

Introduction

On January 29, 2016, University of Maryland (UMD) Vice President and Chief Research Officer Patrick O'Shea formed an ad hoc committee and charged it to review the processes surrounding the conduct and administration of a 2-phase project entitled "Muscle Recovery with Fifth Quarter Fresh" funded through the Maryland Industrial Partnerships (MIPS) program. MIPS, part of the Maryland Technology Enterprise Institute (Mtech) in the A. James Clark School of Engineering, promotes the development and commercialization of products and processes through industry/university research partnerships normally initiated by the companies to meet their own research and development goals. Faculty partners may come from any University System of Maryland (USM) Institution, and funding to support the research comes from both the partner company and the State of Maryland.

The Principal Investigator (PI) for the project is Dr. Jae Shim, Associate Professor, Department of Kinesiology, School of Public Health and head of the Neuromechanics Laboratory, and the industrial partner is Fluid Motion LLC. Fluid Motion's product is called Fifth Quarter Fresh. The review was initiated because Dr. O'Shea had concerns, which were also expressed by several media reports, about the appropriateness of promoting a study that had only preliminary results without the benefit of peer review and endorsing a specific commercial product, and about the possibility of conflict of interest. The committee was asked to review the processes surrounding the conduct and administration of the project and the dissemination of the results, as well as provide recommendations for institutional actions.

The committee reviewed the applications for funding and institutional review board (IRB) approval, the MIPS contracts (Phase 1 and 2, respectively), technical reviews obtained by MIPS prior to funding the project, reports from Dr. Shim to MIPS and Fluid Motion on the project results, press releases, emails, timelines prepared by MIPS, institutional documents on monetary contributions to the laboratory of the PI, applicable institutional policies on Protection of Human Subjects, Conflict of Interest, and Scholarly Misconduct, the USM Policy on the Professional Commitment of Faculty as it relates to potential endorsements, and Guidelines on the use of the University Marks. We interviewed Dr. Peter Sandborn, director of Mtech (parent organization of MIPS), Mr. Joseph Naft, director of MIPS, Dr. James Hagberg, Chair of the IRB, Mr. Joseph Smith, Director of the IRB, Dr. Jane Clark, Dean of the School of Public Health, Dr. Bradley Hatfield, Chair of the Department of Kinesiology, and the PI, Dr. Jae Shim.

Our report contains a detailed sequence of events beginning with the development of the proposal and ending with the release of the study results to the press. We describe our findings and have provided a set of recommendations for institutional action.

Sequence of Events

On May 1, 2013, a formal proposal from Fluid Motion LLC and Dr. Shim was submitted to the MIPS program for funding. It is referred to as proposal 5204. This project came about after Maryland Department of Business and Economic Development (DBED) introduced Fluid Motion to MIPS. An introduction from DBED to MIPS is common, especially for companies in the more rural areas of Maryland. After discussion with Fluid Motion, it was determined that the company did not need product development or process improvement, but rather testing of its product for efficacy. Positive results from the study would enable Fluid Motion to expand its market. Dr. Shim was contacted by MIPS because he had worked on a previous MIPS project involving product testing. Together, Dr. Shim and Fluid Motion developed a written proposal.

The proposal was evaluated by standard MIPS processes that involved outside reviews for technical and commercial merit. Two of the technical reviewers were suggested by Dr. Shim and Fluid Motion; the rest were identified by the Technical Coordinator at MIPS, Martha Connolly, who handled the evaluation of the proposal. According to MIPS, all technical reviewers held the rank of tenured/tenure-track professors or equivalent. Six technical reviews and five economic reviews were requested. Prior to the meeting of the MIPS Evaluation Board on June 20, 2013, four technical and five economic reviews had been received. Two technical reviews were received after the Board had met and were therefore not considered.

The written instructions to reviewers specifically stated that the reviewer was not to evaluate the appropriateness of the project for the university because the dean of the School of Public Health and chair of the Department of Kinesiology had already made that determination.

On June 3, 2013, a summary of the technical reviews was prepared by Martha Connolly, the MIPS Technical Coordinator for this project. All reviewers were from outside the state. The technical reviews were averaged, resulting in an overall assigned score of very good minus. (The two late technical reviews rated the project as good and very good minus.) Several issues on experiment design were raised in the initial technical reviews. At least one reviewer noted that Dr. Shim had no experience in nutritional/supplementation research as proposed and the proposal was missing major design elements that indicate the research staff understands how nutritional studies work in human subjects. The PI reported that MIPS did not share the reviewer comments with him, and MIPS told our committee that no other faculty member was consulted.

The proposal indicated that it was a 2-year project to investigate the effects of post-exercise recovery drink products (dietary supplements) on post-exercise recovery. The study for Year 1 was intended “to test the efficacy of a natural, fat-free chocolate milk recovery drink,” Fifth Quarter Fresh (FQF), at the behavioral level, and Year 2 would look at the mechanical levels. In year one, FQF was to be compared with other commercially available exercise recovery products and water. The proposal also stated that FQF has “advantages over chocolate milk such as 50% more protein, 30% more calcium and essential electrolytes,” and a lower temperature process for pasteurization so the “protein is undamaged and completely available for the body to use.” It also stated that “our product contains more calcium per serving than any of our competitors.” MIPS did not undertake nor request verification of these claims. The proposal also stated that no additional research was required to commercialize the product. The PI declared that there was no

conflict of interest. The PI received salary and benefits for 25% effort for Year 1 and Hyun Kwon, assistant research professor in the Department of Kinesiology, received salary and benefits for 37% effort for Year 1. Effort by the company totaling \$133,000 in salary for 6 employees of Fluid Motion and \$43,535 in purchased items were dedicated by the company to the project. The Total Budget for the university was indicated to be \$100,000 for Phase 1 and \$100,000 for Phase 2. In each year, the company was to provide \$10,000 toward the university costs, in conformity with the standard requirements imposed by MIPS that small startup companies provide 10% of the costs.

The MIPS Evaluation Board selected the proposal for funding on June 20, 2013. The Phase 1 contract was signed on July 11, 2013, by Richard Doak on behalf of the company, on August 1, 2013, by E. Crierie on behalf of Research Administration, on August 5, 2013, by Joseph Naft on behalf of MIPS, and on August 8, 2013, by the PI Dr. Shim.

On August 13, 2013, Dr. Shim submitted an application to the IRB for a Full Review of Phase 1. At that time, the subjects were identified as 40 normal adult healthy males who were students or UMD employees, who were not taking dietary supplements, and who did not have food allergies. All subjects would provide written informed consent. The only research procedure identified on the application was questionnaires/surveys with no biomedical procedures indicated. The application to the IRB differed from the MIPS application in the number of participants and the specifications of the commercially available products to be tested: Fifth Quarter Fresh (FQF), Shamrock Rockin Refuel (SRR), a fat free protein chocolate milk beverage which is pasteurized at ultra-high temperatures, Muscle Milk, a liquid protein supplement, and water.

MIPS Project Phase 1 as submitted and eventually approved by the IRB was designed to measure muscle recovery after vigorous exercise in order to: 1) compare a protein supplement drink, Muscle Milk, to milk protein generally, and 2) compare chocolate milks. Phase 2 was not detailed, but in general, Dr. Shim proposed to use the same products, but look at electrical activity in the muscles, muscle length, fat mass, etc. There was no mention of using high school or college student athletes as research subjects.

On October 17, 2013, questions to the PI from Andrea Dragan of the IRB office were sent and the PI addressed all issues raised.

On November 12, 2013, the Phase 1 project was approved by the IRB under expedited review. The Chair of the IRB, the Director of the IRB, and IRB staff made the decision for an expedited review, even though a Full Board Review had been requested by the PI. The justifications for the expedited review were Categories 4 and 7. A Category 4 exemption applied because the procedures employed by the Neuromechanics Lab were considered noninvasive. Category 7 exemption applies when the “research is on individual or group characteristics or behavior (including, but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey interview, oral history, focus groups, program evaluation human factors evaluation or quality assurance methodologies.” In this case, Category 7 applied to that portion of the protocol specifying data collection by questionnaire.

On April 30, 2014, the Allied Milk Foundation issued a check in the amount of \$20,000 to the University of Maryland College Park Foundation (UMCPF) to support the Neuromechanics Laboratory headed by Dr. Shim. Dr. Shim was informed of the donation by the Allied Milk Foundation in a letter dated April 28, 2014. UMCPF records of the contribution are dated June 6, 2014.

May 1, 2014, Dr. Shim and Fluid Motion submitted an application to MIPS for Phase 2. The focus of the second year of the study was now stated to be “injury healing and prevention, specifically regarding the effects on post-exercise recovery and cumulative minor brain damage.” The company hoped the work “will focus on a unique approach to the prevention of concussions” and “put FQF in the national spotlight.”

On May 1, 2014, Dr. Shim sent an email to Dr. Bradley Hatfield, Chair of Kinesiology, telling him that through multiple donations, Allied Milk will fund those parts of the research proposal that were not funded by MIPS.

On June 19, 2014, the MIPS Evaluation Board met and discussed the Phase 2 proposal. As is customary for continuing projects, Phase 2 was not sent out for review. The project was considered “continuing” because it was proposed by the same professor and company, and the objective of the study, evaluation of the efficacy of FQF, had not changed. There is no indication that concerns were raised in the discussion of the project and Phase 2 was approved for funding. The PI received salary and benefits for 24% effort for one year of Phase 2 and Ross Miller, assistant professor in the Department of Kinesiology, received salary and benefits for 7% effort. Effort by the company totaling \$155,000 in salary for 6 employees of Fluid Motion and \$63,600 in purchased items (primarily materials and supplies) were dedicated by the company to the project. The Total Budget for the university component of the project was \$100,000 for Year 2. The company was to provide \$10,000 toward the university costs, in conformity with the standard requirements of MIPS that small startup companies provide 10% of the costs.

On July 29, 2014, Dr. Shim submitted an IRB application for review of a new protocol titled “Effects of a chocolate milk product on mild traumatic brain injury in youth and collegiate athletes.” The goal of the Phase 2 study was to determine if consumption of a commercially available fat-free high protein chocolate milk is associated with the improvement of the negative consequences of cognition and movement control from mild traumatic brain injury (MTBI) in high school and college student athletes. Three populations proposed as subjects were 1) Washington County High School Football Teams, 2) University of Maryland College Park Women’s Soccer Team, and 3) other non-athlete college women. The UMD Department of Intercollegiate Athletics would administer ImpACT tests on three occasions, Sway Balance, and Biodex Clinical test of sensory integration of balance to members of the UMD Women’s Soccer team, and provide the de-identified data to the PI. Only two ImpACT tests are normally collected by Intercollegiate Athletics. These same tests on non-athletes, as well as several other protocols for all UMD participants, were to be collected by Dr. Shim. The data from Washington County students were collected by the County and were to be de-identified before providing them to the PI. The PI would not have any contact with the high school students. The IRB protocol did not mention that over and above their normal program, an additional ImpACT test was to be administered by Washington County to the high school football players because of the study, as

stated in the MIPS proposal. Dr. Shim also noted on this application that he had no conflict of interest.

On July 29, 2014, the IRB approved Phase 2 under Expedited Review. The Chair of the IRB, the Director of the IRB, and the staff of the IRB determined that the application for IRB approval should be considered under the Expedited Review process based on Categories 4 and 7. These are the same categories for expedited review under which Phase 1 was considered. Category 4 applied to all measurement made in the Neuromechanics Lab because the tests were considered to be noninvasive. Category 7 applied to the protocol specifying data collection from the Washington County high school football players because it was considered to be “research on cognition, and/or research on group characteristics of behavior.” The protocol specifying data collection from the UMD Women’s Soccer Team by the Department of Intercollegiate Athletics qualified because it was “human factors evaluation” and “research on cognition,” and the protocol specifying data collection from non-athletes was considered to be “research on cognition.”

On September 8, 2014, a MIPS contract for Phase 2, project 5204.24, was fully executed. It was signed on that date by Joseph Naft for MIPS, on September 5, 2014, by J. Rattler for Office of Research Administration, on August 14, 2014, by Dr. Shim, and on July 16, 2014, by Fluid Motion.

On October 13, 2014, the Allied Milk Foundation issued a second check in the amount of \$50,000 to the UMCPF to support Dr. Shim’s Neuromechanics Laboratory. Dr. Shim was informed of the donation by a letter from the Allied Milk Foundation on November 5, 2014. UMCPF records of the contribution are dated October 31, 2014.

In October 2014, Dr. Shim submitted a Continuing Review/Progress report for Phase 1 was to the IRB. On the application, Dr. Shim indicated that he had no conflict of interest. The number of approved subjects was changed from 40 to 23 (reflecting the number of subjects that had chosen to sign consent forms), but in other respects, the project remained the same. The IRB approved the continuing project on November 10, 2014.

By May 20, 2015, preparation for Press Release 1 was well underway.

On May 22, 2015, Dr. Shim’s PowerPoint of Phase 1 results were presented to MIPS and Fluid Motion as part of the nine month review. The PowerPoint included the statement that FQF contained improved and increased protein and higher levels of calcium, magnesium, potassium, and sodium. Four products were tested and FQF came out on top for muscular torque endurance after fatiguing, but the products tested did not affect muscular strength differently. He concluded that FQF may facilitate the recovery of muscular endurance. Following the presentation of the PowerPoint, draft press releases were developed and circulated to the PI and among MIPS staff.

June 18, 2015. The Allied Milk Foundation issued a third check in the amount of \$130,000 to the UMCPF for unrestricted research support of Dr. Shim’s Neuromechanics Laboratory; UMCPF records of the contribution are dated July, 15, 2015.

July 15, 2015. Press Release 1 was issued by MIPS. Before the Press Release was issued, MIPS had shared drafts and a request for comments with MIPS staff, Fluid Motion, Dr. Shim, the communications staff of the School of Public Health, the communications staff of the A. James Clark School of Engineering, and the UMD Central Communications Office. Several revisions of drafts were prepared based on feedback from individuals in all of these units. Before Press Release 1 was issued, through phone conversations and emails, MIPS believed all issues were addressed. Dr. Shim approved the press release.

July 21, 2015. Baltimore Sun ran a story based on Press Release 1.

August 7, 2015. IRB approved the Continuing Review/Progress Report for Phase 2.

August 10, 2015. ABC Channel 2 aired a piece about FQF and UMD, including an interview with Dr. Shim.

August 23, 2015. Dr. Shim sent PowerPoint 2 of Phase 2 results to Fluid Motion.

On October 27, 2015, IRB issued approval of a Continuing Review/Progress Report for Phase 1. This approval enabled Phase 1 to continue for a third year. The reason for the request for a continuation expressed by the PI was the need for more subjects for statistical significance. Dr. Shim explained to our committee that these additional subjects were needed for that portion of the study proposed in the MIPS project but not funded by the MIPS grant. These studies were to be paid for by the gifts to the UMCPF from the Allied Milk Foundation. On his IRB application, Dr. Shim indicated that he had no conflict of interest.

December 8, 2015. A new website for FQF, designed by MIPS, went live. Providing startup companies with help in developing websites is common for MIPS. It carried product information and Press Release 1, and after Press Release 2 was issued, it, too, was posted on the website. (On February 4, 2016, at the request of MIPS, the press releases were taken down.)

December 22, 2015. Press Release 2 was issued by MIPS. Prior to its release, several versions of the document were produced and reviewed by Dr. Shim, Fluid Motion, the communications office of the School of Public Health, the communications office of the A. James Clark School of Engineering, and the University's Central Communications Office. Dr. Shim approved the release. Comments were received and incorporated prior to release. Several of the staff brought up the point that the release was based on preliminary results, not on a peer-reviewed publication, but after discussion it was decided that stating these were "preliminary results" was sufficient justification for a release since it had been approved by the PI.

Findings

1. Dr. Shim approved the press releases in which he directly endorses Fifth Quarter Fresh. In the first press release, he stated: "Our data suggest that athletes may be ready faster and better for the next game or practice if they drink Fifth Quarter Fresh chocolate milk." In the second press release he stated: "Athletes who drank the milk [FQF], compared to those who

did not, scored higher after the season than before it started, specifically in the areas of verbal and visual memory.” The communications offices of MIPS, the A. James Clark School of Engineering, the School of Public Health, and University Central Communications relied on his approval for release.

2. Product endorsement attributed to Dr. Shim in two press releases is troubling, but the endorsement does not violate any written university policy. It may violate the Guidelines for Use of University Marks, which addresses the use of the name of the University of Maryland by outside entities because the company posted these press releases on its website. However, the company was not informed about these restrictions. The USM Policy on Professional Commitment of Faculty (II-3.10) specifies: “A faculty member shall not convey endorsement by the institution or the University System of the recommendations or results from his or her consulting or professional services.” The applicability of both of these to a faculty member working on a university-sponsored project is unclear. However, it is surprising that a tenured faculty member would think that product endorsement is appropriate.
3. Fluid Motion was not looking for product or process improvement or product development. They wanted the University of Maryland to validate the efficacy of their product to help their business be successful. The company was likely unaware that the use of the university’s name could be problematic as it was not discussed with the company by MIPS when they entered into the contract, although the contract states that the company would need permission. The MIPS applications states: “Having research underway at the University of Maryland gives our business and its product credibility.” Designing a project that tested brand named competitors against its product and the use of UMD students likely reinforced this expectation especially since the brands that were tested were those recommended by the company.
4. There is no institutional protocol for approval of press releases and lines of authority are poorly defined. In this case, press releases were widely circulated prior to release, but final authority for release was believed to rest with MIPS, although MIPS wanted, felt obligated to request, and believed they had received college and university approval. Approval by the Dr. Shim was, however, the most important factor in finalizing the releases.
5. Neither the Chair of the Department of Kinesiology nor the Dean of the School of Public Health was aware of either press release before they were issued. They did not see the publicity around Press Release 1 and were unaware of the TV appearance by Dr. Shim. It was not until the negative press stories following Press Release 2 that they became aware of the details of the project.
6. The press releases did not directly state that the project was initiated by and received company funding. The releases did state that the projects were funded through MIPS and that this program “jointly funds commercial product development projects” clearly implying company funding, but at least one media report did not understand this statement.
7. There were no deviations from normal practices in the way MIPS handled the Phase 1 and Phase 2 proposals. The fact that the Phase 2 proposal was a significant departure from the

Phase 2 envisioned when the Phase 1 proposal was reviewed did not trigger a new technical review because the PI, company partner, and the product being studied were the same.

8. In the Phase 1 technical review, serious questions were raised by one reviewer who wrote that “the PI does not have any experience in nutritional/supplementation research”, the project is “missing numerous elements that would make this effective in concluding anything that would be useful to the company or to the state of the literature,” and the proposal is “missing major design elements that indicate the research staff understands how nutritional studies work in human subjects.” A second technical review, which was submitted too late for the Phase 1 decision, stated that he/she could not “assess the proposal’s claims regarding the potential benefits of FQF since references are not provided and some claims are without merit,” the PI “does not have extensive experience with nutritional interventions,” and “consultation with researchers in Nutrition/Food Science fields may be advantageous.” Other issues were also raised by reviewers, including lack of control on overall diet of participants. There were also positive comments received. The PI reports that MIPS did not share these reviews or the concerns of the reviewers with the PI, and when funding for Phase 2 was approved, MIPS did not revisit the reviews. The committee is surprised that MIPS did not seek additional opinions when some of the Phase 1 reviews raised such serious concerns about the scientific merit and that MIPS did not revisit the reviews when Phase 2 was proposed. This is especially problematical since two reviewers had raised serious concerns, and Phase 2 involved more than 500 high school students and 50 student athletes, populations that were not mentioned in the Phase 1 application.
9. Because Dr. Shim did not see any of the reviews and was unaware that any concerns had been raised during the MIPS review process, he did not revise his procedures or experimental design.
10. The proposed project was unusual for MIPS in several ways. MIPS projects performed at UMD do not usually involve testing of human subjects. This was the first study comparing proprietary products by name. The vast majority of projects funded by MIPS involve product or process development or product improvement. Marketing advantages are not typically company goals.
11. The Phase 1 project appears more like a service agreement than research aimed at generating and disseminating new knowledge because the contents of the ingested products are not adequately considered in the experiment design. Phase 2 has a similar problem because there are simply too many uncontrolled variables to produce meaningful scientific results. We found this particularly troubling because students were used as subjects. We question if, under these circumstances, the project should have been funded at least until more in-depth reviews had been obtained. The PI, however, appears to have considered this a research project that could be published in a peer-reviewed journal.
12. Neither the Dean nor the Department Chair believe consideration was given to the scientific merit of the projects when they were approved on the routing forms, which are routinely handled by the Associate Dean for Research and the Associate Chair. Although they did not directly consider the appropriateness of the work, the Dean of the School of Public Health

and the Chair of the Department of Kinesiology told the committee after the fact that they were of the opinion that Dr. Shim was qualified to undertake the work because the measurements were in biomechanics, an area in which he is an expert, and the work was appropriate for the university to pursue. In approving proposals for research, their main concerns are how projects affect space, personnel, and budget. In their meeting with the committee, they stated that they do not believe that MIPS projects that compare proprietary products to be inappropriate because they believed that data would go only to the company and they were unaware that press releases would be released. On the other hand, both the Dean of the School of Public Health and Chair of Kinesiology Department thought that the work would qualify as research that could be published in a peer reviewed journal. They placed complete trust in the PI and the IRB for the scientific merit of the work and in the PI, IRB, and the UMD Department of Intercollegiate Athletics for the appropriate use of students and student athletes.

13. Neither MIPS nor the PI nor any of the MIPS technical reviewers ask for data to support the claims made by Fluid Motion in the MIPS applications of “50% more protein and 30% more calcium and essential electrolytes in Fifth Quarter Fresh than in chocolate milk.”
14. The IRB reviews of both Phase 1 and Phase 2 IRB protocols were expedited. Expedited Review means that they were reviewed by the Director of the IRB, IRB staff, and the Chair of the IRB, but no other IRB Board members even though Dr. Shim indicated on his application that he wanted a Full Board review. The IRB staff determined that expedited review was appropriate because the risk for participants was considered to be very low.
15. For Phase 2, the PI indicated in his IRB protocol that only de-identified data would be obtained from the Washington County School System. Therefore, the PI requested waiver of informed consent for the Washington County High School Football Players. In addition, the risk to football players from ingesting chocolate milk was considered very low, and the PI indicated he would have no direct interactions with students. Based on these facts, the IRB approved the PI’s protocol for Phase 2. At the time of the review, the IRB was unaware of an intervention in this study by the PI (the recommendation of an additional post-season ImPACT test by Dr. Shim) because the IRB protocol clearly stated otherwise: “The Washington County Football teams will be running preseason, postseason, and post injury ImPACT and Sway Balance tests regardless of the Neuromechanics lab involvement.” A minor reference to a post-season ImPACT test was mentioned in the accompanying MIPS proposal but was not disclosed in the IRB protocol, which is the main basis for IRB review.
16. Because the IRB judged this project to be of minimal risk, with no experimenter intervention, and involving only de-identified data from the high school football players, the IRB approved a waiver for informed consent. Consistent with its normal practices for projects involving no experimenter intervention and receipt of de-identified data, the IRB also did not evaluate the scientific merit of the research with the Washington County School System.
17. The IRB reviewed carefully the precautions proposed by the PI to ensure that participation by members of the UMD Women’s Soccer team was voluntary. The IRB is aware of the potential for pressure to participate as human subjects when a specific sport is being studied.

There is an established protocol recognized by the IRB for ensuring participation by team members is voluntary and this protocol was followed in this case.

18. The UMD Department of Intercollegiate Athletics received FQF for participants in the study during the fall semester of 2014. After the study was completed, between March 2, 2015, and July 31, 2015, FQF supplied the UMD Department of Intercollegiate Athletics with 15 cases (300 units) each week until June when the amount was reduced to 150 bottles a week until the end of July, totaling approximately 6,600 bottles of FQF with an estimated value of \$8,910. The UMD Department of Intercollegiate Athletics currently purchases FQF at a price that includes a promotional discount.
19. Following the approval of Phase 1, but before Phase 1 was completed, and while the Phase 2 application was being prepared, the UMCPF received the first of three gifts from the Allied Milk Foundation which, during the course of these projects, totaled \$200,000. Officials of Allied Milk Foundation, who are also associated with Fluid Motion and FQF, authorized the gifts. The gifts provided unrestricted funding for the benefit of Dr. Shim's Neuromechanics Laboratory. Dr. Shim did not declare these gifts as a potential conflict of interest when he received them, when he submitted the Phase 2 application, nor in his applications to the IRB for continuing Phase 1 and Phase 2. When initially asked by the Dean of the School of Public Health about funding for the projects following the second press release, he did not disclose the gifts. The Dean only discovered the gifts because she conducted a detailed audit of his funding. MIPS was unaware of the gifts, and they confirmed that gifts to the university from MIPS partners are not requested nor expected by MIPS. The university has received gifts in support of Dr. Shim's laboratory from two previous MIPS partner companies, but according to the PI, in both instances, the gifts were made after the MIPS projects had been completed.
20. Dr. Shim told the committee he intended to use the Allied Milk Foundation contributions to support those portions of the research proposed in the MIPS and IRB applications that could not be funded by the \$100,000 limit of the MIPS grant. This is consistent with the email he sent to his chair, Dr. Bradley Hatfield, on May 1, 2014, when he disclosed the contributions. He maintains, however, that there were no promises made to Allied Milk or Fluid Motion about deliverables from this additional research. In his view, the gift provided unrestricted funds to support his laboratory. However, an email from Fluid Motion to Dr. Shim dated July 18, 2015, makes it clear that their expectation was that the funds were for the direct support of research.
21. The committee has found a concerning lack of understanding of the basic principles of conflict of interest (COI) in research at all levels of the process among those we interviewed (MIPS, administration, and faculty). The PI, as well as several others, expressed less concern for, and were perhaps less attentive to, the potential of a research COI in part because they felt that this project was in support of small business which is highly encouraged by the state and actively promoted by the university. When asked by the committee to explain why he had not declared a COI regarding the funding from the Allied Milk Foundation, Dr. Shim stated that since the money had not gone directly to him, but had been given to UMCPF to

support his research, he did not consider the funding a COI.

22. Dr. Shim has produced two reports on the work with Washington County football players. These reports provide statistical analyses of the same data that appear to be different, but the committee did not evaluate the differences. The differences may be consistent with the sort of revisions that are made during the completion of the analysis of statistical data.
23. Since these events unfolded, MIPS has undertaken a review of its procedures including prohibiting of product or company endorsements by MIPS, recipient institution, and faculty; adding a conflict of interest/follow-on funding notification clause; adding application questions concerning the company's motivation and plans for the use of project results; changing the kick-off discussions with the company to include the prohibition of endorsements and prior approval of company publicity involving MIPS or university faculty; and adding a requirement for acknowledging company funding in publications and presentation of project results. MIPS is also considering additional technical review criteria for Phase 2 proposals.

Recommendations

1. Press releases should never include study data or conclusions, even preliminary, until they have been subject to peer review and, under most circumstances, accepted for publication in an appropriate peer-reviewed journal or book. The strictest standards for peer review should be applied to research results that are based on human subjects or animals. The responsibility for determining that these conditions have been met should rest with the PI, the Department Chair and/or Dean, and MIPS staff. Therefore, the press releases at issue in this matter should be taken down from the university's website immediately.
2. Press releases from MIPS should clearly state that the company provided funding for the work. Although that information is there in the generic statement about how MIPS works, it should be explicitly stated up front so there is no confusion.
3. The university should develop a protocol for the approval of release of information to the press so that clear authority for approval is established. It seems appropriate that the final authority has to lay with a specific office/administrator, although that authority may be different according to content.
4. The university should have a policy for all university-industry collaborations that clarify the circumstances under which the university's name can be used in statements about the collaboration by the industrial partner. The policy should be discussed in advance with every potential business entity with whom a partnership is being considered. This includes all companies who propose MIPS projects. Press releases and other university communications should not imply university endorsement of any company or product by name. No faculty or staff should endorse a product if that person is identified as an employee of the university. This is yet another reason why the press releases at issue in

this matter should be taken down immediately. A university policy on Endorsement should be developed that incorporates these principles.¹

5. Clear distinctions between research, which is intended to lead to generalizable new knowledge published in peer reviewed scientific journals, versus service to business or industry needs to be made in the evaluation of university-industry partnerships not only by MIPS, but also by the IRB in approving projects that involve human subjects.
6. University and industry expectations for the use of data obtained in university-industry partnerships need to be clear prior to the commencement of such partnerships and agreed upon in writing by all partners. The decision as to whether a project qualifies as research with a goal toward peer-reviewed publication should be made by the PI. MIPS should develop guidelines to help explain these distinctions and clarify expectations before embarking on projects.
7. For projects that qualify as research, MIPS should select reviewers who can address the scientific merit of the project, not unlike what is typically done for NSF- and NIH-funded university work. This assessment should go beyond questions of whether enough people can actually be recruited for a study, for example, and should address whether the study is sound science. To facilitate this, the PI should provide adequate references and these should not count against the page limitations of the proposals. Finally, all reviews from referees should be shared with the PI prior to funding with a request that the PI address the concerns raised. This is a standard practice of federal funding agencies and should be implemented at MIPS. It may be helpful to MIPS, in cases where there are substantial questions of scientific merit raised by reviewers, to discuss the project and reviews with a senior UMD faculty member outside the PI's department.
8. The IRB should review its current practice of expedited review and/or approval of a waiver of informed consent in cases in which the protocols involve an intervention with human subjects, even though the potential for harm is minimal, another entity will be collecting the data, the data are de-identified, and the PI is not directly involved with the subjects. Of particular importance is an assessment of the scientific merit of the proposal and whether the benefit gained is important enough to justify research on human subjects in general, but especially when the research involves un-consenting subjects and minors. This is an important issue both for projects involving service to industry and research designed to contribute to generalizable knowledge through publication in peer-reviewed journals and outlets.
9. The IRB should review its guidelines for ensuring that participation by student athletes is voluntary, especially when the UMD Department of Intercollegiate Athletics is actively involved in the projects, and when all of the athletes are members of a single team. The committee is concerned that voluntary consent and participation is very difficult to evaluate under these circumstances.

² Johns Hopkins's comprehensive policy addresses these concerns. It may be found at <http://brand.jhu.edu/use-of-name/>.

10. The review now underway by MIPS will produce a set of changes in operating practices in university-industry partnerships. The proposed revisions should be carefully reviewed by the Senior Vice President and Provost and the Vice President for Research for their completeness and applicability to the issues raised in this review. They should provide guidelines that are applicable to any university-industry partnership, inside or outside of MIPS.
11. For research proposal preparation or press releases announcing university-industry partnerships, the university should not rely on claims made by an industrial partner about its products and processes without verification.
12. Mandatory, in-person training on the principles of what constitutes a conflict of interest (COI) in research and why it must be disclosed should be required for all faculty, staff, and graduate students working on funded research or service projects, including those funded by MIPS, the Vice President for Research, or elsewhere. The committee recognized that this may take some time to implement fully, so priority in training should be given to sponsored research funded by MIPS and companies. This is the research that is most susceptible to COI in particular. Sponsored research by the NIH, NSF, DOE, etc. is less likely to suffer from the commercial bias seen in this case. Currently, there are extensive training programs in Responsible Conduct of Research (RCR) for graduate students and PHS- and NSF-funded projects, and COI training is integral to these programs. However, all staff and faculty are not required to undergo this training. COI training should stress that the university's objectivity and integrity in generating new knowledge is its most precious asset and must be protected at all costs. It should also make clear that a conflict of interest arises because of competing interests, not because of ultimate actions taken in the context of competing interests. A conflict exists where a secondary interest provides an incentive for a researcher to make a judgment or determination in research that differs from what would be made in the absence of the secondary interest. This can often occur when the university decides to support commercial entities. The training should describe management strategies for reducing or eliminating the bias incentive or, if this is not possible, for reducing the consequences of incentive bias. It should also describe the university's process for disclosing and reviewing potential conflicts of interest and under what circumstances they can be managed.
13. The UMCPF should develop a process to inform the Vice President for Research and the relevant dean and department chair of any gift or gifts to support the work of a single faculty member or faculty group. A notice of such a gift to the chair and/or dean should prompt an immediate discussion of potential COI with the faculty member or faculty group and the UMCPF should receive written assurance that no conflict of interest exists before the funds are accepted and made available to that faculty or faculty group.
14. All funds received from Fluid Motion and the Allied Milk Foundation should be returned and the company should be reimbursed for the milk product it provided. (We have been informed by the President's Office that the funds related to this project will be returned.)

