015

Payment 2 – \$2,480,454 due to FNIH on or before April 1, 2016

Payment 3 – \$2,480,454 due to FNIH on or before April 1, 2017

Payment 4 – \$2,480,454 due to FNIH on or before April 1, 2018

Payment 5 – \$2,480,454 due to FNIH on or before April 1, 2019

Payment 6 – \$2,480,454 due to FNIH on or before April 1, 2020

Payment 7 – \$2,480,452 due to FNIH on or before April 1, 2021

7. KEY FNIH AND NIH PERSONNEL:

a. FNIH

Stephanie James, Director of Science Administration

Julie Wolf-Rodda, Director of Development

Emily Acland, Meredith Donnelly, and Renée Bullion, Development Officers

Erika Tarver, Senior Project Administrator

Jolie Mak, Events Manager

Jasmin Miles, Senior Events Coordinator

b. NIH/NINDS

Walter Koroshetz, Deputy Director

Ramona Hicks, Program Manager

8. INCORPORATION BY REFERENCE: The terms and conditions of this Research Plan are hereby incorporated by reference and made a part of the Agreement.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK; SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have executed this Research Plan, effective as of the date first written above.

THE NATIONAL FOOTBALL LEAGUE

By: [Signature]
Name: Jeffrey Pearl
Title: Exec VP
Date: July 17 2014

APPROVED [Signature]
NFL Legal & Business Affairs

FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH, INC.

Approved by Finance

7/18/14

By: [Signature]
Name: MARIA C. FLORES
Title: PRESIDENT
Date: 7-21-14

[Signature]

THE NATIONAL INSTITUTES OF HEALTH/NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

By: [Signature]
Name: Director, NINDS
Title: Director, NINDS
Date: 7/24/14

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health ([NIH \(http://www.nih.gov\)](http://www.nih.gov))

Components of Participating Organizations

National Institute of Neurological Disorders and Stroke ([NINDS \(http://www.ninds.nih.gov\)](http://www.ninds.nih.gov))

Funding Opportunity Title

Detect, Define and Measure the Progression of Chronic Traumatic Encephalopathy (U01)

Activity Code

[U01 \(http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&Search.x=0&Search.y=0&Search_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project – Cooperative Agreements

Announcement Type

New

Related Notices

[NOT-NS-14-031 \(http://grants.nih.gov/grants/guide/notice-files/NOT-NS-14-031.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-NS-14-031.html)

Funding Opportunity Announcement (FOA) Number

RFA-NS-14-012

Companion Funding Opportunity

None

Number of Applications

See [Section III. 3. Additional Information on Eligibility](#).

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.853

Funding Opportunity Purpose

The purpose of this initiative is to detect, characterize and measure the progression of neurodegeneration in individuals with a probable or possible diagnosis of chronic traumatic encephalopathy (CTE) using brain imaging and other biomarkers. The overall goals are increased knowledge concerning the neurological mechanisms and ways to detect CTE as it evolves over a 3 - 5 year period and the development of a consensus diagnosis to inform clinical trials aimed at preventing or slowing disease progression in the future.

Key Dates

Posted Date

July 29, 2014

Open Date (Earliest Submission Date)

September 30, 2014

Letter of Intent Due Date(s)

September 30, 2014

Application Due Date(s)

October 31, 2014, by 5:00 PM local time of applicant organization. All [types of non-AIDS applications](#) allowed for this funding opportunity announcement are due on this date.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

February 2015

Advisory Council Review

May 2015

Earliest Start Date

June 2015

Expiration Date

November 1, 2014

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the [SF424 \(R&R\) Application Guide \(http://grants.nih.gov/grants/guide/redirect.htm?id=12000\)](http://grants.nih.gov/grants/guide/redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts \(http://grants.nih.gov/grants/guide/\)](http://grants.nih.gov/grants/guide/)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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[Part 1. Overview Information](#)

[Part 2. Full Text of the Announcement](#)

[Section I. Funding Opportunity Description](#)

[Section II. Award Information](#)

[Section III. Eligibility Information](#)

[Section IV. Application and Submission Information](#)

[Section V. Application Review Information](#)

[Section VI. Award Administration Information](#)

[Section VII. Agency Contacts](#)

[Section VIII. Other Information](#)

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Research Objectives

The long-term neurological consequences of sports and other activities that expose individuals to repetitive impacts to the head are currently a major public health concern with a limited scientific knowledge base. While first identified in boxers and referred to as “dementia pugilistica”, this condition has also been observed in non-boxers exposed to varying degrees of repetitive neurotrauma and is now referred to as chronic traumatic encephalopathy (CTE). The clinical manifestations of these progressive neurodegenerative changes are not well-characterized, and diagnostic tools and criteria to identify these changes are lacking. A multidisciplinary, multicenter study to detect and clinically characterize the progression of CTE and to develop a consensus diagnosis in living individuals is needed before effective treatments can be developed.

Although a large, natural history longitudinal study of young athletes over many years would be a powerful approach to identify the population incidence and prevalence of neurological deficits caused by brain trauma, it would require several decades to complete the study. Given the urgency of the problem, an alternative approach is to focus on a cohort where early changes in the brain are most likely to be detectable. Previous studies suggest that these changes may be detectable in individuals who are approximately 10 - 15 years past their peak playing years and have symptoms and a medical history suggestive of CTE. Furthermore, previous studies suggest that in such individuals it may be possible to detect progression of the neurodegeneration in 3 - 5 years. Therefore, this initiative aims to support a

multicenter and multidisciplinary longitudinal study of individuals with a "probable" or "possible" diagnosis of chronic traumatic encephalopathy (CTE) using brain imaging and other biomarkers, along with appropriate control groups. Individuals with symptoms that are "probably due to CTE" or "possibly due to CTE" will be the focus of this FOA because currently a definitive diagnosis of CTE requires postmortem assessment of neuropathology. (Note that this FOA builds upon a previous initiative entitled "Collaborative Research on Chronic Traumatic Encephalopathy and Delayed Effects of Traumatic Brain Injury: Neuropathology and Neuroimaging Correlation (U01)" ([RFA-NS-13-013 \(http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-13-013.html\)](http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-13-013.html))), where the purpose is to study post-mortem brains as a foundation for future in vivo studies.)

A successful study is expected to obtain and use longitudinal data, such as MRI and PET imaging, cognitive and behavioral assessments, and CSF or blood for genomic and proteomic analysis, to increase knowledge concerning the neurological mechanisms of CTE as it evolves over a 3 - 5 year period and enable the development of a consensus, evidence-based clinical diagnosis. If successful, this study will also provide a foundation for clinical trials aimed at preventing or slowing disease progression in the future.

The research objectives are:

- 1) to collect and analyze high quality data such as MRI and PET, genetics, cognitive tests, CSF and blood biomarkers to detect and characterize the neurodegenerative changes and progression of CTE over a 3 - 5 year period; and
- 2) to develop consensus criteria for the clinical diagnosis and staging of CTE.

The study team should include the expertise necessary to recruit and follow a relevant study cohort that would include individuals with a "probable" and "possible" diagnosis of CTE and appropriate controls. In addition, the multidisciplinary team should be able to collect and analyze high quality data such as MRI and PET, genetics, cognitive tests, CSF and blood biomarkers to detect and define CTE. The study must include relevant TBI Common Data Elements and comply with the data sharing policies of the FITBIR Informatics System. If new data elements are needed for CTE, the investigators are expected to work with the NINDS Common Data Elements (CDE) Project to develop them (see <http://www.nindscommondataelements.org/> (<http://www.nindscommondataelements.org/>)).

Specific Areas of Research Interest

Areas of interest include but are not limited to:

- Advanced imaging studies, including high field MRI scans, tau-radioligand and/or other PET studies aimed at defining the regional distribution and other characteristic features of CTE in high-risk, symptomatic individuals with "possible" or "probable" CTE.
- A qualitative and quantitative assessment of the progression of the neurodegeneration over a 3 - 5 year period in symptomatic individuals considered to be at high risk for CTE.
- Evaluation of the utility of various neuroimaging approaches and other surrogate markers for establishing a clinical diagnosis of CTE and tracking its progression over a 3 - 5 year period.
- Hypotheses-driven studies to advance knowledge about the underlying pathophysiological mechanisms of CTE and its progression.
- Investigation of the temporal correspondence between the neurodegenerative changes and the clinical signs and symptoms of CTE
- Clinical studies that include data that could lead to the identification of risk factors for CTE.

Section II. Award Information

Funding Instrument

Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed

New

The [OER Glossary \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types.

Funds Available and Anticipated Number of Awards

NIH intends to commit an estimated total of \$2.3 million in 2015 to support 1 award. Future year amounts are expected to be the same.

Award Budget

Application budgets are not limited, but need to reflect the actual needs of the proposed project.

Award Project Period

The scope of the proposed project should determine the project period. The maximum period is 7 years.

NIH grants policies as described in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as [defined in the NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The [NIH Policy on Late Submission of Grant Applications \(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- [Dun and Bradstreet Universal Numbering System \(DUNS\) \(http://fedgov.dnb.com/webform\)](http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\) \(https://www.sam.gov/portal/public/SAM/\)](https://www.sam.gov/portal/public/SAM/) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
 - [NATO Commercial and Government Entity \(NCAGE\) Code \(https://eportal.nspa.nato.int/AC135Public/Docs/US%20Instructions%20for%20NSPA%20NCAGE.pdf\)](https://eportal.nspa.nato.int/AC135Public/Docs/US%20Instructions%20for%20NSPA%20NCAGE.pdf) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons \(https://public.era.nih.gov/elf/jsp/commons/login.jsp?TYPE=33554433&REALMOID=06-1edb031f-46c7-44b3-b803-60b537de74d2&GUID=&SMAUTHREASON=0&METHOD=GET&SMAGENTNAME=-SM-938PYmoLVb4VrDeXo04LZUDVDvc%2b3899ByInEAjuSUvWNIGfB2zRpWiCivYGCogG&TARGET=-SM-http%3a%2f%2fpublic%2eera%2enih%2egov%2fcommons\)](https://public.era.nih.gov/elf/jsp/commons/login.jsp?TYPE=33554433&REALMOID=06-1edb031f-46c7-44b3-b803-60b537de74d2&GUID=&SMAUTHREASON=0&METHOD=GET&SMAGENTNAME=-SM-938PYmoLVb4VrDeXo04LZUDVDvc%2b3899ByInEAjuSUvWNIGfB2zRpWiCivYGCogG&TARGET=-SM-http%3a%2f%2fpublic%2eera%2enih%2egov%2fcommons) - Applicants must have an active DUNS

number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.

- [Grants.gov \(http://www.grants.gov/applicants/organization_registration.jsp\)](http://www.grants.gov/applicants/organization_registration.jsp) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/Pis, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126). (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see [NOT-OD-11-101 \(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

In addition, the NIH will not accept a resubmission (A1) application that is submitted later than 37 months after submission of the new (A0) application that it follows. The NIH will accept submission:

- To an RFA of an application that was submitted previously as an investigator-initiated application but not paid;
- Of an investigator-initiated application that was originally submitted to an RFA but not paid; or
- Of an application with a changed grant activity code.

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity using the “Apply for Grant Electronically” button in this FOA or following the directions provided at [Grants.gov \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11127\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11127).

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the [SF424 \(R&R\) Application Guide \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), including [Supplemental Grant Application Instructions \(https://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf\)](https://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit [Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=41137\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=41137).

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in [Part 1. Overview Information](#), prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Patrick Frost Bellgowan, Ph.D.
National Institutes of Neurological Disorders and Stroke ([NINDS \(http://www.ninds.nih.gov\)](http://www.ninds.nih.gov))
6001 Executive Blvd., Rm. 2205
Bethesda, MD 20852
Telephone: 301-496-1447
Email: [patrick.frostbellgowan@nih.gov \(mailto:patrick.frostbellgowan@nih.gov\)](mailto:patrick.frostbellgowan@nih.gov)

Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11133\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R or Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Research Strategy: A milestone plan that includes a timeline for the enrollment of subjects must be included in the application.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications are expected to include a Data Sharing Plan that adheres to the FITBIR Informatics System data policy <https://fitbir.nih.gov/tbi-portal/> (<https://fitbir.nih.gov/tbi-portal/>) and uses the appropriate TBI Common Data Elements http://www.commondataelements.ninds.nih.gov/tbi.aspx#tab=Data_Standards (http://www.commondataelements.ninds.nih.gov/tbi.aspx#tab=Data_Standards), consistent with achieving the goals of the program.
- Applications proposing to collect biological or genetic samples must agree to conform to the NINDS Repository Biomarkers Discovery Samples Resource https://fitbir.nih.gov/assets/NINDS_Repository_Biomarkers_Discovery_Samples_Resource_Manual.pdf (https://fitbir.nih.gov/assets/NINDS_Repository_Biomarkers_Discovery_Samples_Resource_Manual.pdf)

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

3. Submission Dates and Times

[Part I. Overview Information](#) contains information about Key Dates. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications to [Grants.gov](http://grants.nih.gov/grants/guide/url_redirect.htm?) (http://grants.nih.gov/grants/guide/url_redirect.htm?

[id=11128](#)) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date. If a Changed/Corrected application is submitted after the deadline, the application will be considered late.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review](#). (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11143).

6. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. [Section III. Eligibility Information](#) contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit [Applying Electronically](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11144).

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See [Section III](#) of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See [more tips](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review and responsiveness by [components of participating organizations](#), NIH. Applications that are incomplete and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [NOT-OD-13-](#)

[030 \(http://grants.nih.gov/grants/guide/notice-files/NOT-13-030.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-13-030.html).

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the [NIH mission \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11149\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11149), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Is this study likely to result in an evidence-based consensus clinical diagnosis for CTE?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Are the investigators from multidisciplinary backgrounds needed to accomplish the research?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed? Does the study design and data collection process include plans for collaboration with the NINDS Common Data Elements (CDE) project to develop CDEs for CTE?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and

will particularly risky aspects be managed? Does the study have a testable hypothesis or research question? Is the study designed to provide data needed to develop a consensus diagnosis for CTE? Does the study include a plan for the integration of multicenter and multidisciplinary investigations of the neurodegeneration of CTE? Does the study population include symptomatic individuals with a probable or possible diagnosis of CTE? Does the study include appropriate controls?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Does the research plan leverage valuable resources such as demonstrated access to a relevant study cohort, advanced neuroimaging tools and ligands, and/or biomarker or other core facilities? Are multiple centers included in the study to accelerate the research and enhance the diversity of subjects?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Guidelines for the Review of Human Subjects \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11175\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11174\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains,

ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

FITBIR Data Sharing Compatibility

Is the data sharing plan compatible with the FITBIR Data Sharing Policy?

Applications from Foreign Organizations

Not Applicable

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) [Data Sharing Plan](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11151) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); 2) [Sharing Model Organisms](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11152) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and 3) [Genome Wide Association Studies \(GWAS\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11153) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and

reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the National Institute of Neurological Disorders and Stroke, in accordance with [NIH peer review policy and procedures \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated [review criteria](#). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

[Appeals \(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Neurological Disorders and Stroke (NANDS) Council. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Compliance with resource sharing policies as appropriate.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123).

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11156\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in [Section IV.5. Funding Restrictions](#). Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the [Award Conditions and Information for NIH Grants \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11159\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at [Award Conditions and Information for NIH Grants \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- Determining experimental approaches, designing protocols, setting project milestones and conducting experiments;
- Reporting to NIH Program staff regarding timeline and milestone achievement during the course of the project, as delineated in the terms and conditions of award;
- Submit annual progress reports during the funding period, in a format as agreed upon by NIH Program staff;

Awardees are expected to make new information and materials known to the research community in a timely manner through publications, web announcements, reports to NIH Program staff, and other mechanisms.

Publications

The PD(s)/PI(s) will be responsible for the timely submission of all abstracts, manuscripts and reviews (co)authored by project investigators and supported in whole or in part under this Cooperative Agreement. The PD(s)/PI(s) and Project Leaders are requested to submit manuscripts to the NIH Project Scientist within two weeks of acceptance for publication so that an up-to-date summary of program accomplishments can be maintained. Publications and oral presentations of work conducted under this Cooperative Agreement are the responsibility of the PD(s)/PI(s) and appropriate Project Leaders and will require appropriate acknowledgement of the FNIH Sports Health Research Program and NIH Institutes support. Timely publication of major findings is required.

NIH staff have substantial programmatic involvement that is above and beyond the normal

stewardship role in awards, as described below:

NIH Program staff will have substantial scientific/programmatic involvement during the conduct of this activity through technical assistance, advice and coordination. However, the role of NIH Project Scientists will be to facilitate and not to direct the activities. The NIH Project Scientist will:

- Contribute to the adjustment of research protocols, project milestones or approaches as warranted;
- Serve as a liaison between the awardees, the NIH Institute's Advisory Councils and the larger scientific community;
- Coordinate the efforts of the awardee with others engaged in TBI research, including other awardees under this FOA and those involved in related NIH programs;
- Serve on subcommittees of the FNIH Sports Health Research Program as appropriate;
- Assist in promoting the availability of data and resources developed in the course of this project to the scientific community at large;
- Assist awardees in the development, if needed, of policies for dealing with situations that require coordinated action;
- Retain the option to recommend the withholding or reduction of support from any cooperative agreement that either substantially fails to achieve its goals according to the milestones agreed to at the time of award, fails to maintain state-of-the-art capabilities, or fails to comply with the Terms and Conditions of the award.

Additionally, an agency program official or IC program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

Areas of Joint Responsibility include:

None; all responsibilities are divided between awardees and NIH staff as described above.

Dispute Resolution:

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened. It will have three members: a designee of the Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special dispute resolution procedure does not alter the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

3. Reporting

When multiple years are involved, awardees will be required to submit the annual Non-Competing Progress Report ([PHS 2590 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11160\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11160) or [RPPR \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11168\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11168)) and financial statements as required in the [NIH Grants Policy Statement. \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161)

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at [www.fsrs.gov \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11170\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over \$25,000. See the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161)

(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Commons Help Desk (Questions regarding eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Finding Help Online: <http://grants.nih.gov/support/index.html> (<http://grants.nih.gov/support/index.html>)

Email: commons@od.nih.gov (<mailto:commons@od.nih.gov>)

[Grants.gov Customer Support](http://www.grants.gov/contactus/contactus.jsp) (<http://www.grants.gov/contactus/contactus.jsp>) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)

Contact Center Telephone: 800-518-4726

Web ticketing system: <https://grants-portal.psc.gov/ContactUs.aspx> (<https://grants-portal.psc.gov/ContactUs.aspx>)

Email: support@grants.gov (<mailto:support@grants.gov>)

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)

Telephone: 301-435-0714

Email: GrantsInfo@nih.gov (<mailto:GrantsInfo@nih.gov>)

Scientific/Research Contact(s)

Patrick Frost Bellgowan, Ph.D.

National Institute of Neurological Disorders and Stroke ([NINDS](http://www.ninds.nih.gov) (<http://www.ninds.nih.gov>))

Telephone: 301-496-1447

Email: patrick.frostbellgowan@nih.gov (<mailto:patrick.frostbellgowan@nih.gov>)

Peer Review Contact(s)

Chief, Scientific Review Branch

National Institute of Neurological Disorders and Stroke (NINDS)

Telephone: 301-496-9223

Email: nindsreview.nih.gov@mail.nih.gov (<mailto:nindsreview.nih.gov@mail.nih.gov>)

Financial/Grants Management Contact(s)

Tijuanna DeCoster, Ph.D.

National Institute of Neurological Disorders and Stroke (NINDS)

Telephone: 301-496-9231

Email: decostert@mail.nih.gov (<mailto:decostert@mail.nih.gov>)

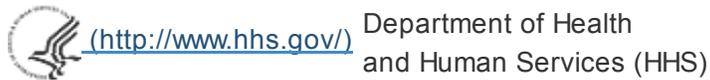
Section VIII. Other Information

Recently issued trans-NIH [policy notices](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92.

[Weekly TOC for this Announcement \(/grants/guide/WeeklyIndex.cfm?08-01-14\)](/grants/guide/WeeklyIndex.cfm?08-01-14)
[NIH Funding Opportunities and Notices \(/grants/guide/index.html\)](/grants/guide/index.html)



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Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see [Help Downloading Files \(/grants/edocs.htm\)](/grants/edocs.htm).

February 12, 2016

Dear Mr. Miller,

We are writing to apprise you, as partners in the Sports and Health Research program, of NIH's plans moving forward with concussion research. Scientifically, the next logical step is to extend this research into youth populations (pre-college ages). NINDS has formed a working group that consists of some of its Advisory Council members and appropriate representatives from other Institutes and Centers, and this group will be tasked with planning and conducting a workshop on this topic. The goal of this workshop will be to assess the state of the science in youth concussions and identify specific research gaps that will inform the development of a scientific research plan for NIH. This plan will serve as the basis for an RFA to support youth concussion research. If the NFL is interested in this research plan once it is developed, then we would welcome the organization as partners in this important endeavor.

The public workshop on youth concussions will occur in 2016, and any related RFAs would likely be issued in 2017. The workshop will be open to all interested participants, and that will be an appropriate venue to discuss any pertinent scientific issues. NIH prefers to use this public forum for scientific discourse, and NFL and its advisors will be welcome to attend this meeting.

Moving forward, we would request that if NFL or its advisors would like to discuss research collaborations with NIH employees, such discussions should include FNIH and the NIH Office of the Director.

Best,

Dr. Kathy Hudson



Walter Koroshetz



CC: Hunt Batjer
Mitch Berger
Rich Ellenbogen
Maria Freire
Russ Lonser
Betsy Nabel



NATIONAL FOOTBALL LEAGUE

March 11, 2016

Dr. Kathy Hudson
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dr. Maria Freire
Foundation for the National Institutes of Health
9650 Rockville Pike
Bethesda, MD 20814

Dr. Walter Koroshetz
National Institute of Neurological Disorders and Stroke
Room 8A52, Building 31, 31 Center Drive
Bethesda, Md, 20892

Dear Drs. Hudson, Freire and Koroshetz,

I am in receipt of your letter dated February 12, 2016, regarding NIH's plans for concussion research, including a public workshop to examine the state of the science on youth concussions. On behalf of the NFL, thank you for the update and the workshop invitation. I am confident that members of the NFL's Head, Neck and Spine Committee will be interested in attending.

From the formation of the Sports and Health Research Program ("SHRP"), the NFL and the NIH have expressed a shared interest in two primary areas of scientific inquiry: 1. Improved understanding of the neuropathology around Chronic Traumatic Encephelopathy ("CTE"); and 2. A prospective longitudinal study to examine the long-term implications of closed head brain injury. These goals were set in October 2012 at a meeting where leaders from the NIH, FNIH and NFL participated.

The NIH addressed the first focus area in December 2013, when it funded eight projects with approximately \$12 million of the NFL's contribution. While much of this research is still in the early stages, these efforts hold the promise of advancing the science around CTE.

The second of these goals, a prospective longitudinal study on the long-term effects of concussion, was the subject of a SHRP-funded and NIH-led public workshop in Bethesda, Maryland in July 2013. At that meeting, national experts, including senior representatives of the NIH, FNIH, as well as members of the NFL's Head, Neck and Spine Committee, reached consensus on the need to fund a prospective longitudinal study with the remainder of the NFL's contribution to the SHRP.

As the NIH pursues its plans for concussion research, we hope you will consider the conclusions reached at the most recent workshop on the importance of a longitudinal study.

We are appreciative of and remain committed to our ongoing relationship with the NIH. We look forward to hearing from you at your convenience and to continuing our work to advance the science on this important public health issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeff Miller".

Jeff Miller
Executive Vice President
National Football League

CC: Dr. Hunt Batjer
Dr. Mitch Berger
Dr. Rich Ellenbogen
Dr. Russ Lonser
Dr. Betsy Nabel



DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Institute of Neurological
Disorders and Stroke

Office of the Director
Building 31, Room 8A52
31 Center Drive MSC 2540
Bethesda, Maryland 20892-2540
Office: (301) 496-3167
Fax: (301) 496-0296
Email: koroshetzw@ninds.nih.gov

April 28, 2016

Jeff Miller
National Football League
345 Park Avenue
New York, New York 10154

Dear Mr. Miller,

Thank you for your letter dated March 11, 2016. I am pleased to learn that NFL Head, Neck, and Spine committee members are interested in attending our planned workshop on the science of youth concussions.

With respect research funded through the Sports and Health Research Program (SHRP) on CTE neuropathology, two team projects focused on neuropathology of CTE were awarded. The projects were *CTE and Post-traumatic Neurodegeneration: Neuropathology and Ex Vivo Imaging* (Principle Investigator Dr. Ann McKee) and *Neuropathology of CTE and Delayed Effects of TBI: Toward in Vivo Diagnostics* (Principle Investigator Dr. Wayne Gordon). In addition to these two projects, SHRP also funded 6 pilot projects focused on improving the diagnosis of concussion and identifying potential biomarkers.

We were puzzled by your comments asking us to consider funding a longitudinal study. Informed by the July 2013 SHRP-funded public workshop on Brain Trauma-Related Neurodegeneration¹ that included national experts from the NIH and the NFL's Head, Neck and Spine Committee, the NIH drafted a proposal for a prospective longitudinal study of "high risk individuals with symptoms and medical history suggestive of CTE." NFL, FNIH and NIH agreed to pursue this longitudinal study in July, 2014 in the attached Research Plan for a "longitudinal study in high risk adults."

As you also know, in December 2015, NINDS did award a grant to a consortium led by Boston University in response to the attached Funding Opportunity Announcement *Detect, Define and Measure the Progression of Chronic Traumatic Encephalopathy*² for a "multicenter and multidisciplinary longitudinal study of individuals with a "probable" or "possible" diagnosis of chronic traumatic encephalopathy (CTE)." The award of this longitudinal study was a direct result of the July 2013 workshop. We eagerly await the results and do not have plans to support an additional longitudinal study for CTE at this time.

Thus, we look forward to your participation in the upcoming youth concussion workshop and working with you on this critical public health issue.

Regards,

Kathy Hudson, Ph.D.
Deputy Director, Science Outreach and Policy, NIH

Walter J. Koroshetz, M.D.
Director, NINDS

CC: Hunt Batjer Rich Ellenbogen Russ Lonser
Mitch Berger Maria Freire Betsy Nabel

¹ http://www.ninds.nih.gov/news_and_events/proceedings/TBI-related_neurodegeneration_workshop_report.htm

² <http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-14-012.html>